



# FEDERAL REGISTER

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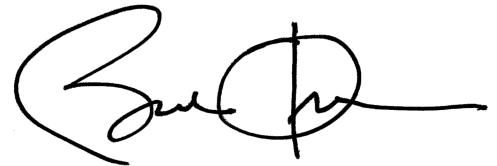
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**Title 3—****Memorandum of August 28, 2015****The President****Delegation of Authority To Transfer Certain Funds in Accordance With Section 610 of the Foreign Assistance Act of 1961****Memorandum for the Secretary of State**

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 610 of the Foreign Assistance Act of 1961 (FAA) and section 301 of title 3, United States Code, I hereby delegate to you the authority, subject to fulfilling the requirements of section 652 of the FAA and section 7009(d) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2014 (Division K, Public Law 113–76), to make the determination necessary for and to execute the transfer of \$19,000,000 of Fiscal Year 2014 International Narcotics Control and Law Enforcement-Overseas Contingency Operations funds to the Economic Support Fund-Overseas Contingency Operations account.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,  
Washington, August 28, 2015



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## Presidential Documents

Proclamation 9320 of September 11, 2015

### National Hispanic-Serving Institutions Week, 2015

By the President of the United States of America

#### A Proclamation

Our higher education system is one of the crown jewels of our Nation, and investing in it is a hallmark of America. In an economy where knowledge is the most valuable asset, the best way to get ahead and ensure mobility to the middle class is to earn a college degree. Hispanic-Serving Institutions (HSIs) help make the promise a college education provides a reality for many Hispanic students across our country, enabling them to secure a better future for themselves and their families. This week, let us recognize the tremendous impact these institutions have and rededicate ourselves to continuing our support of their valuable work.

An education can broaden horizons and empower us to be better people and better citizens, and no one should be left out of that opportunity. Roughly one-quarter of students in our Nation's public schools today are Hispanic, yet less than one-fifth of Hispanics in the United States have a college degree. HSIs help address this disparity, moving us closer to the day when we have the highest proportion of college graduates in the world. HSIs serve more than half of our Nation's undergraduate Hispanics, and they work to provide more Americans—especially low- and middle-income students—with the chance to thrive in an institution of higher learning.

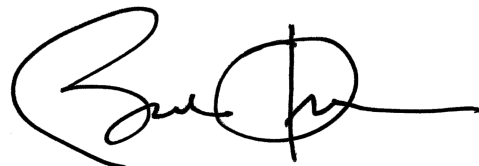
Hispanics are projected to account for almost one-third of our Nation's population by 2060, and ensuring they have access to the best education possible is important to securing America's success. In the last few years, we have seen the dropout rates for Hispanics significantly decrease, while college enrollment has steadily risen. But more work remains to be done to ensure all our people can realize the American dream, and that is why my Administration has pledged \$1 billion in funding over the course of this decade to support HSIs. Additionally, I announced a plan that would open doors of opportunity for millions of people by making community college free for responsible students willing to work hard—because in America, nobody should be denied a college education simply because they do not have the resources to pay for it.

At the heart of our country is a basic bargain: that with determination and grit, you can get ahead—no matter who you are, what you look like, or where you come from. By working to provide many Hispanics with the chance they deserve to get a higher education, HSIs embody this truth and pull the country we all call home a little closer to its founding ideals: that all of us are created equal and all of us should have the chance to make of our lives what we will. This week, let us recommit to strengthening these institutions and pledge our support to all who attend them.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 14 through September 20, 2015, as National Hispanic-Serving Institutions Week. I call on public officials, educators, and all the people of the United States to observe this week with appropriate programs, ceremonies, and activities

that acknowledge the many ways these institutions and their graduates contribute to our country.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of September, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by a circle and a horizontal line.

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## Presidential Documents

Proclamation 9321 of September 11, 2015

### National Grandparents Day, 2015

By the President of the United States of America

#### A Proclamation

Across America, grandparents are loving pillars of comfort and support. After a lifetime of giving back to their families and communities, grandmothers and grandfathers continue to offer compassion and wisdom to their loved ones and inspire us to be our best selves. On National Grandparents Day, we honor the sacrifices they make and continue to show our affection and appreciation for them.

We owe so much of who we are and what we have to our grandparents. With grit and dedication, they helped define a new age and open doors of opportunity for us all. From overcoming the depths of economic collapse to fighting to defend our liberty on battlefields around the world, their determination to ensure we could live better lives than they did helped secure our peace and prosperity. They created the world's largest economy and strongest middle class. They built skyscrapers, made innovative advances, and charted new frontiers. They broke down barriers and instilled fundamental values and ideals. And the extraordinary example they set in striving to forge a better future for their families and our Nation reflects the idea that we are all part of something larger than ourselves.

Today, grandparents continue serving as quiet heroes in every corner of our country. From reading bedtime stories to their grandchildren to volunteering in their communities to acting as primary caregivers, they work hard each and every day while showing love and kindness to their families and those around them. Let us continue to show them the same, and let us forever honor their tremendous efforts to nurture, guide, and drive us in all we do.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 13, 2015, as National Grandparents Day. I call upon all Americans to take the time to honor their own grandparents and those in their community.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of September, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by a circle and a vertical line through it, and a horizontal line extending to the right.

# Rules and Regulations

Federal Register

Vol. 80, No. 180

Thursday, September 17, 2015

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## AGENCY FOR INTERNATIONAL DEVELOPMENT

### 2 CFR Part 700

RIN 0412-AA73

### USAID Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

**AGENCY:** Agency for International Development (USAID).

**ACTION:** Final rule.

**SUMMARY:** USAID is issuing a final rule adopting with amendments the “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,” issued by the Office of Management and Budget and published in **Federal Register** on December 26, 2013.

Consistent with the OMB rule, USAID’s rule supersedes USAID’s “Administration of Assistance Awards to U.S. Non-Governmental Organizations.” Parts of this final rule apply to for-profit entities in limited circumstances and to foreign organizations as described in this guidance.

**DATES:** This final rule is effective October 19, 2015.

**FOR FURTHER INFORMATION CONTACT:** Michael Gushue, Telephone: 202-567-4678, Email: [mgushue@usaid.gov](mailto:mgushue@usaid.gov).

#### SUPPLEMENTARY INFORMATION:

#### A. Background

The Agency for International Development issued an interim final rule with a request for comments adopting the Office of Management and Budget’s “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and published in the **Federal Register** in Vol. 78, No. 248 (Dec. 26, 2013). This OMB rule is codified at 2 CFR part 200

and superseded OMB Circulars A-21, A-87, A-110, A-122, A-89, A-102, and A-133, and the guidance in Circular A-50 on Single Audit Act follow-up. USAID’s interim final rule and subsequent final rule replace 22 CFR part 226, “Administration of Assistance Awards to U.S. Nongovernmental Organizations.” Parts of this final rule also apply to for-profit entities in limited circumstances and to foreign organizations as described in this guidance.

**Regulatory Authority:** The authority for Part 700 reads as follows:

**Authority:** Sec. 621, Public L. 87-195, 75 Stat 445, (22 U.S.C. 2381) as amended, E.O. 12163, Sept 29, 1979, 44 FR 56673; 2 CFR 1979 Comp., p. 435

#### B. Discussion of Comments

The public comment period on the proposed rule closed on March 6, 2015. USAID received comments and suggestions from two organizations on its interim final rule. The following responses address comments that were specific to USAID’s implementation of OMB’s rule. Comments regarding OMB’s Administrative Requirements, Cost Principles, and Audit Requirements at 2 CFR part 200 that did not affect USAID’s implementation at 2 CFR part 700 were not considered.

#### *Applicability of Subparts D and E to Foreign Organizations*

**Comment:** Two commenters addressed USAID’s application of 2 CFR part 200 and 2 CFR part 700 to foreign organizations. Agencies were given decision making authority on the applicability of 2 CFR part 200 to non-US entities, which has resulted in a lack of consistency in applicability to non-US entities across the various federal agencies. Because the goal of this new regulation was to increase uniformity and reduce administrative burden, Subparts A through E of 2 CFR part 200 should be made applicable to all non-US entities, which will simplify and streamline sub-recipient monitoring, as well as implementation. The U.S. Agency for International Development has applied Subpart E inconsistently. Non-US entities will face different administrative requirements when they receive federal awards directly from these agencies. Pass-through entities that subaward funds to local indigenous organizations in host countries as well as to U.S. based entities must craft

differing subaward agreements for each class of subrecipients and monitor and enforce differing requirements. Those non-US based subrecipients who receive funds that originate from USAID and from other federal agencies are subject to policies that are not uniform. We encourage USAID to use references to 2 CFR part 200, subpart D in its policies affecting non-US entities and to use the provisions of 2 CFR 200.207 to differentiate on an individual basis whether differing special conditions are warranted rather than continue to differentiate as they have done.

**Response:** USAID has modified 2 CFR part 700 to clearly identify what parts of 2 CFR part 200 apply to different entities. USAID will continue its longstanding practice of not applying the uniform set of administrative requirements consolidated in the new Uniform Requirements to foreign organizations. The Uniform Requirements would have significant negative implications for USAID’s ongoing operations and awards involving foreign organizations. Taken as a whole, adoption by USAID of the Uniform Requirements to foreign organizations would impose U.S. requirements on local organizations working in English as a second language and unfamiliar with the technical wording and systems logic of federal regulations primarily directed at U.S. recipients, including U.S. and international non-governmental organizations, universities, and research organizations. Application of these requirements would result in an across-the-board increase of administrative burden on local organizations and would seriously undermine USAID’s development and sustainability goals that have been the subject of significant efforts to reduce such burdens and barriers to local organization partnerships with USAID.

More broadly, these changes would have a significant impact on the Agency’s ongoing efforts to work directly with capable local organizations to fulfill our overall mandate to support sustainable development.

#### *Applicability to Commercial Organizations*

**Comment:** Two commenters addressed the application of cost principles to for-profit entities. Section 2 CFR 200.101 indicates that Federal

agencies may apply the Cost Principles, found in Subpart E, to commercial entities. OMB's decision to permit Federal awarding agencies to decide whether to apply the provisions of the Uniform Guidance to commercial organizations and its discussion of the applicability of Subpart E of 2 CFR part 200 has created confusion as to the continuing role that the cost principles for commercial organizations contained in 48 CFR Subpart 31.2 have when the Federal award is made to a commercial organization.

In particular, the statement in 2 CFR 200.101(a) (*i.e.*, "These requirements are applicable to all costs related to Federal awards."), the chart that follows in 2 CFR 200.101(b), and particularly the statement contained in 2 CFR 200.101(c) lead to the conclusion that OMB's intent is for commercial organizations to follow Subpart E when administering grants and cooperative agreements. However, Subpart E only applies to non-commercial entities, while 48 CFR Subpart 31.2 applies to commercial entities. It is clear that when those organizations are administering a Federal contract, they would be directed to follow 48 CFR Subpart 31.2, leading to potential inconsistency of costing. The Department of State has addressed this subject by promulgating 2 CFR 600.101(b) to assure cost consistency shows that this clarification should be made on a government-wide basis.

*Response:* USAID has revised 2 CFR part 700 to clarify that Subpart E does not apply to for-profit entities.

### Regulatory Findings

For the regulatory findings regarding this rulemaking, please refer to the analysis prepared by OIRA in the interim final rule, which is incorporated herein. 79 FR at 75876.

### List of Subjects in 22 CFR Part 700

Accounting, Administrative practice and procedure, Audit requirements, Grant administration, Grant programs, Reporting and recordkeeping requirements.

### Regulatory Text

For the reasons stated in the preamble, The Agency for International Development amends 2 CFR Chapter VII by revising part 700 to read as follows:

## **PART 700—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS**

Sec.

### **Subpart A—Acronyms and Definitions**

700.1 Definitions.

### **Subpart B—General Provisions**

700.2 Adoption of 2 CFR part 200.  
700.3 Applicability.  
700.4 Exceptions.  
700.5 Supersession.

### **Subpart C—Pre-Federal Award Requirements and Contents of Federal Awards**

700.6 Metric system of measurement.  
700.7 Advance payment.

### **Subpart D—Post Federal Award Requirements**

700.8 Payment.  
700.9 Property standards.  
700.10 Cost sharing or matching.  
700.11 Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms.  
700.12 Contract provisions.  
700.13 Additional provisions for awards to for-profit entities.

### **Termination and Disputes**

700.14 Termination.  
700.15 Disputes.

### **USAID—Specific Requirements**

700.16 Marking.

**Authority:** Sec. 621, Public L. 87-195, 75 Stat 445, (22 U.S.C. 2381) as amended, E.O. 12163, Sept 29, 1979, 44 FR 56673; 2 CFR 1979 Comp., p. 435.

### **Subpart A—Acronyms and Definitions**

#### **§ 700.1 Definitions.**

These are the definitions for terms used in this part. Different definitions may be found in Federal statutes or regulations that apply more specifically to particular programs or activities.

*Activity* means a set of actions through which inputs—such as commodities, technical assistance, training, or resource transfers—are mobilized to produce specific outputs, such as vaccinations given, schools built, microenterprise loans issued, or policies changed. Activities are undertaken to achieve objectives that have been formally approved and notified to Congress.

*Agreement Officer* means a person with the authority to enter into, administer, terminate and/or closeout assistance agreements subject to this part, and make related determinations and findings on behalf of USAID. An Agreement Officer can only act within the scope of a duly authorized warrant or other valid delegation of authority. The term "Agreement Officer" includes persons warranted as "Grant Officers." It also includes certain authorized representatives of the Agreement Officer acting within the limits of their authority as delegated by the Agreement Officer.

*Apparently successful applicant(s)* means the applicant(s) for USAID funding recommended for an award after merit review, but who has not yet been awarded a grant, cooperative agreement or other assistance award by the Agreement Officer. Apparently successful applicant status confers no right and constitutes no USAID commitment to an award, which still must be executed by the Agreement Officer.

*Award* means financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants, cooperative agreements, and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient. The term does not include: Technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; contracts which are required to be entered into and administered under procurement laws and regulations.

*Branding strategy* means a strategy the apparently successful applicant submits at the specific request of an USAID Agreement Officer after merit review of an application for USAID funding, describing how the program, project, or activity is named and positioned, as well as how it is promoted and communicated to beneficiaries and cooperating country citizens. It identifies all donors and explains how they will be acknowledged. A Branding Strategy is required even if a Presumptive Exception is approved in the Marking Plan.

*Commodities* mean any material, article, supply, goods or equipment, excluding recipient offices, vehicles, and non-deliverable items for recipient's internal use in administration of the USAID-funded grant, cooperative agreement, or other agreement or subagreement.

*Date of completion* means the date on which all work under an award is completed or the date on the award document, or any supplement or amendment, on which USAID sponsorship ends.

*Marking plan* means a plan that the apparently successful applicant submits at the specific request of a USAID Agreement Officer after merit review of an application for USAID funding, detailing the public communications, commodities, and program materials and other items that will visibly bear the USAID Identity. Recipients may request approval of Presumptive Exceptions to

marking requirements in the Marking Plan.

*Principal officer* means the most senior officer in an USAID Operating Unit in the field, e.g., USAID Mission Director or USAID Representative. For global programs managed from Washington but executed across many countries such as disaster relief and assistance to internally displaced persons, humanitarian emergencies or immediate post conflict and political crisis response, the cognizant Principal Officer may be an Office Director, for example, the Directors of USAID/W/ Office of Foreign Disaster Assistance and Office of Transition Initiatives. For non-presence countries, the cognizant Principal Officer is the Senior USAID officer in a regional USAID Operating Unit responsible for the non-presence country, or in the absence of such a responsible operating unit, the Principle U.S Diplomatic Officer in the non-presence country exercising delegated authority from USAID.

*Program* means an organized set of activities and allocation of resources directed toward a common purpose, objective, or goal undertaken or proposed by an organization to carry out the responsibilities assigned to it. Projects include all the marginal costs of inputs (including the proposed investment) technically required to produce a discrete marketable output or a desired result (for example, services from a fully functional water/sewage treatment facility).

*Public communications* are documents and messages intended for distribution to audiences external to the recipient's organization. They include, but are not limited to, correspondence, publications, studies, reports, audio visual productions, and other informational products; applications, forms, press and promotional materials used in connection with USAID funded programs, projects or activities, including signage and plaques; Web sites/Internet activities; and events such as training courses, conferences, seminars, press conferences and the like.

*Suspension* means an action by USAID that temporarily withdraws Federal sponsorship under an award, pending corrective action by the recipient or pending a decision to terminate the award. Suspension of an award is a separate action from suspension under USAID regulations implementing E.O.'s 12549 and 12689, "Debarment and Suspension." See 2 CFR part 780.

*Unrecovered indirect cost* means the difference between the amount awarded and the amount which could have been

awarded under the recipient's approved negotiated indirect cost rate.

*USAID* means the United States Agency for International Development.

*USAID Identity* (Identity) means the official marking for the United States Agency for International Development (USAID) comprised of the USAID logo or seal and new brandmark with the tagline that clearly communicates our assistance is "from the American people." In exceptional circumstances, upon a written determination by the USAID Administrator, the definition of the USAID Identity may be amended to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency Federal initiative that requires consistent and uniform branding and marking by all participating agencies. The USAID Identity (including any required presidential initiative or related identity) is available on the USAID Web site at <http://www.usaid.gov/branding> and is provided without royalty, license or other fee to recipients of USAID funded grants or cooperative agreements or other assistance awards.

## Subpart B—General Provisions

### § 700.2 Adoption of 2 CFR Part 200.

Under the authority listed above the Agency for International Development adopts the Office of Management and Budget (OMB) guidance Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards to Non-Federal Entities (subparts A through F of 2 CFR part 200), as supplemented by this part, as the Agency for International Development (USAID) policies and procedures for financial assistance administration. This part satisfies the requirements of 2 CFR 200.110(a) and gives regulatory effect to the OMB guidance as supplemented by this part.

### § 700.3 Applicability.

(a) Subparts A through D of 2 CFR part 200 apply to for-profit entities. The Federal Acquisition Regulation (FAR) at 48 CFR part 30, Cost Accounting Standards, and Part 31, Contract Cost Principles and Procedures, takes precedence over the cost principles in Subpart E for Federal awards to for-profit entities.

(b) Subpart E applies to foreign organizations and foreign public entities, except where the Federal awarding agency determines that the application of these subparts would be inconsistent with the international obligations of the United States or the

statute or regulations of a foreign government.

### § 700.4 Exceptions.

Consistent with 2 CFR 200.102(b):

(a) Exceptions on a case-by-case basis for individual non-Federal entities may be authorized by USAID's Assistant Administrator, Bureau for Management, or designee as delegated in Agency policy, except where otherwise required by law or where OMB or other approval is expressly required by this Part. No case-by-case exceptions may be granted to the provisions of Subpart F—Audit Requirements of this Part.

(b) USAID's Assistant Administrator, Bureau for Management, or designee as delegated in Agency policy, is also authorized to approve exceptions, on a class or an individual case basis, to USAID program specific assistance regulations other than those which implement statutory and executive order requirements.

(c) The Federal awarding agency may apply more restrictive requirements to a class of Federal awards or non-Federal entities when approved by OMB, required by Federal statutes or regulations except for the requirements in Subpart F—Audit Requirements of this part. A Federal awarding agency may apply less restrictive requirements when making awards at or below the simplified acquisition threshold, or when making fixed amount awards as defined in Subpart A—Acronyms and Definitions of 2 CFR part 200, except for those requirements imposed by statute or in Subpart F—Audit Requirements of this part.

### § 700.5 Supersession.

Effective December 26, 2014, this part supersedes the following regulations under Title 22 of the Code of Federal Regulations: 22 CFR part 226, "Administration of Assistance Awards To U.S. Non-Governmental Organizations."

## Subpart C—Pre-Federal Award Requirements and Contents of Federal Awards

### § 700.6 Metric system of measurement.

(a) The Metric Conversion Act, as amended by the Omnibus Trade and Competitiveness Act (15 U.S.C. 205) declares that the metric system is the preferred measurement system for U.S. trade and commerce.

(b) Wherever measurements are required or authorized, they must be made, computed, and recorded in metric system units of measurement, unless otherwise authorized by the Agreement Officer in writing when it

has been found that such usage is impractical or is likely to cause U.S. firms to experience significant inefficiencies or the loss of markets. Where the metric system is not the predominant standard for a particular application, measurements may be expressed in both the metric and the traditional equivalent units, provided the metric units are listed first.

#### **§ 700.7 Advance payment.**

Advance payment mechanisms include, but are not limited to, Letter of Credit, Treasury check and electronic funds transfer and must comply with applicable guidance in 31 CFR part 205.

### **Subpart D—Post Federal Award Requirements**

#### **§ 700.8 Payment.**

(a) Use of resources before requesting advance payments. To the extent available, the non-Federal entity must disburse funds available from program income (including repayments to a revolving fund), rebates, refunds, contract settlements, audit recoveries, and interest earned on such funds before requesting additional cash payments. This paragraph is not applicable to such earnings which are generated as foreign currencies.

(b) Standards governing the use of banks and other institutions as depositories of advance payments under Federal awards are as follows:

(1) Except for situations described in paragraph (b)(2) of this section, USAID does not require separate depository accounts for funds provided to a non-Federal entity or establish any eligibility requirements for depositories for funds provided to the non-Federal entity. However, the non-Federal entity must be able to account for receipt, obligation and expenditure of funds.

(2) Advance payments of Federal funds must be deposited and maintained in insured accounts whenever possible.

#### **§ 700.9 Property standards.**

(a) *Real property.* Unless the agreement provides otherwise, title to real property will vest in accordance with 2 CFR 200.311.

(b) *Equipment.* Unless the agreement provides otherwise, title to equipment will vest in accordance with 2 CFR 200.313.

#### **§ 700.10 Cost sharing or matching.**

Unrecovered indirect costs, including indirect costs on cost sharing or matching may be included as part of cost sharing or matching. Unrecovered indirect cost means the difference between the amount charged to the

Federal award and the amount which would have been charged to the Federal award under the non-Federal entity's approved negotiated indirect cost rate.

#### **§ 700.11 Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms.**

(a) Make information on forthcoming opportunities available and arrange time frames for purchases and contracts to encourage and facilitate participation by small businesses, minority-owned firms, and women's business enterprises. To permit USAID, in accordance with the small business provisions of the Foreign Assistance Act of 1961, as amended, to give United States small business firms an opportunity to participate in supplying commodities and services procured under the award, the recipient must to the maximum extent possible provide the following information to the Office of Small Disadvantaged Business Utilization (OSDBU), USAID, Washington, DC 20523, at least 45 days prior to placing any order or contract in excess of the simplified acquisition threshold:

- (1) Brief general description and quantity of goods or services;
  - (2) Closing date for receiving quotations, proposals or bids; and
  - (3) Address where solicitations or specifications can be obtained.
- (b) [Reserved]

#### **§ 700.12 Contract provisions.**

(a) The non-Federal entity's contracts must contain the applicable provisions described in Appendix II to Part 200—Contract Provisions for non-Federal Entity Contracts Under Federal Awards.

(b) All negotiated contracts (except those for less than the simplified acquisition threshold) awarded by the non-Federal entity must include a provision to the effect that the non-Federal Entity, USAID, the Comptroller General of the United States, or any of their duly authorized representatives, must have access to any books, documents, papers and records of the contractor which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.

#### **§ 700.13 Additional provisions for awards to for-profit entities.**

(a) This paragraph contains additional provisions that apply to awards to for-profit entities. These provisions supplement and make exceptions for awards to for-profit entities from other provisions of this part.

(1) Prohibition against profit. No funds will be paid as profit to any for-profit entity receiving or administering Federal financial assistance as a

recipient or subrecipient. Federal financial assistance does not include contracts as defined at 2 CFR 200.22, other contracts a Federal agency uses to buy goods or services from a contractor, or contracts to operate Federal government owned, contractor operated facilities (GOCOs). Profit is any amount in excess of allowable direct and indirect costs.

(2) Program income. As described in § 200.307(e)(2), program income earned by a for-profit entity may not be added to the Federal award.

(b) [Reserved]

### **Termination and Disputes**

#### **§ 700.14 Termination.**

If at any time USAID determines that continuation of all or part of the funding for a program should be suspended or terminated because such assistance would not be in the national interest of the United States or would be in violation of an applicable law, then USAID may, following notice to the recipient, suspend or terminate the award in whole or in part and prohibit the recipient from incurring additional obligations chargeable to the award other than those costs specified in the notice of suspension. If a suspension is put into effect and the situation causing the suspension continues for 60 calendar days or more, then USAID may terminate the award in whole or in part on written notice to the recipient and cancel any portion of the award which has not been disbursed or irrevocably committed to third parties.

#### **§ 700.15 Disputes.**

(a) Any dispute under or relating to a grant or agreement will be decided by the USAID Agreement Officer. The Agreement Officer must furnish the recipient a written copy of the decision.

(b) Decisions of the USAID Agreement Officer will be final unless, within 30 calendar days of receipt of the decision, the recipient appeals the decision to USAID's Assistant Administrator, Bureau for Management, or designee as delegated in Agency policy. Appeals must be in writing with a copy concurrently furnished to the Agreement Officer.

(c) In order to facilitate review of the record by the USAID's Assistant Administrator, Bureau for Management, or designee as delegated in Agency policy, the recipient will be given an opportunity to submit written evidence in support of its appeal. No hearing will be provided.

(d) Decisions by the Assistant Administrator, Bureau for Management, or designee as delegated in Agency policy, will be final.



**USAID—Specific Requirements****§ 700.16 Marking.**

(a) USAID policy is that all programs, projects, activities, public communications, and commodities, specified further at paragraphs (c) through (f) of this section, partially or fully funded by a USAID grant or cooperative agreement or other assistance award or subaward must be marked appropriately overseas with the USAID Identity, of a size and prominence equivalent to or greater than the recipient's, other donor's or any other third party's identity or logo.

(1) USAID reserves the right to require the USAID Identity to be larger and more prominent if it is the majority donor, or to require that a cooperating country government's identity be larger and more prominent if circumstances warrant; any such requirement will be on a case-by-case basis depending on the audience, program goals and materials produced.

(2) USAID reserves the right to request pre-production review of USAID funded public communications and program materials for compliance with the approved Marking Plan.

(3) USAID reserves the right to require marking with the USAID Identity in the event the recipient does not choose to mark with its own identity or logo.

(4) To ensure that the marking requirements "flow down" to subrecipients of subawards, recipients of USAID funded grants and cooperative agreements or other assistance awards are required to include a USAID-approved marking provision in any USAID funded subaward, to read as follows:

As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient's, subrecipient's, other donor's or third party's is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.

(b) Subject to § 700.16(a), (h), and (j), program, project, or activity sites funded by USAID, including visible infrastructure projects (for example, roads, bridges, buildings) or other programs, projects, or activities that are physical in nature (for example, agriculture, forestry, water management), must be marked with the USAID Identity. Temporary signs or plaques should be erected early in the construction or implementation phase. When construction or implementation is complete, a permanent, durable sign, plaque or other marking must be installed.

(c) Subject to § 700.16(a), (h), and (j), technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities and other promotional, informational, media, or communications products funded by USAID must be marked with the USAID Identity.

(1) Any "public communications" as defined in § 700.1, funded by USAID, in which the content has not been approved by USAID, must contain the following disclaimer:

This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.

(2) The recipient must provide the Agreement Officer's Representative (AOR) or other USAID personnel designated in the grant or cooperative agreement with at least two copies of all program and communications materials produced under the award. In addition, the recipient must submit one electronic and/or one hard copy of all final documents to USAID's Development Experience Clearinghouse.

(d) Subject to § 700.16(a), (h), and (j), events financed by USAID such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities, must be marked appropriately with the USAID Identity. Unless directly prohibited and as appropriate to the surroundings, recipients should display additional materials such as signs and banners with the USAID Identity. In circumstances in which the USAID Identity cannot be displayed visually, recipients are encouraged otherwise to acknowledge USAID and the American people's support.

(e) Subject to § 700.16(a), (h), and (j), all commodities financed by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs, and all other equipment, supplies and other materials funded by USAID, and their export packaging, must be marked with the USAID Identity.

(f) After merit review of applications for USAID funding, USAID Agreement Officers will request apparently successful applicants to submit a Branding Strategy, defined in § 700.1. The proposed Branding Strategy will not be evaluated competitively. The Agreement Officer will review for adequacy the proposed Branding

Strategy, and will negotiate, approve and include the Branding Strategy in the award. Failure to submit or negotiate a Branding Strategy within the time specified by the Agreement Officer will make the apparently successful applicant ineligible for award.

(g) After merit review of applications for USAID funding, USAID Agreement Officers will request apparently successful applicants to submit a Marking Plan, defined in § 700.1. The Marking Plan may include requests for approval of Presumptive Exceptions, paragraph (h) of this section. All estimated costs associated with branding and marking USAID programs, such as plaques, labels, banners, press events, promotional materials, and the like, must be included in the total cost estimate of the grant or cooperative agreement or other assistance award, and are subject to revision and negotiation with the Agreement Officer upon submission of the Marking Plan. The Marking Plan will not be evaluated competitively. The Agreement Officer will review for adequacy the proposed Marking Plan, and will negotiate, approve and include the Marking Plan in the award. Failure to submit or negotiate a Marking Plan within the time specified by the Agreement Officer will make the apparently successful applicant ineligible for award.

Agreement Officers have the discretion to suspend the implementation requirements of the Marking Plan if circumstances warrant. Recipients of USAID funded grant or cooperative agreement or other assistance award or subaward should retain copies of any specific marking instructions or waivers in their project, program or activity files. Agreement Officer's Representatives will be assigned responsibility to monitor marking requirements on the basis of the approved Marking Plan.

(h) Presumptive exceptions:

(1) The above marking requirements in § 700.16(a) through (e) may not apply if marking would:

(i) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials, such as election monitoring or ballots, and voter information literature; political party support or public policy advocacy or reform; independent media, such as television and radio broadcasts, newspaper articles and editorials; public service announcements or public opinion polls and surveys.

(ii) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent.

(iii) Undercut host-country government "ownership" of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications better positioned as "by" or "from" a cooperating country ministry or government official.

(iv) Impair the functionality of an item, such as sterilized equipment or spare parts.

(v) Incur substantial costs or be impractical, such as items too small or other otherwise unsuited for individual marking, such as food in bulk.

(vi) Offend local cultural or social norms, or be considered inappropriate on such items as condoms, toilets, bed pans, or similar commodities.

(vii) Conflict with international law.

(2) These exceptions are presumptive, not automatic and must be approved by the Agreement Officer. Apparently successful applicants may request approval of one or more of the presumptive exceptions, depending on the circumstances, in their Marking Plan. The Agreement Officer will review requests for presumptive exceptions for adequacy, along with the rest of the Marking Plan. When reviewing a request for approval of a presumptive exception, the Agreement Officer may review how program materials will be marked (if at all) if the USAID identity is removed. Exceptions approved will apply to subrecipients unless otherwise provided by USAID.

(i) In cases where the Marking Plan has not been complied with, the Agreement Officer will initiate corrective action. Such action may involve informing the recipient of a USAID grant or cooperative agreement or other assistance award or subaward of instances of noncompliance and requesting that the recipient carry out its responsibilities as set forth in the Marking Plan and award. Major or repeated non-compliance with the Marking Plan will be governed by the uniform suspension and termination procedures set forth at 2 CFR 200.338 through 2 CFR 200.342, and 2 CFR 700.14.

(j)(1) *Waivers*. USAID Principal Officers, defined for purposes of this provision at § 700.1, may at any time after award waive in whole or in part the USAID approved Marking Plan, including USAID marking requirements for each USAID funded program, project, activity, public communication or commodity, or in exceptional circumstances may make a waiver by region or country, if the Principal Officer determines that otherwise USAID required marking would pose

compelling political, safety, or security concerns, or marking would have an adverse impact in the cooperating country. USAID recipients may request waivers of the Marking Plan in whole or in part, through the AOR. No marking is required while a waiver determination is pending. The waiver determination on safety or security grounds must be made in consultation with U.S. Government security personnel if available, and must consider the same information that applies to determinations of the safety and security of U.S. Government employees in the cooperating country, as well as any information supplied by the AOR or the recipient for whom the waiver is sought. When reviewing a request for approval of a waiver, the Principal Officer may review how program materials will be marked (if at all) if the USAID Identity is removed. Approved waivers are not limited in duration but are subject to Principal Officer review at any time due to changed circumstances. Approved waivers "flow down" to recipients of subawards unless specified otherwise. Principal Officers may also authorize the removal of USAID markings already affixed if circumstances warrant. Principal Officers' determinations regarding waiver requests are subject to appeal to the Principal Officer's cognizant Assistant Administrator. Recipients may appeal by submitting a written request to reconsider the Principal Officer's waiver determination to the cognizant Assistant Administrator.

(2) *Non-retroactivity*. Marking requirements apply to any obligation of USAID funds for new awards as of January 2, 2006. Marking requirements also will apply to new obligations under existing awards, such as incremental funding actions, as of January 2, 2006, when the total estimated cost of the existing award has been increased by USAID or the scope of effort is changed to accommodate any costs associated with marking. In the event a waiver is rescinded, the marking requirements will apply from the date forward that the waiver is rescinded. In the event a waiver is rescinded after the period of performance as defined in 2 CFR 200.77 but before closeout as defined in 2 CFR 200.16., the USAID mission or operating unit with initial responsibility to administer the marking requirements must make a cost benefit analysis as to requiring USAID marking requirements after the date of completion of the affected programs, projects, activities, public communications or commodities.

(k) The USAID Identity and other guidance will be provided at no cost or

fee to recipients of USAID grants, cooperative agreements or other assistance awards or subawards. Additional costs associated with marking requirements will be met by USAID if reasonable, allowable, and allocable under 2 CFR part 200, subpart E. The standard cost reimbursement provisions of the grant, cooperative agreement, other assistance award or subaward must be followed when applying for reimbursement of additional marking costs.

(End of award term)

**Angelique M. Crumbly**,  
Agency Regulatory Official, U.S. Agency for  
International Development.

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## OFFICE OF PERSONNEL MANAGEMENT

### 5 CFR Parts 890 and 892

RIN 3206-AN08

#### Federal Employees Health Benefits Program Self Plus One Enrollment Type

**AGENCY:** Office of Personnel  
Management.

**ACTION:** Final rule.

**SUMMARY:** The United States Office of Personnel Management (OPM) is issuing a final rule to amend the Federal Employees Health Benefits (FEHB) Program regulations to add an additional enrollment type called "self plus one" for premium rating and family member eligibility purposes.

**DATES:** This rule is effective September 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** Chelsea Ruediger at [Chelsea.Ruediger@opm.gov](mailto:Chelsea.Ruediger@opm.gov) or (202) 606-0004.

**SUPPLEMENTARY INFORMATION:** The U.S. Office of Personnel Management (OPM) issued a Notice of Proposed Rulemaking on December 2, 2014 to amend title 5 of the Code of Federal Regulations parts 890 and 892 to include a self plus one enrollment type to comply with the 2013 Bipartisan Budget Act. During the comment period on the proposed rule, OPM received 64 comments including 5 from Federal Employees Health Benefits (FEHB) Program carriers, 2 from employee organizations or unions, 1 from a carrier organization, and 56 from individuals, many of them enrollees in the FEHB Program. These comments are addressed below.

**General Comments Regarding Self Plus One**

OPM received a variety of comments, mostly from FEHB enrollees, expressing excitement about the self plus one enrollment type. Commenters indicated that the enrollment type will benefit them personally and financially.

One commenter requested justification for the implementation of the self plus one enrollment type and expressed concern over the level of complexity that this additional statutorily required enrollment type introduces to consumer choice in the FEHB Program. The commenter noted that under the current two-tier system, “the typical enrollee . . . has a choice of about 20 plan options” and projected that options available for families may double and premiums might vary greatly.

OPM is updating 5 CFR parts 890 and 892 to comply with provisions of the 2013 Bipartisan Budget Act. This more closely aligns insurance offerings for Federal employees with those available in the commercial market and to more equitably spread costs among the enrollment types offered.

OPM is aware that creation of a new enrollment tier may create additional complexity. However, this complexity is limited because the rule only introduces a new enrollment type. Benefits design will not differ from other enrollment types offered within the same plan option, which minimizes the complexity introduced by the rule. To alleviate potential concerns about complexity during the introductory year, § 892.207(d) has been amended in this final rule to include a one-time limited enrollment period to be held in early 2016. Final dates for the Limited Enrollment Period will be announced by OPM following the publication of this rule. During this period, enrollees will be allowed to decrease enrollment from self and family to self plus one. Enrollment changes made in conjunction with the limited enrollment period will be effective on the first day of the first pay period following the one in which the appropriate request is

received by the employing office. Because enrollees who do not participate in premium conversion (pre-tax deduction of premiums), including annuitants, may decrease their enrollment at any time, this limited enrollment period is intended only for premium conversion participants. No new enrollments, changes in plan or plan option, or increases in enrollment will be allowed in conjunction with the limited enrollment period.

In advance of Open Season each year, OPM, agencies and carriers inform employees and annuitants of their enrollment options and provide them with decision-making tools. Given the addition of the self plus one enrollment type, this communications strategy will be augmented for the 2015 Open Season. OPM communications will encourage enrollees to carefully review the options available to them for plan year 2016.

An FEHB carrier requested clarification that “enrollees will need to make a positive election through their agency or retirement office in order to switch from self only or self and family to self plus one.” This statement is correct. Just as is the case under the current two-tier system, enrollees must inform their agency, either through an electronic or paper copy of the Standard Form 2809, when they increase or decrease coverage. Agencies are responsible for submitting this information to carriers. This requirement will be no different for self plus one.

**Comments on Effective Dates**

Several commenters requested additional information about the timing of the implementation of the self plus one enrollment type. Others requested that OPM delay implementation by at least one year in order to conduct additional analysis. Another questioned the decision to implement the new self plus one enrollment option for plan year 2016, as this date was not required by law.

The effective date in this final rule has not been altered. The Bipartisan

Budget Act was passed in 2013 and OPM has been working diligently to implement this statutory mandate within a reasonable timeframe. Enrollees who have been looking forward to this change will now be able to select a self plus one enrollment type during the 2015 Open Season for effective dates in January of 2016.

**Comments on Family Member Eligibility**

OPM received three comments about family member eligibility. Two commenters asked about the eligibility of domestic partners and cohabitating (unmarried) opposite sex couples. A third comment asked if a sibling could be covered.

Family member eligibility is defined in title 5 U.S. Code section 8901 and includes spouses and children up to age 26. As stated in the supplementary information of the proposed rule, family member eligibility guidelines remain the same as in place under the two tier system. Domestic partners, cohabitating (unmarried) couples, and siblings are not considered eligible family members under the law at this time.

**Switching a Covered Family Member**

The proposed rule outlined the circumstances in which an enrollee with a self plus one enrollment would be allowed to switch their covered family member. Some commenters expressed concerns that these provisions might lead to adverse selection. OPM believes that adequate protection against adverse selection is provided in the manner in which Qualifying Life Events (QLEs) allowing such a change have been limited. Further, the general rule applies that the change must be consistent with the QLE experienced. The following chart, which was published with the proposed rule, clarifies which QLE codes will allow an enrollee to switch a covered family member outside of Open Season (definitions for each of the event codes can be found on the SF2809 at [http://www.opm.gov/forms/pdf\\_fill/sf2809.pdf](http://www.opm.gov/forms/pdf_fill/sf2809.pdf)):

Change	Permitted for the following event codes
<b>For Enrollees Participating in Premium Conversion</b>	
Switch covered family member under a self plus one enrollment .....	1B, 1C, 1I, 1J, 1M, 1N, 1O, 1P, 1Q, 1R
<b>For Annuitants (decreases in enrollment type are allowed at any time)</b>	
Switch covered family member under a self plus one enrollment .....	2A, 2B, 2F, 2G, 2H, 2I, 2J
<b>For Former Spouses Under the Spouse Equity Provision (decreases in enrollment type are allowed at any time)</b>	
Switch covered family member under a self plus one enrollment .....	3B, 3C, 3F, 3G, 3H, 3I

Change	Permitted for the following event codes
<b>For Temporary Continuation of Coverage (TCC) for Eligible Former Employees, Former Spouses, and Children (decreases in enrollment type are allowed at any time)</b>	
Switch covered family member under a self plus one enrollment .....	4B, 4C, 4D, 4F, 4G, 4H
<b>For Employees Not Participating in Premium Conversion (decreases in enrollment type are allowed at any time)</b>	
Switch covered family member under a self plus one enrollment .....	5B, 5C, 5F, 5G, 5H, 5I, 5J, 5N

One carrier organization requested that OPM require a 30 day advance notice to carriers before allowing a switch in covered family member in order to prevent overpayments as well as verification of alternative health insurance for the family member being removed. OPM declines to make this change. It is expected that carriers will utilize current standard operating procedures to process the switching of a covered family member; generally changes are effective at the beginning of the next pay period after receipt by the agency.

A commenter urged OPM to treat the switch as a cancellation for the family member who is being removed from the self plus one enrollment, thereby rendering the individual ineligible for the 31 day extension of coverage. Just as is the case under the two tier system, under § 890.401(a)(1) eligibility for the 31 day extension of coverage is provided for covered family members whose coverage is terminated other than by cancellation of the enrollment or discontinuance of the plan, in whole or in part. For family members, terminations are typically based on a loss of eligibility such as, in the case of a child, turning age 26; or, in the case of a spouse, a divorce. Cancellation is typically a voluntary election to no longer be covered under an FEHB plan, for example when a family member becomes eligible for other group coverage. Switching a covered family member may occur as the result of either a termination or a cancellation. Therefore, OPM declines to make this change.

One commenter urged OPM to apply a blanket policy against discretionary retroactive switching of a covered family member. Section 892.207(b) has been updated in the final rule to include switching a covered family member in order to accommodate this suggestion. Enrollment changes made under § 892.207 are, in general, effective on the first day of the first pay period following the one in which the appropriate request is received by the employing office. In addition, paragraph (f)(2) has been added to § 890.302 in the final rule to specify that the effective

date for switching a covered family member will be prospective. A definition of the term “switching a covered family member” has also been added to § 890.101.

One commenter requested that OPM clarify that “enrollees cannot switch the covered family member under the self plus one without a QLE to validate dependent eligibility.” As described in the proposed rule, and supported in the final rule, enrollees must experience a QLE in order to switch their covered family member.

One commenter requested additional information about how carriers will be notified of the designated covered family member under the self plus one enrollment. The Standard Form 2809 and electronic enrollment transmissions will be utilized just as they are currently to communicate enrollment information. Additionally, OPM is assessing other methods, including updating enrollment systems government-wide to allow for the transmittal of changes in the designated family member from agencies to carriers.

One commenter asked that OPM require the capture of a Social Security Number for dependents. As this is outside the scope of this rule, we decline to comment at this time.

**Qualifying Life Events (QLE)**

One commenter requested that OPM clarify whether or not enrollees must experience a QLE in order to decrease enrollment outside of Open Season. Under § 892.208, enrollees who participate in premium conversion must experience a QLE in order to decrease enrollment outside of Open Season. Under § 890.301(e), enrollees who do not participate in premium conversion may decrease enrollment at any time. This final rule has not altered these requirements.

Another commenter requested that OPM clarify that “retired federal employees/annuitants will have the option to change plans and/or enrollment types upon retirement, regardless of Medicare eligibility or age at the time of retirement.”

Retirement is not a QLE and therefore no changes may be made based solely on retirement. Retirement is a change from one payroll office to another. After an individual is retired, under the provisions in § 890.301(e), they may decrease enrollment or cancel coverage at any time. QLEs are still required for increasing coverage or changing plans outside of Open Season.

It was requested that OPM clarify the process for handling an annuitant who, upon experiencing the death of her spouse, forgets to decrease her enrollment to self only. As this question is beyond the scope of this regulation, OPM declines to comment at this time.

Additional guidance was requested regarding carrier responsibilities to notify enrollees and agencies when a family member has aged out of eligibility or passed away. OPM encourages carriers to contact their enrollees when a child ages out or if they learn of the death of a covered family member in order to inform the enrollee of their QLE opportunity at that time.

**Alternative Enrollment Types**

Four commenters suggested alternative enrollment types. One commenter suggested that OPM provide rates based on the number of family members enrolled. Another suggested an enrollment type available to only those enrolled in both FEHB and Medicare. A third commenter suggested that, instead of self plus one, OPM alter eligibility guidelines to allow spouses and dependents to enroll in their own right in self only enrollments. Finally, an FEHB carrier commented that OPM should implement a four-tier system: Self only, employee and spouse, employee and one non-spousal family member, and self and family. Commenters urged OPM to consider methods for encouraging or requiring Medicare enrollment. One suggested that OPM should consider reducing premiums for annuitants enrolled in Medicare as FEHB is the secondary payer. Another expressed concerns that the addition of the self plus one enrollment type would exacerbate an existing problem in which younger

enrollees subsidize higher cost annuitants.

OPM is unable to implement these suggested changes. The FEHB statute only allows the following enrollment types: Self only, self plus one, and self and family. Any other enrollment types, including separate enrollment tiers for individuals enrolled in Medicare, would require legislative change.

#### Definition of Self Plus One

OPM received four comments indicating that the definition of self plus one in the proposed rule, which does not preclude an individual with only one eligible family member from enrolling in self and family, has potentially negative consequences. These commenters indicated the definition, coupled with concerns that self plus one premiums and/or enrollee shares may rise above self and family premiums and/or enrollee shares, could result in revenue shortfall for carriers. They predicted that some consumers with only one eligible family member will likely select a self and family enrollment if the enrollee share is lower, leading to a financial loss for plans with higher claims costs for self plus one enrollments.

Individual choice is, and always has been, one of the hallmarks of the FEHB Program. Before the addition of the self plus one enrollment type, individuals have been free to select a self only or self and family enrollment, regardless of whether or not they have eligible family members. In that tradition, the final rule adopts the proposed rule's provision, providing individuals the freedom to select among all three enrollment types available, regardless of the number of their eligible family members.

One commenter requested that OPM use this opportunity to expressly state that all eligible family members are covered under a self and family enrollment. Current regulatory language, which has not been altered in this rule, already adequately expresses this. Section 890.302(a)(1) states that an enrollment for self and family includes all family member who are eligible to be covered by the enrollment. Further, the definition of self and family, as added by this final rule states that self and family enrollment means an enrollment that covers the enrollee and all eligible family members.

#### Government Contribution Calculations

The government contribution to premium is calculated based on weighted average of the subscription charges described in 5 U.S. Code section 8906. One commenter points out that most carriers are unable to predict the

government contribution for their plans because they do not cover an adequate portion of the total market to estimate actual FEHB enrollment to determine the weighted average. Thus, many plans propose total premiums to OPM without a complete understanding of what the government and enrollee contributions will be, putting them at a disadvantage in a competitive market. Given the additional uncertainty for plan year 2016, with the addition of the self plus one enrollment type, the commenter requested that OPM provide carriers more flexibility to adjust final premium rates during the negotiation process after the government contribution has been calculated. OPM will adhere to standard operating procedures for plan year 2016 final rate negotiations.

An FEHB carrier requested that OPM provide additional information to carriers concerning rate setting for plan year 2016. In addition, they cautioned OPM against applying the same government contribution for both self plus one and self and family enrollments for plan year 2016 as this method might lead to increased "unpredictability of which subscribers will choose which tier." Many commenters requested additional information about the weighted averages that would be used to determine the government contribution for plan year 2016.

The 2013 Bipartisan Budget Act provides OPM with flexibility in the first year that self plus one is offered to "determine the weighted average of the subscription charges that will be in effect for the contract year for enrollments for self plus one under such chapter based on an actuarial analysis."<sup>1</sup> The weighted average is used to calculate the Government contribution, according to a formula set in statute (5 U.S.C. 8906). OPM takes a count of enrollments with Government contributions in March of each year (referred to in the following paragraphs as the "March enrollment count"). This March enrollment count is used to determine the maximum Government contribution for the following plan year. For each enrollment type, OPM sums the product of the new premium and the March enrollment count for each option and divides the sum by the total number of individuals enrolled in that enrollment type.

Because we do not have self plus one data from our March 2015 enrollment count, OPM has determined that it will use the 2015 self and family March

enrollment count to calculate the weighted average for both the 2016 self plus one and self and family enrollment types. The weighted average for self plus one will be based on the 2016 self plus one premiums and the 2015 self and family March enrollment count. OPM provides rate-setting guidance to carriers on an annual basis. For the 2016 plan year, OPM requested that carriers propose self plus one premiums that are no greater than self and family premiums.<sup>2</sup> Although OPM does not expect this policy to change in the out years, the right to reevaluate is reserved.

#### Rate-Setting and the Cost of Self Plus One

Comments were received that indicated the addition of the self plus one enrollment type would translate into cost savings for enrollees with only one eligible family member. Commenters in this category praised OPM for implementing the new enrollment type. Other commenters expressed concerns about rate setting for the new self plus one enrollment type. In particular, a concern that self and family premiums would rise drastically in plan year 2016 in order to accommodate the new self plus one enrollment type. It was suggested that OPM impose a 10% cap on such growth in the final rule, especially for the first year of implementation. Others expressed concerns about the differential between the three enrollment tiers. OPM was asked to clarify whether or not the enrollee share of a self plus one enrollment would be less than or exactly equal to two self only enrollments. One carrier projected that, although self plus one premiums might not rise above self and family premiums, the differential between the two would be negligible, calling into question the cost-benefit of such a change given the high administrative burden of implementation.

Other commenters expressed concerns about actual claims costs. One highlighted the unique nature of the FEHB risk pool because the annuitant population is combined with the active employee population, indicating that many annuitants, who traditionally have higher claims costs, have only one eligible family member and therefore might make up the bulk of self plus one enrollees. Two commenters pointed out that HMO plans might be especially impacted. They expressed concerns that, if OPM were to require that self

<sup>1</sup> Full text available at <http://www.gpo.gov/fdsys/pkg/BILLS-113hjres59enr/pdf/BILLS-113hjres59enr.pdf>.

<sup>2</sup> United States Office of Personnel Management, Federal Employees Health Benefits Program Call Letter, Fiscal Year 2016, Issued March 13, 2015. <https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-02.pdf>

plus one total premiums remain below self and family total premiums, the end result would be an even more dramatic increase for self and family enrollees. The commenter projected that this change would render some regional HMOs non-competitive, forcing them out of the FEHB market.

The final rule does not set differentials between tiers, nor does it impose caps on premium growth. Under the three tier system, carriers will set rate differentials between tiers that are appropriate for the expected population, just as they do under the two tier system. An artificial cap is unwarranted because plans must set rates that reflect the costs of the population they will be covering. Further, enrollees have free choice to stay in their current plan or shop for a less expensive plan or option that meets their needs. Because the FEHB Program is market-based, artificial caps on premium are likely to cause adverse consequences such as inadequate rates for some products.

One commenter requested that rate information be provided earlier than normally scheduled to provide individuals adequate time to analyze their options. Given the rate negotiation process outlined in § 890.501, OPM cannot set the government contribution before September 1st for the following plan year.

### Comments on the Regulatory Impact Analysis

Commenters who discussed OPM's Regulatory Impact Analysis (RIA) in the proposed rule asked that OPM provide a more robust analysis for public comment. Four commenters suggested that the RIA provided in the proposed rule was insufficient under requirements outlined in the Administrative Procedures Act, Executive Order 12866, Executive Order 13563, and the Congressional Review Act. They suggested a delay in implementation in order to conduct additional analysis, provide details to the public, and allow for an additional comment period. One commenter stated OPM had failed to properly justify the change and to explain the potential impacts on the FEHB Program. Multiple commenters disagreed with OPM's assertion that self plus one premiums would likely be lower than self and family. One commenter noted that the RIA failed to discuss the possibility of rate differentials between the enrollment types. The commenter suggested that all carriers should be required to maintain the same differentials between their plan tiers. The commenter requested an actuarial analysis of the method that will be

utilized to determine the weighted average of all FEHB plans for plan year 2015.

OPM believes the analysis provided in the proposed rule fulfills legal requirements. As noted in the proposed and reiterated in the final rule, this change is being implemented to comply with the 2013 Bipartisan Budget Act. In addition, this change aligns insurance offerings with those available in the commercial market and more equitably spreads costs among the enrollment types offered.

### Information Provided to Carriers

Four commenters requested that we clarify information for carriers. One commenter asked OPM to release details, including the final rule, by March 31, 2015 to allow carriers ample time to prepare. Another commenter asked for additional details on enrollment and eligibility under the new self plus one enrollment type; however, provided no specific questions.

One commenter asked that OPM clarify benefits structures including deductibles and out of pocket maximums. OPM addressed these issues through normal carrier communications including the annual call letter, carrier letters, and teleconferences. OPM utilizes several methods for communicating with carriers including, but not limited to carrier letters, brochure tools, and teleconferences. Some of the information requested during the public comment period either has already been released or is forthcoming via these alternative communication methods.

### Systems Updates

OPM received three comments relative to the systems updates required to implement the new self plus one enrollment type. One commenter also asked that the brochure template language be available early. Two commenters suggested that OPM improve processes by which dependent information is communicated to carriers. An employee organization noted that the number of enrollment changes in Open Season 2015 is likely to far exceed the average Open Season and expressed concerns that the overall system would not be able to handle this increased number of enrollment changes.

OPM has carefully and deliberately been reviewing, modifying, and testing internal systems to ensure that enrollee information is accurately collected and disseminated to carriers. In addition, numerous communications have been distributed on the required systems

changes with agencies, carriers, and enrollment systems. We are confident that, through all of these efforts, all necessary systems updates will be completed in time for a smooth implementation of the self plus one enrollment type in plan year 2016.

### Paperwork Reduction Act (PRA)

OPM has reviewed this final rule for PRA implications and has determined that it does not apply to this section.

### Regulatory Impact Analysis

Executive Order 12866 and Executive Order 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules that may have economically significant effects (*i.e.*, effects of \$100 million or more in at least one year). Given that there are approximately 8.2 million members participating in the FEHB Program, including approximately one million two-person self and family enrollments, and participation involves hundreds of dollars per member per month, we cannot rule out the possibility that this final rule's changes to the FEHB Program will have effects that meet the threshold for economic significance. We do expect the overall federal budget impact of this final rule to be net neutral, though this is subject to uncertainty.

The new enrollment tier will align FEHB Program offerings with the commercial market and serve to more equitably spread costs across different enrollment types; in other words, it will shift costs among program participants. For plan year 2016, OPM has required that that the self plus one enrollment type have total premiums no greater than self and family total premiums.

### Current FEHB Enrollment Trends

In plan year 2015 there were over 4 million FEHB contracts. This includes 1.89 million self only contracts (47%) and 2.13 million self and family contracts (53%).

During a typical year, approximately 6% of FEHB enrollees change their enrollment by selecting a new plan option or a new enrollment type (approximately 8% of active employees and 4% of annuitants). However, as this is the first time the FEHB Program has experienced a large-scale programmatic change as the addition of a new enrollment type, it is expected that

movement will be greater in the coming years as enrollees learn more about their options.

#### *Predicting Enrollment Trends Under the Three Tier System*

In order to estimate the impact of the addition of the self plus one enrollment type, OPM has conducted an analysis to predict the potential shift in enrollment that may occur.

OPM determined that the following movement patterns were possible:

- FEHB eligible individuals who are currently not enrolled may choose to enroll in FEHB after self plus one becomes available.
- Current self only enrollees may choose to increase enrollment to include coverage for an eligible family member who is not currently covered under an FEHB enrollment.
- Current self only enrollees may choose to cancel coverage in order to be covered under a spouse or parent's self plus one FEHB enrollment.
- Current self and family enrollees with only one eligible family member may choose to decrease to a self plus one enrollment.
- Current self and family enrollees with two or more eligible family members may choose to decrease to a self plus one enrollment to cover only one of their eligible family members.
- Some FEHB enrollees in either self only or self and family may choose to cancel their enrollments.
- Enrollees in either self only or self and family may choose to remain in their current enrollment type.

Based on available data and experience, OPM estimates that much of the movement that will occur will result in a shift from one enrollment type to another. There are a limited number of circumstances where the addition of the self plus one enrollment type may result in new FEHB enrollees or in enrollees leaving the program. It is difficult to estimate how many individuals may newly enroll in the program. Most employees who do not participate in the FEHB Program do so because they have access to other insurance options. This rule will not alter access to other insurance for FEHB eligible employees. Also, because OPM does not have government-wide eligible and covered family member data, it is not known exactly how many individuals are covered under self and family enrollments, nor is it known how many eligible family members exist but are not currently covered because the enrollee has chosen a self only enrollment.

In order to learn more about potential movement between enrollment types,

OPM requested data on covered enrollees and family members from carriers with the 2014 rate proposals. Carriers reported that over one million self and family contracts had only one dependent listed. Of those enrollments, approximately 60% were annuitants and 40% were active employees. While this number does not capture the universe of enrollees who may choose a self plus one enrollment, it does provide a starting place for estimating the potential movement between tiers.

OPM also examined enrollment data for the Federal Employees Dental and Vision Insurance Program (FEDVIP). FEDVIP has offered self plus one as an enrollment option since its inception in 2007. There are currently approximately 2.7 million FEDVIP contracts. Of those, 41% are self only, 32% are self plus one, and 27% are self and family.

Comparing FEHB and FEDVIP enrollment patterns may be illustrative because the pool of eligible individuals is roughly the same. Most FEDVIP enrollees are also eligible for FEHB. However, there are some key differences between the programs. First, family member eligibility guidelines are slightly different. Eligible children are covered under FEDVIP enrollments until the age of 22 whereas eligible children are covered under FEHB until the age of 26. Second, FEDVIP has lower participation as it is an employee-pay-all program with no government contribution towards the premium. In addition, benefits offered in standalone dental and vision programs are limited, and therefore, enrollee behavior and motivation based on those benefits would be different.

Examining the types of movement that are possible and comparing FEHB enrollment trends with other programs provides only a limited view of the complex factors that affect enrollment decisions for enrollees. Enrollee choice and movement is an individualized decision based on the needs of the enrollee and their dependents. Self plus one uptake is dependent on a combination of factors including premiums, benefits structures, and the level of communication from agencies, carriers, and OPM about new enrollment options.

For most enrollees, the enrollee share for self plus one will be lower than for self and family; however, it is possible that, because of the statutory formula used to calculate the government contribution, some plans may have a higher enrollee share for self plus one than for self and family. This will make it even more important for enrollees to review their enrollment options before selecting a plan and an enrollment type

that meets their needs. OPM is implementing a robust communications strategy to ensure that as many enrollees as possible are aware of the new self plus one enrollment type.

Plan design remains the same between enrollment types offered in the same plan option. Therefore, OPM expects that cognitive costs for enrollees would be relatively low. For those enrollees that do not typically reevaluate their enrollment every Open Season, the cognitive costs of a review of the plans, plan options, and enrollment types available may well be worth incurring, as they may discover better alternatives (though these improvements may represent transfers from other members of society, rather than benefits to society as whole). Ultimately, actual enrollment decisions cannot be predicted with precision. Further, it will likely take years for enrollment numbers to reach an equilibrium following this Program change.<sup>3</sup>

#### *Cost Analysis*

OPM's Fiscal Year 2014 Congressional Budget Justification<sup>4</sup> included a projection that the addition of the self plus one enrollment would have a net neutral impact on the Federal budget. This projection, based on FEHB carriers' relative costs and population

<sup>3</sup> As discussed in more detail elsewhere in this analysis, plan switching—in which federal employees and annuitants with one eligible family member gravitate toward plans with relatively low self plus one premiums and federal employees and annuitants with multiple eligible family members gravitate toward plans with relatively low self and family premiums—would lead to further changes in premiums, and several iterations of switching activity and premium adjustments may occur before the new equilibrium is reached. Moreover, because health insurance decisions tend to be characterized by inertia, the behavioral changes discussed here and throughout this analysis may be relatively rare when this rule is first implemented and then become more widespread over time, as turnover occurs in the federal workforce and there is an accumulation of qualifying life events that cause FEHB participants to reconsider their health insurance choices.

<sup>4</sup> United States Office of Personnel Management, Congressional Budget Justification Performance Budget, Fiscal Year 2014, Submitted April 2013, available at <https://www.opm.gov/about-us/budget-performance/budgets/congressional-budget-justification-fy2014.pdf>. See also Congressional Budget Office, Cost Estimate, Bipartisan Budget Act of 2013, dated December 11, 2013, available at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/Bipartisan%20Budget%20Act%20of%202013.pdf>. In estimating potential premium changes, OPM used data on FEHB enrollees' medical expenditures, while CBO used data on medical expenditures for the general population. Because of the large number of annuitants in the FEHB enrolled population, two-person FEHB enrollments tend to have higher costs than two-person enrollments in the nation as a whole, thus explaining some of the difference between OPM's and CBO's estimates.

distributions, included the following assumptions:

- The average premium for self plus one coverage will be approximately 94% of the cost of existing self and family coverage.
- The average premium for self and family coverage will be approximately 107% of the cost of existing self and family coverage.
- 33% of active employees with existing self and family will shift to self plus one coverage.
- Only 20% of annuitants with existing self and family coverage will retain that coverage (80% will shift to self plus one).

As discussed above, there are several ways in which enrollees may choose to change their enrollment based on the addition of the self plus one enrollment type. The magnitudes of these changes (and the effects experienced by the government that depend on FEHB participants' behavior) would be correlated with the amount that participant premium contributions change. If, as shown above, self plus one premiums are only slightly lower than baseline self and family premiums, then two-person families will have little incentive to transfer family members from other coverage to FEHB. Similarly, if self and family premiums increase only slightly as a result of this rule, then families larger than two people will have little incentive to switch some or all of their members from FEHB to other health insurance coverage. As a result, in this example, a change in the cost of the Program would be contingent, in part, upon the amount of switching into or out of FEHB from/to other health insurance.

Current enrollees with self and family coverage who only have one dependent and choose to decrease enrollment to self plus one, will likely benefit from lower premiums. Those with more than one dependent covered under a self and family enrollment will likely incur higher premiums. A large percentage of annuitants who currently have self and family coverage would likely benefit from the lower total premiums of a self plus one enrollment type, resulting in score-able savings to the government because the government share of annuitant premiums will decrease.

OPM estimated that, in total, savings for annuitants and the government would rise above \$450 million in the first year of self plus one. Conversely, costs for non-Postal employees and the government would rise about \$450 million for the same time frame. This converse relationship between costs associated with annuitants and employees continues into future year

projections and results in the overall net-neutral projection.

Actual cost shifting cannot be measured until rate negotiations are finalized and enrollment changes take place. As enrollees shift from self only and self and family enrollments, OPM will closely monitor the effect on premiums. If premiums for active employees with two or more covered family members rise, there will be increasing costs to government agencies (assuming appropriation of necessary funds).<sup>5</sup>

The impact of this final rule hinges upon the relative premiums for self plus one and self and family enrollment types. Because the self and family option includes coverage for a larger number of people, a natural assumption would be that premiums would be lower for a self plus one enrollment type than for a self and family enrollment type. For plan year 2016, OPM instructed carriers to propose total premiums for self plus one that were less than or equal to total premiums for self and family. In that case, several rule-induced outcomes are likely:

- Federal employees and annuitants who, in the absence of the rule, would choose self and family enrollment for themselves and either a spouse or a child would switch to a self plus one enrollment, resulting in lower total premium payments between employees, annuitants and the federal government.
- Federal employees and annuitants choosing self and family enrollment for themselves and at least two family members would experience an increase in premiums and therefore, in some cases, may choose to switch from FEHB to an alternative health insurance option. If all such families continued with FEHB participation, the government would experience an increase in premium payments that would (in theory) exactly offset the decreases associated with two-person families switching from self and family to self plus one enrollment; however, any switching away from FEHB would mitigate the premium increases experienced by the federal government, instead potentially leading to payment increases by any contributors to the newly-chosen insurance options (an obvious example would be the employer

of a federal employee's or annuitant's spouse if that employer sponsors the newly-chosen insurance).

- Federal employees and annuitants who, in the absence of the rule, would choose self only enrollment in spite of having a spouse who would be eligible for coverage under self and family enrollment may choose self plus one enrollment. This might occur if a self and family premium is greater than the combined premiums for a federal employee's self only enrollment and a spouse's self only enrollment in health insurance through his or her own non-federal employer, but the relevant FEHB self plus one premium is less than the combined premiums.<sup>6</sup> In this type of scenario in which the federal employee's or annuitant's enrollment increases, the federal government would pay more in premiums (relative to a baseline in which this rule is not finalized) but the federal employee's or annuitant's family would pay less. Any contributors to the insurance in which the family member would be enrolled in the absence of the rule—such as the non-federal employer of the federal employee's spouse in the preceding example—would also pay less.

To the extent that new patterns of enrollment do not change how society uses its resources (*i.e.*, amount or quality of medical services provided), then the effects described above would be transfers between members of society, rather than social costs or benefits.

It is possible that two-person families are, on average, less healthy than larger families; indeed, multiple comments to the docket provided evidence that some plans' expenditures for two-person enrollments are higher than for enrollments with three or more total family members. For the 2016 plan year, because OPM has requested that carriers propose self plus one premiums no greater than self and family premiums, plans with this medical expenditure pattern will presumably set equal premiums for self plus one and self and family enrollment types. In the event that OPM does not repeat this request for future years, plans with higher average expenditures for two-person than for larger families will presumably set premiums higher for self plus one enrollment than for self and family

<sup>5</sup> United States Office of Personnel Management, Congressional Budget Justification Performance Budget, Fiscal Year 2014, Submitted April 2013, available at <https://www.opm.gov/about-us/budget-performance/budgets/congressional-budget-justification-fy2014.pdf>. See also Congressional Budget Office, Cost Estimate, Bipartisan Budget Act of 2013, dated December 11, 2013, available at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/Bipartisan%20Budget%20Act%20of%202013.pdf>.

<sup>6</sup> Similarly, federal employees and annuitants who, in the absence of the rule, would choose not to participate in the FEHB Program may choose a self plus one enrollment. For example, this outcome might occur if the self plus one option available in the FEHB Program is less expensive than either a family or plus-one enrollment available via a federal employee's spouse or the combined premiums for the federal employee's self only enrollment and the spouse's self only enrollment.



enrollment. If this pattern—in which self plus one premiums are greater than or equal to self and family premiums—held universally, the lack of premium decrease to give federal employees and annuitants an incentive to switch from self and family to self plus one enrollment would lead to the rule’s enrollment impact being negligible.<sup>7</sup> However, as indicated by docket submissions, relative expenditures on (and thus premiums for) two-person and larger enrollments differ across plans, and hence the effect of adding the self plus one option may be to increase switching between plans, as federal employees and annuitants with one eligible family member gravitate toward plans with relatively low self plus one premiums and federal employees and annuitants with multiple eligible family members gravitate toward plans with relatively low self and family premiums. Plan switching of this type would lead to further changes in premiums and several iterations of switching activity and premium adjustments may occur.

Additionally, the rule imposes implementation costs, such as the costs of systems updates, on FEHB-participating health insurance plans, federal agencies, and on OPM itself. These expenses are encompassed in existing workloads. OPM has no specific estimate for these costs, but expects them to be marginal.

Though regulatory alternatives to this rule are limited due to the statutory mandate, OPM did consider delaying implementation of the rule until the 2017 plan year. OPM rejected this option for two reasons. First, delaying implementation will not provide additional information. Because OPM contracts with a number of carriers, proposed rates are proprietary and cannot be released publically without compromising confidential negotiation processes. Until first year negotiations are completed and enrollment changes occur, OPM would not have a precise understanding of the impact of the self plus one enrollment type on premiums.

Second, implementation has already been delayed. After the passage of the 2013 Bipartisan Budget Act, the first year that implementation would have been possible was plan year 2015. OPM determined that this was not adequate time to implement the new enrollment type and chose to delay implementation

until 2016. OPM, carriers, and Federal agencies are well into the implementation process. Rate negotiations between OPM and FEHB carriers have begun under the assumption that the 2016 plan year would include the self plus one enrollment type. Agencies and carriers are currently implementing the systems changes required to accommodate three tier enrollments. Delaying implementation would adversely impact the Federal benefits Open Season which is scheduled to begin in early November of this year.

**Congressional Review Act**

OPM has determined that this regulatory action is not subject to the Congressional Review Act, 5 U.S.C. 801–08, because it relates to agency management and personnel. The program is not statutorily for general application but rather governs employment fringe benefits for Federal employees, annuitants and their families. Moreover, OPM has been statutorily granted discretion in terms of deciding how its actions may affect non-agency parties, such as carriers, by its authority to regulate enrollment. See, 5 U.S.C. 8905(a), 8905(g)(2), and 8913(b).

**Regulatory Flexibility Act**

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation only adds a self plus one enrollment tier to the current self only and self and family enrollment tiers under FEHB.

**Executive Orders 13563 and 12866, Regulatory Review**

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Orders 13563 and 12866.

**Federalism**

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

**List of Subjects**

5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Military personnel, Reporting and recordkeeping requirements, Retirement.

5 CFR Part 892

Administrative practice and procedure, Government employees, Health insurance, Taxes, Wages.

U.S. Office of Personnel Management.

**Beth F. Cobert,**  
*Acting Director.*

Accordingly, OPM is amending title 5, Code of Federal Regulations as follows:

**PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM**

■ 1. The authority citation for part 890 continues to read as follows:

**Authority:** 5 U.S.C. 8913; Sec. 890.301 also issued under sec. 311 of Pub. L. 111–03, 123 Stat. 64; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521; Sec. 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604; 5 U.S.C. 8913; Sec. 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; Sec. 890.102 also issued under sections 11202(f), 11232(e), 11246(b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061.

- 2. Amend § 890.101 as follows:
  - a. By revising the definitions of “Change the enrollment” and “Covered family member.”
  - b. By adding the definitions of “Decrease enrollment type,” “Increase enrollment type,” “Self and family enrollment,” “Self only enrollment,” “Self plus one enrollment,” and “Switch a covered family member” in alphabetical order.

The revisions and additions read as follows:

**§ 890.101 Definitions; time computations.**

\* \* \* \* \*

*Change the enrollment* means to submit to the employing office an appropriate request electing a change of enrollment to a different plan or option, or to a different type of coverage (self only, self plus one, or self and family).

\* \* \* \* \*

*Covered family member* means a member of the family of an enrollee with a self plus one or self and family enrollment who meets the requirements of §§ 890.302, 890.804, or 890.1106(a), as appropriate to the type of enrollee.

\* \* \* \* \*

*Decrease enrollment type* means a change in enrollment from self and family to self plus one or to self only or a change from self plus one to self only.

\* \* \* \* \*

*Increase enrollment type* means a change in enrollment from self only to self plus one or to self and family or a

<sup>7</sup> This negligible-impact outcome may not occur if the government contribution, as determined by statutory formula, was such that enrollee contributions were lower for self plus one enrollments than for self and family enrollments even in cases where total premiums for self plus one enrollments were greater than or equal to total premiums for self and family enrollments.

change from self plus one to self and family.

\* \* \* \* \*

*Self and family enrollment* means an enrollment that covers the enrollee and all eligible family members.

*Self only enrollment* means an enrollment that covers only the enrollee.

*Self plus one enrollment* means an enrollment that covers the enrollee and one eligible family member.

\* \* \* \* \*

*Switch a covered family member* means, under a self plus one enrollment, to terminate or cancel the enrollment of the designated covered family member and designate another eligible family member for coverage.

\* \* \* \* \*

■ 3. Amend § 890.201 by revising paragraph (a)(6) to read as follows:

**§ 890.201 Minimum standards for health benefits plans.**

(a) \* \* \*

(6) Provide a standard rate structure that contains, for each option, one standard self only rate, one standard self plus one rate and one standard self and family rate.

\* \* \* \* \*

■ 4. Amend § 890.301 by revising paragraphs (e), (f)(3), (g)(1) and (3), (h) heading and introductory text, (i) introductory text, (i)(1), and (m) to read as follows:

**§ 890.301 Opportunities for employees who are not participants in premium conversion to enroll or change enrollment; effective dates.**

\* \* \* \* \*

(e) *Decreasing enrollment type.* (1) Subject to two exceptions, an employee may decrease enrollment type at any time. *Exceptions:*

(i) An employee participating in health insurance premium conversion may decrease enrollment type during an open season or because of and consistent with a qualifying life event as defined in part 892 of this chapter.

(ii) An employee who is subject to a court or administrative order as discussed in paragraph (g)(3) of this section may not decrease enrollment type in a way that eliminates coverage of a child identified in the order as long as the court or administrative order is still in effect and the employee has at least one child identified in the order who is still eligible under the FEHB Program, unless the employee provides documentation to the agency that he or she has other coverage for the child(ren). The employee may not elect self only as long as he or she has one child identified as covered, but may elect self plus one.

(2) A decrease in enrollment type takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the enrollee and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the self plus one or self and family enrollment, or only one family member eligible for coverage under the self and family enrollment, as appropriate, the employing office may make the change effective on the first day of the pay period following the one in which there was, in the case of a self plus one enrollment, no family member or, in the case of a self and family enrollment, only one or no family member.

(f) \* \* \*

(3) With one exception, during an open season, an eligible employee may enroll and an enrolled employee may decrease or increase enrollment type, may change from one plan or option to another, or may make any combination of these changes. *Exception:* An employee who is subject to a court or administrative order as discussed in paragraph (g)(3) of this section may not cancel his or her enrollment, decrease enrollment type, or change to a comprehensive medical plan that does not serve the area where his or her child or children live as long as the court or administrative order is still in effect, and the employee has at least one child identified in the order who is still eligible under the FEHB Program, unless the employee provides documentation to the agency that he or she has other coverage for the child(ren). The employee may not elect self only as long as he or she has one child identified as covered, but may elect self plus one.

\* \* \* \* \*

(g) *Change in family status.* (1) An eligible employee may enroll and an enrolled employee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the employee's family status changes, including a change in marital status or any other change in family status. The employee must enroll or change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

\* \* \* \* \*

(3)(i) If an employing office receives a court or administrative order on or after October 30, 2000, requiring an employee to provide health benefits for his or her child or children, the employing office

will determine if the employee has a self plus one or self and family enrollment, as appropriate, in a health benefits plan that provides full benefits in the area where the child or children live. If the employee does not have the required enrollment, the agency must notify him or her that it has received the court or administrative order and give the employee until the end of the following pay period to change his or her enrollment or provide documentation to the employing office that he or she has other coverage for the child or children. If the employee does not comply within these time frames, the employing office must enroll the employee involuntarily as stated in paragraph (g)(3)(ii) of this section.

(ii) If the employee is not enrolled or does not enroll, the agency must enroll him or her for self plus one or self and family coverage, as appropriate, in the option that provides the lower level of coverage in the Service Benefit Plan. If the employee is enrolled but does not increase the enrollment type in a way that is sufficient to cover the child or children, the employing office must change the enrollment to self plus one or self and family, as appropriate, in the same option and plan, as long as the plan provides full benefits in the area where the child or children live. If the employee is enrolled in a comprehensive medical plan that does not serve the area in which the child or children live, the employing office must change the enrollment to self plus one or self and family, as appropriate, in the option that provides the lower level of coverage in the Service Benefit Plan.

\* \* \* \* \*

(h) *Change in employment status.* An eligible employee may enroll and an enrolled employee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the employee's employment status changes. Except as otherwise provided, an employee must enroll or change the enrollment within 60 days after the change in employment status. Employment status changes include, but are not limited to—

\* \* \* \* \*

(i) *Loss of coverage under this part or under another group insurance plan.* An eligible employee may enroll and an enrolled employee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the employee or an eligible family member of the employee loses coverage under this part or another group health benefits plan. Except as otherwise

provided, an employee must enroll or change the enrollment within the period beginning 31 days before the date of loss of coverage, and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self plus one or to self only, of the covering enrollment.

\* \* \* \* \*

(m) *An employee or eligible family member becomes eligible for premium assistance under Medicaid or a State Children's Health Insurance Program (CHIP).* An eligible employee may enroll and an enrolled employee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the employee or an eligible family member of the employee becomes eligible for premium assistance under a Medicaid plan or CHIP. An employee must enroll or change his or her enrollment within 60 days after the date the employee or family member is determined to be eligible for assistance.

■ 5. Amend § 890.302 by revising paragraphs (a)(1), (a)(2)(ii), and (c) introductory text and adding paragraph (f) to read as follows:

**§ 890.302 Coverage of family members.**

(a)(1) An enrollment for self plus one includes the enrollee and one eligible family member. An enrollment for self and family includes all family members who are eligible to be covered by the enrollment. Except as provided in paragraph (a)(2) of this section, no employee, former employee, annuitant, child, or former spouse may enroll or be covered as a family member if he or she is already covered under another person's self plus one or self and family enrollment in the FEHB Program.

(2) \* \* \*

(ii) *Exception.* An individual described in paragraph (a)(2)(i) of this section may enroll if he or she or his or her eligible family members would otherwise not have access to coverage, in which case the individual may enroll in his or her own right for self only, self plus one, or self and family coverage, as appropriate. However, an eligible individual is entitled to receive benefits under only one enrollment regardless of whether he or she qualifies as a family member under a spouse's or parent's enrollment. To ensure that no person receives benefits under more than one enrollment, each enrollee must promptly notify the insurance carrier as to which person(s) will be covered

under his or her enrollment. These individuals are not covered under the other enrollment. Examples include but are not limited to:

(A) To protect the interests of married or legally separated Federal employees, annuitants, and their children, an employee or annuitant may enroll in his or her own right in a self only, self plus one, or self and family enrollment, as appropriate, even though his or her spouse also has a self plus one or self and family enrollment if the employee, annuitant, or his or her children live apart from the spouse and would otherwise not have access to coverage due to a service area restriction and the spouse refuses to change health plans.

(B) When an employee who is under age 26 and covered under a parent's self plus one or self and family enrollment acquires an eligible family member, the employee may elect to enroll for self plus one or self and family coverage.

\* \* \* \* \*

(c) *Child incapable of self-support.* When an individual's enrollment for self plus one or self and family includes a child who has become 26 years of age and is incapable of self-support, the employing office must require such enrollee to submit a physician's certificate verifying the child's disability. The certificate must—

\* \* \* \* \*

(f) *Switching a covered family member.* (1) An enrollee with a self plus one enrollment may switch his or her covered family member during the annual Open Season, upon a change in family status, upon a change in coverage, or upon a change in eligibility, so long as switching a covered family member is consistent with the event that has taken place.

(2) Switching a covered family member under a self plus one enrollment will be effective on the first day of the first pay period that begins after the date the employing office receives an appropriate request to switch the covered family member.

■ 6. Amend § 890.303 by revising paragraphs (c), (d)(2)(ii), and the heading of paragraph (d)(3) to read as follows:

**§ 890.303 Continuation of enrollment.**

\* \* \* \* \*

(c) *On death.* The enrollment of a deceased employee or annuitant who is enrolled for self plus one or self and family (as opposed to self only) is transferred automatically to his or her eligible survivor annuitant(s) covered by the enrollment, as applicable. For self and family, the enrollment is considered to be that of:

(1) The survivor annuitant from whose annuity all or the greatest portion of the withholding for health benefits is made; or

(2) The surviving spouse entitled to a basic employee death benefit. The enrollment covers members of the family of the deceased employee or annuitant. In those instances in which the annuity is split among surviving family members, multiple enrollments are allowed. A remarried spouse is not a member of the family of the deceased employee or annuitant unless annuity under section 8341 or 8442 of title 5, United States Code, continues after remarriage.

(d) \* \* \*

(2) \* \* \*

(ii) If the surviving spouse of a deceased employee or annuitant is enrolled as an employee with a self plus one or self and family enrollment (or, if both the decedent and the surviving spouse were enrolled in a self only or self plus one enrollment) at the time the surviving spouse becomes a survivor annuitant and the surviving spouse is thereafter separated without entitlement to continued enrollment as a retiree, the surviving spouse is entitled to enroll as a survivor annuitant. The change from coverage as an employee to coverage as a survivor annuitant must be made within 30 days of separation from service.

\* \* \* \* \*

(3) *Insurable interest survivor annuity.*

\* \* \*

\* \* \* \* \*

■ 7. Amend § 890.306 by revising paragraphs (e), (f)(1)(i), (g)(1), (l) introductory text, (l)(1), (n), and (r) to read as follows:

**§ 890.306 When can annuitants or survivor annuitants change enrollment or reenroll and what are the effective dates?**

\* \* \* \* \*

(e) *Decreasing enrollment type.* (1) With one exception, an annuitant may decrease enrollment type at any time. Exception: An annuitant who, as an employee, was subject to a court or administrative order as discussed in § 890.301(g)(3) at the time he or she retired may not, after retirement, decrease enrollment type in a way that eliminates coverage of a child identified in the order as long as the court or administrative order is still in effect and the annuitant has at least one child identified in the order who is still eligible under the FEHB Program, unless the annuitant provides documentation to the retirement system that he or she has other coverage for the child or children. The annuitant may not elect

self only as long as he or she has one child identified as covered, but may elect self plus one.

(2) A decrease in enrollment type takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the annuitant and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the self plus one or self and family enrollment, or only one family member eligible for coverage under the self and family enrollment, as appropriate, the employing office may make the change effective on the first day of the pay period following the one in which there was, in the case of a self plus one enrollment, no family member or, in the case of a self and family enrollment, only one or no family member.

(f) \* \* \*

(1) \* \* \*

(i) With one exception, an enrolled annuitant may decrease or increase enrollment type, may change from one plan or option to another, or may make any combination of these changes. Exception: An annuitant who, as an employee, was subject to a court or administrative order as discussed in § 890.301(g)(3) at the time he or she retired may not cancel or suspend his or her enrollment, decrease enrollment type in a way that eliminates coverage of a child identified in the order or change to a comprehensive medical plan that does not serve the area where his or her child or children live after retirement as long as the court or administrative order is still in effect and the annuitant has at least one child identified in the order who is still eligible under the FEHB Program, unless the annuitant provides documentation to the retirement system that he or she has other coverage for the child or children. The annuitant may not elect self only as long as he or she has one child identified as covered, but may elect self plus one.

\* \* \* \* \*

(g) *Change in family status.* (1) An enrolled former employee in receipt of an annuity may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the annuitant's family status changes, including a change in marital status or any other change in family status. In the case of an enrolled survivor annuitant, a change in family status based on additional family members occurs only if the additional family members are

family members of the deceased employee or annuitant. The annuitant must change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

\* \* \* \* \*

(l) *Loss of coverage under this part or under another group insurance plan.* An annuitant who meets the requirements of paragraph (a) of this section, and who is not enrolled but is covered by another enrollment under this part may continue coverage by enrolling in his or her own name when the annuitant loses coverage under the other enrollment under this part. An enrolled annuitant may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the annuitant or an eligible family member of the annuitant loses coverage under this part or under another group health benefits plan. Except as otherwise provided, an annuitant must enroll or change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self plus one or self only, of the covering enrollment;

\* \* \* \* \*

(n) *Overseas post of duty.* An annuitant may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes within 60 days after the retirement or death of the employee on whose service title to annuity is based, if the employee was stationed at a post of duty outside a State of the United States or the District of Columbia at the time of retirement or death.

\* \* \* \* \*

(r) *Sole survivor.* When an employee or annuitant enrolled for self plus one or self and family dies, leaving a survivor annuitant who is entitled to continue the enrollment, and it is apparent from available records that the survivor annuitant is the sole survivor entitled to continue the enrollment, the office of the retirement system which is acting as employing office must decrease the enrollment to self only, effective on the commencing date of the survivor annuity. On request of the survivor annuitant made within 31 days after the first installment of annuity is paid, the office of the retirement system

which is acting as employing office must rescind the action retroactive to the effective date of the change to self only, with corresponding adjustment in withholdings and contributions.

\* \* \* \* \*

■ 8. Amend § 890.401 by revising paragraph (a)(1) to read as follows:

**§ 890.401 Temporary extension of coverage and conversion.**

(a) *Thirty-one day extension and conversion.* (1) An enrollee whose enrollment is terminated other than by cancellation of the enrollment or discontinuance of the plan, in whole or part, and a covered family member whose coverage is terminated other than by cancellation of the enrollment or discontinuance of the plan, in whole or in part, is entitled to a 31-day extension of coverage for self only, self plus one, or self and family, as the case may be, without contributions by the enrollee or the Government, during which period he or she is entitled to exercise the right of conversion provided for by this part. The 31-day extension of coverage and the right of conversion for any person ends on the effective date of a new enrollment under this part covering the person.

\* \* \* \* \*

■ 9. Amend § 890.501 by revising paragraphs (b) introductory text, (b)(2)(i), and (b)(3) to read as follows:

**§ 890.501 Government contributions.**

\* \* \* \* \*

(b) In accordance with the provisions of 5 U.S.C. 8906(a) which take effect with the contract year that begins in January 1999, OPM will determine the amounts representing the weighted average of subscription charges in effect for each contract year, for self only, self plus one, and self and family enrollments, as follows:

\* \* \* \* \*

(2) \* \* \*

(i) When a subscription charge for an upcoming contract year applies to a plan that is the result of a merger of two or more plans which contract separately with OPM during the determination year, or applies to a plan which will cease to offer two benefits options, OPM will combine the self only enrollments, the self plus one enrollments, and the self and family enrollments from the merging plans, or from a plan's benefits options, for purposes of weighting subscription charges in effect for the successor plan for the upcoming contract year.

\* \* \* \* \*

(3) After OPM weights each subscription charge as provided in

paragraph (b)(2) of this section, OPM will compute the total of subscription charges associated with self only enrollments, self plus one enrollments, and self and family enrollments, respectively. OPM will divide each subscription charge total by the total number of enrollments such amount represents to obtain the program-wide weighted average subscription charges for self only and for self plus one and self and family enrollments, respectively.

\* \* \* \* \*

■ 10. Amend § 890.804 by revising paragraph (a) to read as follows:

**§ 890.804 Coverage.**

(a) *Type of enrollment.* A former spouse who meets the requirements of § 890.803 may elect coverage for self only, self plus one, or self and family. A self and family enrollment covers only the former spouse and all eligible children of both the former spouse and the employee, former employee, or employee annuitant, provided such children are not otherwise covered by a health plan under this part. A self plus one enrollment covers only the former spouse and one eligible child of both the former spouse and the employee, former employee, or employee annuitant, provided the child is not otherwise covered by a health plan under this part. A child must be under age 26 or incapable of self-support because of a mental or physical disability existing before age 26. No person may be covered by two enrollments.

\* \* \* \* \*

■ 11. Amend § 890.806 by revising paragraphs (e), (f)(1)(i), (g)(1), (j) introductory text, and (j)(1) to read as follows:

**§ 890.806 When can former spouses change enrollment or reenroll and what are the effective dates?**

\* \* \* \* \*

(e) *Decreasing enrollment type.* (1) A former spouse may decrease enrollment type at any time.

(2) A decrease in enrollment type takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the former spouse and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the self plus one or self and family enrollment, or only one family member eligible for coverage under the self and family enrollment, as appropriate, the employing office may make the change effective on the first

day of the pay period following the one in which there was, in the case of a self plus one enrollment, no family member or, in the case of a self and family enrollment, only one or no family member.

(f) \* \* \*

(1) \* \* \*

(i) An enrolled former spouse may decrease enrollment type, increase enrollment type provided the family member(s) to be covered under the enrollment is eligible for coverage under § 890.804, change from one plan or option to another, or make any combination of these changes.

\* \* \* \* \*

(g) *Change in family status.* (1) An enrolled former spouse may increase enrollment type, change from one plan or option to another, or make any combination of these changes within the period beginning 31 days before and ending 60 days after the birth or acquisition of a child who meets the eligibility requirements of § 890.804.

\* \* \* \* \*

(j) *Loss of coverage under this part or under another group insurance plan.* An enrolled former spouse may decrease or increase enrollment type, change from one plan or option to another or make any combination of these changes when the former spouse or a child who meets the eligibility requirements under § 890.804 loses coverage under another enrollment under this part or under another group health benefits plan. Except as otherwise provided, the former spouse must change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage, provided he or she continues to meet the eligibility requirements under § 890.803. Losses of coverage include but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self plus one or self only, of the covering enrollment;

\* \* \* \* \*

■ 12. Amend § 890.1103 by revising paragraphs (a)(2) and (3) to read as follows:

**§ 890.1103 Eligibility.**

(a) \* \* \*

(2) Individuals whose coverage as children under the self plus one or self and family enrollment of an employee, former employee, or annuitant ends because they cease meeting the requirements for being considered covered family members. For the purpose of this section, children who

are enrolled under this part as survivors of deceased employees or annuitants are considered to be children under a self plus one or self and family enrollment of an employee or annuitant at the time of the qualifying event.

(3) Former spouses of employees, of former employees having continued self plus one or self and family coverage under this subpart, or of annuitants, if the former spouse would be eligible for continued coverage under subpart H of this part except for failure to meet the requirement of § 890.803(a)(1) or (3) or the documentation requirements of § 890.806(a), including former spouses who lose eligibility under subpart H within 36 months after termination of the marriage because they ceased meeting the requirement of § 890.803(a)(1) or (3).

\* \* \* \* \*

■ 13. Amend § 890.1106 by revising paragraph (a) introductory text to read as follows:

**§ 890.1106 Coverage.**

(a) *Type of enrollment.* An individual who enrolls under this subpart may elect coverage for self only, self plus one, or self and family.

\* \* \* \* \*

■ 14. Amend § 890.1108 by revising paragraphs (d), (e)(1), (f)(1) and (2), (h) introductory text, and (h)(1) to read as follows:

**§ 890.1108 Opportunities to change enrollment; effective dates.**

\* \* \* \* \*

(d) *Decreasing enrollment type.* (1) An enrollee may decrease enrollment type at any time.

(2) A decrease in enrollment type takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the enrollee and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the self plus one or self and family enrollment, or only one family member eligible for coverage under the self and family enrollment, as appropriate, the employing office may make the change effective on the first day of the pay period following the one in which there was, in the case of a self plus one enrollment, no family member or, in the case of a self and family enrollment, only one or no family member.

(e) *Open season.* (1) During an open season as provided by § 890.301(f), an enrollee (except for a former spouse who is eligible for continued coverage

under § 890.1103(a)(3) may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes. A former spouse who is eligible for continued coverage under § 890.1103(a)(3) may change from one plan or option to another, but may not increase enrollment type unless the individual to be covered under the self plus one or self and family enrollment qualifies as a family member under § 890.1106(a)(2).

(f) *Change in family status.* (1) Except for a former spouse, an enrollee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the enrollee's family status changes, including a change in marital status or any other change in family status. The enrollee must change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

(2) A former spouse who is covered under this section may increase enrollment type, change from one plan or option to another, or make any combination of these changes within the period beginning 31 days before and ending 60 days after the birth or acquisition of a child who qualifies as a covered family member under § 890.1106(a)(2).

(h) *Loss of coverage under this part or under another group insurance plan.* An enrollee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the enrollee loses coverage under this part or a qualified family member of the enrollee loses coverage under this part or under another group health benefits plan. Except as otherwise provided, an enrollee must change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or change to self plus one or to self only, of the covering enrollment.

■ 15. Amend § 890.1202 by revising the definition of "Covered family members" to read as follows:

**§ 890.1202 Definitions.**

\* \* \* \* \*

*Covered family members* as it applies to individuals covered under this subpart has the same meaning as set forth in § 890.101(a). For eligible survivors of individuals enrolled under this subpart, a self plus one enrollment covers only the survivor or former spouse and one eligible child of both the survivor or former spouse and hostage. A self and family enrollment covers only the survivor or former spouse and any eligible children of both the survivor or former spouse and hostage.

■ 16. Amend § 890.1203 by revising paragraph (b) to read as follows:

**§ 890.1203 Coverage.**

(b) An individual who is covered under this subpart is covered under the Standard Option of the Service Benefit Plan. The individual has a self and family enrollment unless the U.S. Department of State determines that the individual is married and has no eligible children, or is unmarried and has one eligible child, in which case the individual is covered under a self plus one enrollment, or unless the U.S. Department of State determines that the individual is unmarried and has no eligible children, in which case the individual has a self only enrollment.

■ 17. Amend § 890.1205 by revising paragraphs (a) and (b) to read as follows:

**§ 890.1205 Change in type of enrollment.**

(a) Individuals covered under this subpart or eligible survivors enrolled under this subpart may increase enrollment type if they acquire an eligible family member. The change may be made at the written request of the enrollee at any time after the family member is acquired. An increase in enrollment type under this paragraph (a) becomes effective on the 1st day of the pay period after the pay period during which the request is received by the U.S. Department of State, except that a change based on the birth or addition of a child as a new family member is effective on the 1st day of the pay period during which the child is born or otherwise becomes a new family member.

(b) Individuals covered under this subpart or eligible survivors enrolled under this subpart may decrease enrollment type from a self and family enrollment when the last eligible family member (other than the enrollee) ceases to be a family member or only one family member remains; and may decrease enrollment type from a self plus one enrollment when no family

member remains. The change may be made at the written request of the enrollee at any time after the last family member is lost and it becomes effective on the 1st day of the pay period after the pay period during which the request is received by the U.S. Department of State.

\* \* \* \* \*

■ 18. Amend § 890.1209 by revising paragraph (c) to read as follows:

**§ 890.1209 Responsibilities of the U.S. Department of State.**

\* \* \* \* \*

(c) The U.S. Department of State must determine the number of eligible family members, if any, for the purpose of coverage under a self only, self plus one, or self and family enrollment as set forth in § 890.1203(b). If the number of eligible family members of the individual cannot be determined, the U.S. Department of State must enroll the individual for self and family coverage.

**PART 892—FEDERAL FLEXIBLE BENEFITS PLAN: PRE-TAX PAYMENT OF HEALTH BENEFITS PREMIUMS**

■ 19. The authority citation for part 892 is revised to read as follows:

**Authority:** 5 U.S.C. 8913; 5 U.S.C. 1103(a)(7); 26 U.S.C. 125.

■ 20. In § 892.101, the definition of "Qualifying life event" is amended by revising the introductory text and paragraphs (9) and (13) to read as follows:

**§ 892.101 Definitions.**

\* \* \* \* \*

*Qualifying life event* means an event that may permit changes to your FEHB enrollment as well as changes to your premium conversion election as described in Treasury regulations at 26 CFR 1.125-4. For purposes of determining whether a qualifying life event has occurred under this part, a stepchild who is the child of an employee's domestic partner as defined in part 890 of this chapter shall be treated as though the child were a dependent within the meaning of 26 CFR 1.125-4 even if the child does not so qualify under such Treasury regulations. Such events include the following:

\* \* \* \* \*

(9) An employee becomes entitled to Medicare. (For change to self only, self plus one, cancellation, or change in premium conversion status see paragraph (11) of this definition.)

\* \* \* \* \*

(13) An employee or eligible family member becomes eligible for premium

assistance under Medicaid or a State Children's Health Insurance Program (CHIP). An eligible employee may enroll and an enrolled employee may decrease or increase enrollment type, change from one plan or option to another, or make any combination of these changes when the employee or an eligible family member of the employee becomes eligible for premium assistance under a Medicaid plan or a State Children's Health Insurance Program. An employee must enroll or change his or her enrollment within 60 days after the date the employee or family member is determined to be eligible for assistance.

■ 21. Amend § 892.207 by revising paragraph (b) and adding paragraph (d) to read as follows:

**§ 892.207 Can I make changes to my FEHB enrollment while I am participating in premium conversion?**

\* \* \* \* \*

(b) However, if you are participating in premium conversion there are two exceptions: You must have a qualifying life event to decrease enrollment type, switch a covered family member, or to cancel FEHB coverage entirely. (See §§ 892.209 and 892.210.) Your change in enrollment must be consistent with and correspond to your qualifying life event as described in § 892.101. These limitations apply only to changes you may wish to make outside open season.

\* \* \* \* \*

(d) During the first plan year in which the self plus one enrollment type is available, OPM will administer a limited enrollment period for enrollees who participate in premium conversion. During this limited enrollment period, enrollees who participate in premium conversion will be allowed to decrease enrollment from self and family to self plus one during a time period determined by OPM. No other changes, including changes in plan or plan option or increases in enrollment, will be allowed. Enrollments will be effective on the first day of the first pay period following the one in which the appropriate request is received by the employing office.

■ 22. Revise § 892.208 to read as follows:

**§ 892.208 Can I decrease my enrollment type at any time?**

If you are participating in premium conversion you may decrease your FEHB enrollment type under either of the following circumstances:

(a) *During the annual open season.* A decrease in enrollment type made during the annual open season takes effect on the 1st day of the first pay period that begins in the next year.

(b) *Within 60 days after you have a qualifying life event.* A decrease in enrollment type made because of a qualifying life event takes effect on the first day of the first pay period that begins after the date your employing office receives your appropriate request. Your change in enrollment must be consistent with and correspond to your qualifying life event. For example, if you get divorced and have no dependent children, changing to self only would be consistent with that qualifying life event. As another example, if both you and your spouse are Federal employees, and your youngest dependent turns age 26, changing from a self and family to a self plus one or two self only enrollments would be consistent and appropriate for that event.

(c) If you are subject to a court or administrative order as discussed in § 890.301(g)(3), you may not decrease enrollment type in a way that eliminates coverage of a child identified in the order as long as the court or administrative order is still in effect and you have at least one child identified in the order who is still eligible under the FEHB Program, unless you provide documentation to your agency that you have other coverage for your child or children. See also §§ 892.207 and 892.209. If you are subject to a court or administrative order as discussed in § 890.301(g)(3), you may not change your enrollment to self plus one as long as the court or administrative order is still in effect and you have more than one child identified in the order who is still eligible under the FEHB Program, unless you provide documentation to your agency that you have other coverage for your children. See also §§ 892.207 and 892.209.

[FR Doc. 2015-23348 Filed 9-16-15; 8:45 am]

**BILLING CODE 6325-63-P**

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**7 CFR Part 319**

[Docket No. APHIS-2014-0002]

RIN 0579-AD98

**Importation of Kiwi From Chile Into the United States**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the fruits and vegetables regulations to list kiwi

(*Actinidia deliciosa* and *Actinidia chinensis*) from Chile as eligible for importation into the United States subject to a systems approach. Under this systems approach, the fruit will have to be grown in a place of production that is registered with the Government of Chile and certified as having a low prevalence of *Brevipalpus chilensis*. The fruit will have to undergo pre-harvest sampling at the registered production site. Following post-harvest processing, the fruit will have to be inspected in Chile at an approved inspection site. Each consignment of fruit will have to be accompanied by a phytosanitary certificate with an additional declaration stating that the fruit had been found free of *Brevipalpus chilensis* based on field and packinghouse inspections. This rule allows for the safe importation of kiwi from Chile using mitigation measures other than fumigation with methyl bromide.

**DATES:** Effective October 19, 2015.

**FOR FURTHER INFORMATION CONTACT:** Ms. Claudia Ferguson, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; (301) 851-2352.

**SUPPLEMENTARY INFORMATION:**

**Background**

Under the regulations in “Subpart-Fruits and Vegetables” (7 CFR 319.56-1 through 319.56-73, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

On October 16, 2014, we published in the **Federal Register** (79 FR 62055-62058, Docket No. APHIS-2014-0002) a proposal<sup>1</sup> to amend the regulations by listing kiwi (*Actinidia deliciosa* and *Actinidia chinensis*) from Chile as eligible for importation into the United States under the same systems approach as baby kiwi from Chile, which are eligible for importation under the conditions in § 319.56-53. We also prepared a commodity import evaluation document (CIED) titled “Importation of Fresh Fruits of Kiwi (*Actinidia deliciosa* and *Actinidia chinensis*) from Chile into the United

<sup>1</sup> To view the proposed rule, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0002>.

States.” The CIED assesses the risks associated with the importation of kiwi from Chile into the United States under the listed phytosanitary measures.

We solicited comments concerning our proposal for 60 days ending December 15, 2014. We received seven comments by that date. They were from private citizens, a fruit exporter, an industry group, and representatives of State and foreign governments. Four of the comments were supportive. Three commenters expressed concerns regarding aspects of the proposed rule. Those concerns are discussed below.

In the proposed rule, we proposed that a random sample of kiwi would have to be washed using a flushing method, placed in a 20-mesh sieve on top of a 200-mesh sieve, sprinkled with a liquid soap and water solution, washed with water at high pressure, and washed with water at low pressure. The washing process would then have to be repeated immediately after the first washing. The contents of the 200-mesh sieve would then be placed on a petri dish and analyzed for the presence of live *Brevipalpus chilensis* mites. This mite sampling method is identical to the method currently in use for baby kiwi production areas in Chile and has been found to be successful in identifying production areas within Chile with high and low populations of mites.

One commenter stated that the washing process should be expanded to include all fruit in a shipment.

The washing process is used as a way to sample for the presence of *B. chilensis* in order to confirm the low prevalence of *B. chilensis* in certified

production areas within Chile. It is not intended as a phytosanitary measure.

Two commenters recommended that 270 mesh be used in place of 200 mesh for sampling at the port of entry because they stated that 200 mesh may not be fine enough to detect immature stages of *B. chilensis*.

Fruit has been imported from Chile since 1997 using a systems approach based on sampling for mites using a 200 mesh screen. Any eggs or nymphs found using a finer mesh sieve cannot be identified to species. This systems approach is based on low prevalence for adult mites, not pest freedom. If even one adult *B. chilensis* mite is found in a shipment, it is enough to disqualify a place of production from the export program. APHIS has successfully used this approach for 18 years for determining areas of low prevalence for a number of Chilean fruits.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

**Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. Production, consumption, and trade of kiwi by the United States have been expanding and are expected to continue to increase, as

shown in table 1. Over the 5 years from 2008 through 2012, U.S. kiwi production and imports expanded by about 29 percent and 24 percent, respectively, and U.S. exports by 48 percent. U.S. consumption of kiwi grew by about 23 percent over this same period.

The United States is dependent on imports for the major share of its kiwi supply. In 2012, nearly four of every five kiwis consumed were imported. Chile is the principal foreign source, supplying one-half of the kiwis imported by the United States in 2012, up from approximately one-third of U.S. kiwi imports in 2008. Chile is expected to continue to dominate the supply of kiwi to the United States in the near term. Under this rule, Chile’s kiwi exporters will have the option of using the systems approach rather than relying on fumigation with methyl bromide to meet import requirements.

Although the United States is a net importer of kiwi, the percentage increase in U.S. kiwi exports between 2008 and 2012 was twice the percentage increase in U.S. kiwi imports; U.S. producers are actively expanding their sales to other countries. We also note that kiwi imports from Chile are largely counter-seasonal to kiwi sales by domestic producers. California produces 98 percent the kiwis grown in the United States, and the California season runs October through May.<sup>2</sup> Kiwi from Chile is predominantly imported during the spring and summer months. Ninety-four percent of Chilean kiwi imported in 2012 arrived between April and September.<sup>3</sup>

TABLE 1—U.S. KIWI PRODUCTION, IMPORTS, EXPORTS, AND CONSUMPTION, AND KIWI IMPORTS FROM CHILE, 2008 AND 2012, METRIC TONS

	2008	2012 <sup>1</sup>	Percentage increase over 5 years
U.S. Production .....	20,865	26,853	28.7
U.S. Imports .....	50,322	62,372	23.9
U.S. Exports .....	6,883	10,204	48.2
U.S. Consumption <sup>2</sup> .....	64,304	79,021	22.9
U.S. Imports from Chile .....	17,248	31,668	83.6
Chile’s Share of Imports .....	34.3%	50.8%	.....
Imports from Chile as a Percentage of U.S. Consumption .....	26.8%	40.1%	.....

**Sources:** For U.S. production, the U.N. Food and Agriculture Organization; for U.S. imports and exports, the U.S. Census Bureau, as reported by Global Trade Information Services, Inc.

<sup>1</sup> U.S. kiwi production data for 2012 are the most recently reported.  
<sup>2</sup> U.S. consumption calculated as production plus imports minus exports.

Although kiwi production in the United States is expanding, it remains a relatively small agricultural industry, with fewer than 300 growers whose

farms average about 13 acres. Nevertheless, it is a vibrant industry with an expanding export market. This fact, together with the counter-

seasonality of kiwi imports from Chile, suggests that the economic impact of the rule for U.S. small entities will be minor.

<sup>2</sup> California Kiwifruit Commission, <http://www.kiwifruit.org/about/availability.aspx>.

<sup>3</sup> Based on U.S. Census data, as reported by Global Trade Information Services, Inc.



Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

**Executive Order 12988**

This final rule allows kiwi to be imported into the United States from Chile. State and local laws and regulations regarding kiwi imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

**Paperwork Reduction Act**

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

**Lists of Subjects in 7 CFR Part 319**

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

**PART 319—FOREIGN QUARANTINE NOTICES**

■ 1. The authority citation for part 319 continues to read as follows:

**Authority:** 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 319.56–53 is amended as follows:

- a. By revising the section heading;
- b. By revising the introductory paragraph;
- c. By redesignating paragraphs (a), (b), (c), (d), and (e) as paragraphs (b), (c), (d), (e), and (f), respectively, and adding a new paragraph (a);
- d. By revising the first and second sentences after the heading of newly designated paragraph (b);
- e. By revising the third sentence after the heading of newly designated paragraph (e), introductory text; and
- f. By revising newly designated paragraph (f).

The revisions and addition read as follows:

**§ 319.56–53 Fresh kiwi and baby kiwi from Chile.**

Fresh kiwi (*Actinidia deliciosa* and *Actinidia chinensis*) may be imported into the United States from Chile, and fresh baby kiwi (*Actinidia arguta*) may be imported into the continental United States from Chile under the following conditions:

(a) The national plant protection organization (NPPO) of Chile must provide a workplan to APHIS that details the activities that the NPPO of Chile will, subject to APHIS’ approval of the workplan, carry out to meet the requirements of this section.

(b) \* \* \* The production site where the fruit is grown must be registered with the NPPO of Chile. Harvested kiwi and baby kiwi must be placed in field cartons or containers that are marked to show the official registration number of the production site. \* \* \*

(e) \* \* \* Kiwi in any consignment may be shipped to the United States, and baby kiwi in any consignment may be shipped to the continental United States, under the conditions of this section only if the consignment passes inspection as follows:

(f) *Phytosanitary certificate.* Each consignment of fresh kiwi and fresh baby kiwi must be accompanied by a phytosanitary certificate issued by the NPPO of Chile that contains an additional declaration stating that the fruit in the consignment was inspected and found free of *Brevipalpus chilensis* and was grown, packed, and shipped in accordance with the requirements of 7 CFR 319.56–53.

Done in Washington, DC, this 11th day of September 2015.

**Michael C. Gregoire,**  
*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015–23383 Filed 9–16–15; 8:45 am]

**BILLING CODE 3410–34–P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 71**

[Docket No. FAA–2015–1623; Airspace Docket No. 15–AWP–10]

**Amendment of Class E Airspace; Tracy, CA**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule, correction.

**SUMMARY:** This action corrects an error in a final rule published in the **Federal Register** of August 31, 2015, by amending the geographic coordinates of Tracy Municipal Airport, Tracy, CA, in Class E airspace. This does not affect the boundaries or operating requirements of the airspace.

**DATES:** Effective 0901 UTC, October 15, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

**FOR FURTHER INFORMATION CONTACT:** Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA, 98057; Telephone: (425) 203–4563.

**SUPPLEMENTARY INFORMATION:**

**History**

The FAA published a final rule, in the **Federal Register**, amending Class E airspace extending upward from 700 feet above the surface at Tracy Municipal Airport, Tracy, CA (80 FR 52392 August 31, 2015). Subsequent to publication the FAA identified an error in the longitudinal coordinate of the airport reference point for Tracy Municipal Airport. This action corrects the error.

**Correction to Final Rule**

Accordingly, pursuant to the authority delegated to me, in the **Federal Register** of August 31, 2015 (80 FR 52392) FR Doc. 2015–21414, the longitude coordinate in the regulatory text on page 52393, column 2, line 10, is corrected as follows:

**§ 71.1 [Amended]**

**AWP CA E5 Tracy, CA (Corrected)**

- Remove “long. 121°26’31” W.” and add in its place “long. 121°26’30” W.”

Issued in Seattle, Washington, on September 08, 2015.

**Christopher Ramirez,**

*Manager, Operations Support Group, Western Service Center.*

[FR Doc. 2015-23271 Filed 9-16-15; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Chapter I

[Docket No.: FAA-2015-1006]

#### Discontinuation of Airport Advisory Service in the Contiguous United States, Puerto Rico, and Hawaii

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of policy.

**SUMMARY:** This action discontinues the availability Airport Advisory services within the contiguous United States, Puerto Rico, and Hawaii. The FAA is taking this action because the frequency of Remote Airport Advisories service use at the 19 locations within the contiguous United States, Puerto Rico, and Hawaii, no longer justifies the continuation of the service due to the lack of productivity.

**DATES:** Effective date October 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Alan Wilkes, Manager, Flight Service NAS Initiative Operations/Implementation, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone 202-267-7771; Fax (202) 267-6310; email [Alan.Wilkes@faa.gov](mailto:Alan.Wilkes@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### History

On June 30, 2015, the FAA published in the **Federal Register** (80 FR 37356-37358) a notice of proposed policy to inform the public regarding proposed revisions to the criteria set forth in FAA Order 7110.10, Flight Services, Chapter 4, Section 4; and FAA Order 7210.3, Facility Operation and Administration, paragraph 13-4-5, so that the policy would apply to the State of Alaska only. Interested parties were invited to participate in this policy change by submitting written comments of the proposal. No comments were received.

##### Background

The criteria for providing Airport Advisory (AA) services at Flight Service Stations (FSS) is provided in FAA Order 7210.3, and specifies the criteria for providing Airport Advisory (AA) services; specifically, paragraph 13-4-5,

addresses Local Airport Advisory (LAA), Remote Airport Advisory (RAA) and Remote Airport Information Service (RAIS). Section (b) of that paragraph requires, in part, that Flight Service Stations provide RAA when the employee productivity factor is high enough to justify the cost of providing the service.<sup>1</sup>

Currently, Lockheed Martin provides RAA services at 19 locations. At 18 of the 19 locations, a sample of historical data reflects that pilots contact the RAA service an average of less than 1 time per day. At Millville Municipal Airport in Millville, NJ, pilots contact the RAA service an average of 14 times per day.<sup>2</sup> The frequency of RAA service use no longer justifies the continuation of the service due to the lack of productivity.

The FAA will discontinue the requirement for FSSs to provide AA services in the contiguous United States, Puerto Rico, and Hawaii effective October 1, 2015, resulting in services no longer being available at the 19 locations. The AA services in the state of Alaska will not be affected by this change, and will remain due to the unique challenges presented by the remote mountainous terrain and weather conditions across the state.

##### Applicability

The FAA will revise the criteria set forth in FAA Order 7110.10, Chapter 4, Section 4; and FAA Order 7210.3, paragraph 13-4-5 to only be applicable to the State of Alaska, and AA services will be discontinued at locations within the CONUS, Puerto Rico, and Hawaii. Due to the policy change, RAA service would no longer be provided at the following airports:

Altoona-Blair County Airport (AOO), Altoona, Pennsylvania;  
Columbia Regional Airport (COU), Columbia, Missouri;  
Elkins-Randolph Airport (EKN), Elkins, West Virginia;  
Huron Regional Airport (HON), Huron, South Dakota;  
Jackson-McKellar-Sipes Regional Airport (MKL), Jackson, Tennessee;  
Jonesboro Municipal Airport (JBR), Jonesboro, Arkansas;  
Macon-Middle Georgia Regional Airport (MCN), Macon, Georgia;  
Anderson Regional Airport (AND), Anderson, South Carolina;

<sup>1</sup> The facility's productivity factor is determined by dividing the annual RAA service count by 16,000. The productivity factor is compared to the number of employees used to provide the service and must be equal to or greater than the number of employees needed to provide the service. Normally about 2.5 employees are factored annually to provide 10 hours of service per day.

<sup>2</sup> Lockheed Martin contact history daily averages, July 12-26 and October 1-15, 2014.

Anniston Metropolitan Airport (ANB), Anniston, Alabama;  
Casper-Natrona County International Airport (CPR), Casper, Wyoming;  
Gainesville Regional Airport (GNV), Gainesville, Florida;  
Grand Forks International Airport (GFK), Grand Forks, North Dakota;  
Greenwood-Lefflore Airport (GWO), Greenwood, Mississippi;  
Louisville-Bowman Field Airport (LOU), Louisville, Kentucky;  
Millville Municipal Airport (MIV), Millville, New Jersey;  
Prescott-Ernest A. Love Field Airport (PRC), Prescott, Arizona;  
St. Louis-Spirit of St. Louis Airport (SUS), St. Louis, Missouri;  
St. Petersburg-Clearwater International Airport (PIE), St. Petersburg, Florida; and  
Miami-Kendall-Tamiami Executive Airport (TMB), Miami, Florida.

## II. Additional Information

### A. Availability of Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

1. Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visiting the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies](http://www.faa.gov/regulations_policies) or
3. Accessing the Government Printing Office's Web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680. Commenters must identify the docket or amendment number of this notice.

All documents the FAA considered in developing this notice, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

Issued in Washington, DC, on August 25, 2015.

**Jeanne Giering,**

*Director of Flight Services.*

[FR Doc. 2015-21784 Filed 9-16-15; 8:45 am]

**BILLING CODE 4910-13-P**

## PENSION BENEFIT GUARANTY CORPORATION

### 29 CFR Parts 4000, 4041A, and 4281

RIN 1212-AB28

#### Multiemployer Plans; Electronic Filing Requirements

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends Pension Benefit Guaranty Corporation's (PBGC) regulations to require electronic filing of certain multiemployer notices. These changes make the provision of information to PBGC more efficient and effective.

**DATES:** Effective October 19, 2015. See Applicability in **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion (*klion.catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, or Donald McCabe (*mccabe.donald@pbgc.gov*), Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005-4026; 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

**SUPPLEMENTARY INFORMATION:**

### Executive Summary

#### *Purpose of the Regulatory Action*

This final rule is part of PBGC's ongoing implementation of the Government Paperwork Elimination Act and is consistent with the Office of Management and Budget's directive to remove regulatory impediments to electronic transactions. The rule builds in flexibility to allow PBGC to update the electronic filing process as technology advances.

PBGC's legal authority for this regulatory action comes from section 4002(b)(3) of the Employee Retirement Income Security Act of 1974 (ERISA), which authorizes PBGC to issue regulations to carry out the purposes of title IV of ERISA; section 4041A(f)(2), which gives PBGC authority to prescribe reporting requirements for terminated plans; section 4245(e)(4), which authorizes PBGC to issue regulations on notices related to insolvency and resource benefit levels; and section 4281(d), which directs PBGC to prescribe by regulation the notice requirements to plan participants and beneficiaries in the event of a benefit suspension under an insolvent plan.

#### *Major Provisions of the Regulatory Action*

This final rule requires the following notices to be filed electronically with PBGC: Notices of termination under part 4041A, notices of insolvency and of insolvency benefit level under parts 4245 and 4281, and applications for financial assistance under part 4281.

This final rule does not involve any conforming amendments reflecting the

Multiemployer Pension Reform Act of 2014 (MPRA).<sup>1</sup> The rule affects only notices to PBGC (not notices to participants or other parties).

### Background

The Pension Benefit Guaranty Corporation (PBGC) is a federal corporation created under the Employee Retirement Income Security Act of 1974 (ERISA) to guarantee the payment of pension benefits earned by more than 41 million American workers and retirees in nearly 24,000 private-sector defined benefit pension plans. PBGC administers two insurance programs—one for single-employer defined benefit pension plans and a second for multiemployer defined benefit pension plans.

The multiemployer plan program protects benefits of approximately 10 million workers and retirees in approximately 1,400 plans. A multiemployer plan is a collectively bargained pension arrangement involving two or more unrelated employers, usually in a common industry such as construction or trucking, where workers move from employer to employer on a regular basis. Under PBGC's multiemployer program, when a plan becomes insolvent, PBGC provides financial assistance directly to the insolvent plan sufficient to pay guaranteed benefits to participants and beneficiaries, and the reasonable and necessary administrative expenses of the insolvent plan.

ERISA section 4041A provides for two types of multiemployer plan terminations: mass withdrawal and plan amendment. A mass withdrawal termination occurs when all employers withdraw or cease to be obligated to contribute to the plan. A plan amendment termination occurs when the plan adopts an amendment that provides that participants will receive no credit for service with any employer after a specified date, or an amendment that makes it no longer a covered plan. Unlike terminated single-employer plans, terminated multiemployer plans generally continue to pay all vested benefits out of existing plan assets and withdrawal liability payments.

#### *Multiemployer Plan Notices*

PBGC's regulation on Termination of Multiemployer Plans (29 CFR part

<sup>1</sup> Division O of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235, enacted December 16, 2014. On June 19, 2015, (at 80 FR 35220), PBGC published an interim final rule on Partitions of Eligible Multiemployer Plans under MPRA, <http://www.pbgc.gov/documents/2015-14930.pdf>. PBGC expects to publish further guidance under MPRA.

4041A) implements these provisions, among other things by requiring the plan sponsor of a terminated multiemployer plan to file with PBGC a notice of termination containing basic information necessary to alert PBGC to possible demands on the multiemployer insurance program.

ERISA section 4245(e) requires two types of notices:

- Notice of insolvency, which states a plan sponsor's determination that the plan is or may become insolvent.
- Notice of insolvency benefit level, which states the level of benefits that will be paid during an insolvency year.

Section 4245(e)(4) provides that these notices are to be given in accordance with rules promulgated by PBGC. PBGC's regulation on Notice of Insolvency, 29 CFR part 4245, establishes the procedure for complying with these notice requirements. The regulation allows a single notice of insolvency to cover more than one plan year, thereby generally permitting plan sponsors to file only a single notice (a notice of insolvency benefit level) for any future year. The regulation also prescribes, among other things, the manner in which the notices must be given. The recipients of these notices include PBGC, in addition to other parties.

PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281) implements the requirements of ERISA section 4281. The regulation prescribes rules under which plan sponsors must:

- Provide notices to PBGC and to participants and beneficiaries that a plan is, or will be, insolvent (§§ 4281.43 and 4281.44).
- Provide notices of insolvency benefit level to PBGC and to participants and beneficiaries who are in pay status or may reasonably be expected to enter pay status during the year (§§ 4281.45 and 4281.46).
- Submit an application to PBGC for financial assistance if a plan is, or will be, unable to pay guaranteed benefits when due (§ 4281.47).

#### *Mandatory Electronic Filing: Current Requirements*

Section 4000.3 of PBGC's regulation on Filing, Issuance, Computation of Time, and Record Retention (29 CFR part 4000) requires electronic filing of premium declarations under part 4007 (Payment of Premiums) and information required under part 4010 (Annual Financial and Actuarial Information Reporting).

### Regulatory Review

On January 18, 2011, the President issued Executive Order 13563 “Improving Regulation and Regulatory Review,” to ensure that Federal regulations seek more affordable, less intrusive means to achieve policy goals, and that agencies give careful consideration to the benefits and costs of those regulations. PBGC’s Plan for Regulatory Review,<sup>2</sup> identifies several regulatory areas for review, including the multiemployer regulations referred to above. PBGC will continue to review its regulations with a view to developing more ideas for improvement.

### Proposed Rule

On April 3, 2015 (at 80 FR 18172), PBGC published a proposed rule to amend parts 4000, 4041A, and 4281 to require electronic filing of certain multiemployer notices.<sup>3</sup> PBGC received no comments on the proposed rule. The final regulation is unchanged from the proposed regulation.

### Regulatory Changes

The final regulation requires electronic filing with PBGC of the following multiemployer plan filings:

- Notices of termination under part 4041A.
- Notices of insolvency and of insolvency benefit level under part 4245.
- Notices of insolvency and of insolvency benefit level under part 4281 (following mass withdrawal).
- Applications for financial assistance under part 4281 (following mass withdrawal).

PBGC will grant case-by-case exemptions to the electronic filing requirement in appropriate circumstances for filers that demonstrate good cause for exemption. PBGC believes that requiring electronic filing for these notices will result in benefits for both the public and the government.

Electronic filing will simplify the filing process for the public by building in all required and optional fields and including readily accessible guidance in the application. Electronic filing is expected to reduce the need to contact PBGC for assistance. PBGC estimates that the amendments in the rule will result in a total savings in administrative burdens for the public of 25 percent (about 22 hours and \$99,000 annually).

Electronic filing will also result in greater efficiencies for the government.

Up to now, documents submitted by filers needed to be manually uploaded to electronic depositories. With electronic filing, those documents will be automatically uploaded. Electronic filing will also save the government time by reducing the need to provide assistance to filers. It will also improve the government’s recordkeeping, records retrieval, and records archiving process by eliminating the possibility of missing or lost paper files due to human error.

Moreover, the PBGC expects electronic filing will improve the government’s ability to protect potential personally identifiable information (PII), or otherwise sensitive information, since only pre-approved personnel will have access to PBGC’s electronic records systems, and limited access will be approved for officials of pension plans.

PBGC did not propose to require electronic filing of notices of benefit reduction and of restoration of benefits under part 4281. PBGC may in the future require that other multiemployer filings also be made electronically.

### Applicability

The amendments in this final rule will be applicable for filings made on or after January 1, 2016.

### Compliance With Rulemaking Requirements

*Executive Order 12866 “Regulatory Planning and Review” and Executive Order 13563 “Improving Regulation and Regulatory Review”*

PBGC has determined that this final rule is not a “significant regulatory action” under Executive Order 12866. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Under Section 3(f)(1) of Executive Order 12866, a regulatory action is economically significant if “it is likely to result in a rule that may . . . [h]ave an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.” PBGC has determined that this final rule does

not cross the \$100 million threshold for economic significance and is not otherwise economically significant (see discussion above).

### Regulatory Flexibility Act

The Regulatory Flexibility Act imposes certain requirements with respect to rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the Regulatory Flexibility Act requires that the agency present a regulatory flexibility analysis at the time of the publication of the final rule describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations and governmental jurisdictions.

For purposes of the Regulatory Flexibility Act requirements with respect to this final rule, PBGC considers a small entity to be a plan with fewer than 100 participants. This is the same criterion PBGC uses in other aspects of its regulations involving small plans, and is consistent with certain requirements in Title I of ERISA and the Internal Revenue Code, as well as the definition of a small entity that the Department of Labor (DOL) has used for purposes of the Regulatory Flexibility Act.

Thus, PBGC believes that assessing the impact of the rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business based on size standards promulgated by the Small Business Administration (13 CFR 121.201) pursuant to the Small Business Act. Therefore, in the proposed rule, PBGC requested comments on the appropriateness of the size standard used in evaluating the impact on small entities of the amendments to the benefit payments regulation. No comments were received on this point.

On the basis of its definition of small entity, PBGC certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that the amendments in this rule will not have a significant economic impact on a substantial number of small entities. Very few multiemployer plans are

<sup>2</sup> <http://www.pbgc.gov/documents/plan-for-regulatory-review.pdf>.

<sup>3</sup> <http://www.gpo.gov/fdsys/pkg/FR-2015-04-03/pdf/2015-07602.pdf>.

small.<sup>4</sup> And, as discussed above, the amendments will not have a significant economic impact on entities of any size. Accordingly, as provided in section 605 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), sections 603 and 604 will not apply.

**Paperwork Reduction Act**

PBGC is submitting the information requirements under this final rule to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The collection of information in part 4041A is approved under control number 1212-0020 (expires June 30, 2017). PBGC estimates that there will be 10 respondents each year and that the total annual burden of the collection of information will be about 17 hours and \$3,850.00 (about 2 hours and \$385 per respondent).

The collection of information in part 4245 is approved under control number 1212-0033 (expires June 30, 2017). PBGC estimates that there will be one respondent each year and that the total annual burden of the collection of information will be about \$1,550.

The collection of information in part 4281 is approved under control number 1212-0032 (expires July 31, 2017). PBGC estimates that there will be 324 respondents each year and that the total annual burden of the collection of information will be about 61 hours and \$309,000 (about \$950 per respondent).

**List of Subjects**

29 CFR Part 4000

Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Parts 4041A and 4281

Employee benefit plans, Pension insurance, Reporting and recordkeeping requirements.

For the reasons given above, the PBGC is amending 29 CFR parts 4000, 4041A, and 4281 as follows.

<sup>4</sup> According to data from 2012 5500 filings, only 32 of 1,407 active plans have fewer than 100 participants. Further, PBGC is not aware of a multiemployer plan that was established and covered by ERISA that was not initially a large plan. Generally it is only after a plan terminates and employers withdraw from the plan that a plan might reduce in size to fewer than 100 participants.

**PART 4000—FILING, ISSUANCE, COMPUTATION OF TIME, AND RECORD RETENTION**

■ 1. The authority citation for part 4000 continues to read as follows:

**Authority:** 29 U.S.C. 1082(f), 1302(b)(3).

■ 2. In § 4000.3, revise paragraph (b)(3) to read as follows:

**§ 4000.3 What methods of filing may I use?**

\* \* \* \* \*

(b) \* \* \*

(3) When making filings to PBGC under parts 4041A, 4245, and 4281 of this chapter (except for notices of benefit reductions and notices of restoration of benefits under part 4281), you must submit the information required under these parts electronically in accordance with the instructions on the PBGC's Web site, except as otherwise provided by the PBGC.

\* \* \* \* \*

**PART 4041A—TERMINATION OF MULTIEMPLOYER PLANS**

■ 3. The authority citation for part 4041A continues to read as follows:

**Authority:** 29 U.S.C. 1302(b)(3), 1341a, 1441.

■ 4. In § 4041A.11, add paragraph (d) to read as follows:

**§ 4041A.11 Requirement of notice.**

\* \* \* \* \*

(d) *How and where to file.* Filings to PBGC under this subpart must be submitted in accordance with the rules in subpart A of part 4000 of this chapter. See § 4000.4 of this chapter for information on where to file.

**§ 4041A.25 [Amended]**

■ 5. In § 4041A.25, amend paragraph (d) by removing the words “of the PBGC” and adding in their place “to the PBGC”.

**PART 4281—DUTIES OF PLAN SPONSOR FOLLOWING MASS WITHDRAWAL**

■ 6. The authority citation for part 4281 continues to read as follows:

**Authority:** 29 U.S.C. 1302(b)(3), 1341a, 1399(c)(1)(D), and 1441.

■ 7. In § 4281.3, revise paragraph (b) to read as follows:

**§ 4281.3 Filing and issuance rules.**

\* \* \* \* \*

(b) *Method of issuance.* For rules on method of issuance to interested parties, see § 4281.32(c) for notices of benefit reductions, § 4281.43(e) for notices of

insolvency, and § 4281.45(c) for notices of insolvency benefit level.

\* \* \* \* \*

■ 8. In § 4281.43, revise paragraph (a) to read as follows:

**§ 4281.43 Notices of insolvency.**

(a) *Requirement of notices of insolvency.* A plan sponsor that determines that the plan is, or is expected to be, insolvent for a plan year shall file with the PBGC and issue to plan participants and beneficiaries notices of insolvency. Once notices of insolvency have been filed with the PBGC and issued to plan participants and beneficiaries, no notice of insolvency needs to be issued for subsequent insolvency years. Notices shall be delivered in the manner and within the time prescribed in this section and shall contain the information described in § 4281.44.

\* \* \* \* \*

■ 9. In § 4281.47, revise paragraph (b) to read as follows:

**§ 4281.47 Application for financial assistance.**

\* \* \* \* \*

(b) *When, how, and where to apply.* When the plan sponsor determines a resource benefit level that is less than guaranteed benefits, it shall apply for financial assistance at the same time that it submits its notice of insolvency benefit level pursuant to § 4281.45. When the plan sponsor determines an inability to pay guaranteed benefits for any month, it shall apply for financial assistance within 15 days after making that determination. Application to the PBGC for financial assistance shall be made in accordance with the rules in subpart A of part 4000 of this chapter. See § 4000.4 of this chapter for information on where to apply.

\* \* \* \* \*

Issued in Washington, DC, this 14 day of September, 2015.

**Alice C. Maroni,**  
*Acting Director, Pension Benefit Guaranty Corporation.*

[FR Doc. 2015-23361 Filed 9-16-15; 8:45 am]

**BILLING CODE 7709-02-P**

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 938**

[SATS No. PA-159-FOR; Docket No. OSM-2010-0017; S1D1S SS08011000 SX064A000 156S180110; S2D2S SS08011000 SX064A000 15XS501520]

**Pennsylvania Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSMRE) is removing a required amendment to the Pennsylvania regulatory program (the Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). OSMRE has determined that the information submitted by Pennsylvania satisfies a previously required amendment regarding bonding in Pennsylvania. Therefore, OSMRE is removing the previously required amendment from the Pennsylvania program as Pennsylvania has demonstrated that its program is being administered in a manner consistent with SMCRA and the corresponding Federal regulations.

**DATES:** Effective September 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** Ben Owens, Chief, Pittsburgh Field Division; Telephone: (412) 937-2827, Email: [bowens@osmre.gov](mailto:bowens@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Pennsylvania Program
- II. Description of the Submission
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Procedural Determinations

**I. Background on the Pennsylvania Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act . . . ; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program, effective July 31,

1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Pennsylvania program in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning the Pennsylvania program and program amendments at 30 CFR 938.11, 938.12, 938.13, 938.15, and 938.16.

**II. Description of the Submission**

OSMRE published a final rule in the August 10, 2010, **Federal Register** (75 FR 48526), herein referred to as the 2010 final rule, requiring Pennsylvania "to ensure that its program provides suitable, enforceable funding mechanisms that are sufficient to guarantee coverage of the full cost of land reclamation at all sites originally permitted and bonded under the [alternative bonding system (ABS)]." This was codified in the Federal regulations at 30 CFR 938.16(h). OSMRE approved several changes in the 2010 final rule. However, OSMRE concluded that two sites, originally permitted and bonded under the ABS, held insufficient bonds after the conversion to a full cost bonding system to guarantee that the land would be reclaimed in the event forfeiture occurred.

The two sites at issue are anthracite operations that were permitted by Lehigh Coal & Navigation (LCN) and Coal Contractors Inc. (CCI). Before the 2010 final rule was published, Pennsylvania had indicated that these two sites were bonded in an amount that was less than the full cost needed to complete reclamation in the event that forfeiture occurred. Although Pennsylvania contended that these sites were not reclamation liabilities, as the bond deficiency at both sites was being addressed through other means, OSMRE determined that Pennsylvania's approach to resolving this issue did not provide the same level of financial assurance as that guaranteed by posting a full cost bond. As a result, OSMRE revised 30 CFR 938.16(h), and required that Pennsylvania demonstrate that sufficient funds existed to ensure the land reclamation would be completed at the LCN and CCI sites.

In response to OSMRE's 2010 final rule, Pennsylvania submitted information which it believed demonstrated that it is able to guarantee sufficient funds to cover the full reclamation costs at the LCN and CCI sites. After providing three submissions, Pennsylvania requests the removal of the required amendment. Each submission is discussed below.

*Submission No. 1:* By letter dated October 1, 2010 (Administrative Record No. PA 802.72), Pennsylvania sent us a response as required by 30 CFR 938.16(h). We announced receipt of this submission in the February 7, 2011, **Federal Register** (76 FR 6587). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the submission. OSMRE received comments, but did not hold a public hearing or meeting because neither was requested. The public comment period ended on March 9, 2011.

In the first submission, Pennsylvania provided information that it believed demonstrated that available funds were more than sufficient to guarantee coverage of the full cost of land reclamation at the two sites. The information submitted to support Pennsylvania's contention included a demonstration of available funding, the Coal Contractors 2009 Annual Bond Review, LCN's annual bond review, updated estimates for the ABS bond forfeiture discharge treatment sites, and updated land reclamation estimates. Based on this information, Pennsylvania requested the removal of the previously required amendment.

At the time of this submission, the following conditions existed:

LCN Land Reclamation Estimate:

\$11,230,429

Current Bonds Available: \$7,759,000

Additional Reclamation Funding

Needed: \$3,471,429

CCI Land Reclamation Estimate:

\$2,863,982

Current Bonds Available: \$804,625

Additional Reclamation Funding

Needed: \$2,059,357

The submission indicated a balance of \$19,496,955 in the Surface Mining Conservation and Reclamation Fund (SMCR Fund) that was available for ABS land and discharge treatment for ABS legacy sites. Projected expenses at the time for ABS land reclamation and discharge treatment (design and construction) was \$12,877,636, leaving a balance of \$6,619,319 available to address the reclamation funding needs of \$5,530,786 for the LCN and CCI sites, if forfeited.

Pennsylvania also stated that in the unlikely event that both of these sites would require expenditure of funds for land reclamation, then at least some of the cost for the design and construction of the ABS bond forfeiture discharge treatment facilities would be paid for using the Reclamation Fee Operation and Maintenance account (RFO&M account). There was approximately \$1

million of immediately available funds in this account that could be used for this purpose exclusively. Pennsylvania believed that this demonstration of available funding warranted removal of the required amendment.

*Submission No. 2:* On June 13, 2011 (Administrative Record No. PA 802.80), we received additional information from Pennsylvania regarding recent developments with the LCN site. The permit had been transferred to BET Associates IV, LLC (BET), resulting in the posting of a full cost bond in an amount to cover the land reclamation obligation. We announced this submission in the October 17, 2011, **Federal Register** (76 FR 64048). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the submission. OSMRE received comments, but did not hold a public hearing or meeting because neither was requested. The public comment period ended on November 1, 2011.

Included in the second submission was the mining permit, Part C (Authorization to Mine), and the calculation sheet documenting the bond amount. At the time of this submission, the following conditions existed:

LCN Land Reclamation Estimate:  
\$10,523,000  
Current Bonds Available: \$10,523,000  
Additional Reclamation Funding Needed: \$0

*Submission No. 3:* On November 6, 2012, we received additional information from Pennsylvania regarding recent developments involving the CCI permit bonding status (Administrative Record No. PA 802.85). We announced receipt of this submission in the February 19, 2013, **Federal Register** (78 FR 11617). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the submission. OSMRE received comments, but did not hold a public hearing or meeting because neither was requested. The public comment period ended on March 6, 2013.

The third submission included a letter to the operator regarding the annual bond review, along with the supporting documentation supporting the review, which included the annual bond calculation summary.

At the time of this submission, the following conditions existed:

CCI Land Reclamation Estimate:  
\$403,691  
Current Bonds Available: \$804,625  
Additional Reclamation Funding Needed: \$0

After three submissions, Pennsylvania believed it had provided sufficient information as required by OSMRE to satisfy the 30 CFR 938.16(h) requirements. As a result, Pennsylvania requested that OSMRE remove the previously required amendment.

### III. OSMRE's Findings

Discussed below are our findings concerning this request to remove a previously required amendment to the Pennsylvania program pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. After reviewing the information submitted, OSMRE is removing the previously required amendment that was codified at 30 CFR 938.16(h).

OSMRE finds that Pennsylvania demonstrated through its bonding calculations and reclamation estimates that sufficient funds are available to guarantee coverage of the reclamation needs at the LCN and CCI sites, in satisfaction of the previously required amendment. Therefore, we are approving this request to remove paragraph (h) of 30 CFR 938.16.

### IV. Summary and Disposition of Comments

#### *Public Comments*

We asked for public comments on each of the three submissions. No requests for public meetings were received. On March 5, 2013, we received comments from a group of citizen organizations collectively known as "the Federation," which represents six organizations: (1) Citizens for Pennsylvania's Future (PennFUTURE), (2) Pennsylvania Federation of Sportsmen's Clubs, Inc., (3) Sierra Club, (4) Pennsylvania Council of Trout Unlimited, (5) Center for Coalfield Justice, and (6) Mountain Watershed Association.

PennFUTURE serves as legal counsel for these organizations with respect to alleged inadequacies of Pennsylvania's bonding program and continues to serve in that capacity by responding to related matters, such as this program amendment. PennFUTURE provided comments on Pennsylvania's initial submission, which we responded to in the 2010 final rule (Administrative Record No. PA 802.43).

In addition to the March 5, 2013, comments (Administrative Record No. PA 802.88) on the latest submission from Pennsylvania, PennFUTURE also submitted comments on March 9, 2011 (Administrative Record No. PA 802.79), regarding the initial October 1, 2010, submission and on November 1, 2011 (Administrative Record No. PA 802.83),

regarding Pennsylvania's first supplemental submission dated June 13, 2011 (Administrative Record No. PA 802.80), concerning the LCN site.

PennFUTURE originally contended that the program amendment submission was deficient for various reasons. As noted in our findings, however, subsequent events occurred after the original submission, which affected the financial solvency and prior bond deficiency at the two sites. Since the comments submitted by PennFUTURE have largely restated its earlier comments, OSMRE is addressing those comments still applicable. We are addressing the March 5, 2013, comments first and they are as follows:

#### A. The CCI Site

PennFUTURE submitted previous comments regarding the adequacy of this site. However, subsequent to the receipt of those comments, PennFUTURE now agrees that, as a result of the reclamation work performed at the CCI site since Submission No. 1, the site finally appears to have an enforceable, full cost reclamation guarantee in place considering the current bond amount and the estimated cost to complete reclamation of the site. Since the most recent bond calculation summary submitted (revised summary for 2011) was prepared, PennFUTURE recommends that OSMRE review CCI's annual bond calculation summary for 2012 to confirm that the site is adequately bonded.

*OSMRE's Response:* On August 20, 2013, Pennsylvania advised OSMRE that the CCI site had been backfilled and graded, with five acres to be seeded in the fall of 2013. There has been no corresponding bond reduction. The amount remains \$804,625, which is sufficient to complete reclamation (Administrative Record No. PA 802.65).

#### B. The LCN Site/Perpetual Post-Mining Discharge and Land Reclamation Bond

According to PennFUTURE, Pennsylvania has not demonstrated that an enforceable, full cost land reclamation guarantee exists for the LCN site because there is no fully funded guarantee of perpetual treatment for the LCN site's post-mining discharge. PennFUTURE asserts that the perpetual post-mining discharge from the LCN site puts the adequacy of the treatment trust for that discharge directly at issue in this program amendment proceeding. As a result, PennFUTURE contends that OSMRE must decide a number of issues concerning Pennsylvania's implementation of treatment trusts raised in PennFUTURE's February 27,

2009, comments on Pennsylvania's August 1, 2008, proposed ABS program amendment (Administrative Record No. PA 802.60).

PennFUTURE states that \$8,423,000 is needed for land reclamation only and does not apply to discharges. The perpetual post-mining discharge from the LCN site puts the adequacy of the treatment trust for that discharge directly at issue in this proceeding. In order to demonstrate that the surety reclamation bond for the LCN site fully guarantees all land reclamation at the site and will not be used to address mine drainage treatment liability, Pennsylvania must demonstrate that the treatment trust for the LCN site is both adequate in amount and fully funded, which it has failed to do as explained below.

PennFUTURE states that its November 1, 2011, comments on Pennsylvania's first supplemental program amendment submission included the May 5, 2011, Post-Mining Treatment Trust Consent Order and Agreement between Pennsylvania and BET (BET Trust CO&A), which established a payment schedule for funding a perpetual treatment trust.

PennFUTURE states that its comments showed that Pennsylvania had failed to demonstrate that the surety bond posted by BET fully guarantees all outstanding land reclamation at the LCN site because it had failed to demonstrate that an adequate and fully funded trust is in place that guarantees perpetual treatment of the post-mining discharge from the LCN site. PennFUTURE's earlier comment letter concluded:

"Under Pennsylvania's approved regulatory program, surety bonds cover all varieties of potential reclamation liabilities at a permitted coal mine. Thus, until a fully funded treatment trust is in place that fully guarantees perpetual treatment of the post-mining discharge from the LCN site, the \$8,423,000 surety bond posted by BET is stretched too thin, covering an estimated \$8,423,000 in land reclamation liability plus perhaps an equivalent amount in mine drainage treatment liability. As a result, the surety bond currently does not provide fully, dollar-for-dollar coverage of the potential land reclamation liabilities at the LCN site. [Pennsylvania] therefore has not carried its burden of demonstrating that the combination of BET's surety bond and the transferred [Land Reclamation Financial Guarantees (LRFG)] 'are sufficient to guarantee coverage of the full cost of land reclamation' at the LCN site."

PennFUTURE states that for any primacy mine with a post-mining

discharge, like the LCN site, the conventional reclamation bond covers both the outstanding land reclamation obligation and the outstanding discharge treatment obligation, unless and until the mine operator posts a treatment trust or other financial guarantee that is both: (1) Adequate in amount to provide perpetual treatment and (2) fully funded. It follows that in order to find that the surety bond posted by BET for the LCN site is unencumbered by any potential mine drainage treatment liability, and therefore, is adequate to fully guarantee the outstanding land reclamation liability, OSMRE must find that the treatment trust for the LCN site is both (1) adequate in amount to provide perpetual treatment and (2) fully funded. PennFUTURE goes on to comment about the calculation and assumptions used to estimate the valuing of trust assets to derive a treatment trust amount that results in financial solvency. These issues were raised in detail in their 2009 comments on Pennsylvania's initial submission. PennFUTURE further asserts that the current program amendment presents, concretely for one specific mine, the issues OSMRE declined to address in the abstract, for a range of potential future scenarios, in ruling on the ABS program amendment in the 2010 final rule.

PennFUTURE references several developments relevant to the adequacy and funding status of the LCN site treatment trust since the submission of their last comment letter on November 1, 2011. The developments include the LCN site's pollutant discharge limits and PennFUTURE's submission of comment letters detailing the reasons why the pollutant loads and effluent limitations Pennsylvania proposed for relocating discharge from the LCN site are excessive. PennFUTURE further states that correcting those errors and reducing the allowable pollutant loads and applicable effluent limitations will increase the estimated costs of treating the discharge from the LCN site and thus, the required amount of the treatment trust. Additionally, PennFUTURE also references the completion of a 2012 OSMRE report documenting a review of the Al Hamilton Treatment Trust Fund. While this report is not directly related to the LCN site, PennFUTURE provides it as an example of perceived trust inadequacies. This report documents that when the trust was established in 2003, roughly half of its assets were coal reserves that now appear to be valueless, leaving the primary portion of

the trust at only a fraction of the value required to provide adequate and perpetual treatment of the dozens of mine discharges it covers. In reference to OSMRE's Al Hamilton Trust Fund Report attached in its letter dated March 5, 2013, PennFUTURE stated that the fractional funding of the trust has forced Pennsylvania "to triage and prioritize the systems needing attention, to spread out the expenditures to reduce the financial stress," leaving some discharges wholly or partially untreated and others lacking adequate treatment.

PennFUTURE states that the harsh lessons provided by this example are that something appearing to have great value today may, in fact, be worthless when needed in the future, and that for a financial mechanism that is required to provide a rock-solid, perpetual guarantee, only money in the bank qualifies as money in the bank. In light of this concern, no discharge treatment trust should be considered fully funded—that is, to provide the iron-clad reclamation guarantee required by law—unless the primary portion of the trust consists of cash or assets that are easily and immediately convertible to cash.

PennFUTURE states that when Pennsylvania enters into a CO&A with a mine operator establishing a payment schedule for funding a treatment trust, it typically does not immediately consider the trust fully funded based on the operator's documented payment obligation. To the contrary, it is only when the mine operator makes the final payment and the trustee has the cash in hand that Pennsylvania changes the designation from "payment plan" to "fully funded".

According to PennFUTURE, the inability to market the Al Hamilton Treatment Trust's coal reserves shows that any trust asset that is not easily and immediately convertible to cash is something like a payment plan—it may or may not deliver the expected value when the time comes. Just as a payment plan trust is not considered fully funded until the last payment is delivered, PennFUTURE states that any trust containing an asset like coal reserves may not be considered fully funded until the asset actually delivers its estimated value by being converted to cash.

*OSMRE's Response:* Pennsylvania's regulations require adjustment of the reclamation fee, which is deposited into the RFO&M account, to cover any increased costs of water treatment for all ABS forfeited sites in any given year. Pennsylvania's annual adjustments to the reclamation fee amount will be evaluated by OSMRE through its oversight authority. In short, the



regulations create the mandate to fully fund discharge treatment costs for all existing and potential ABS legacy sites in perpetuity. Therefore, should the LCN site-specific bond be forfeited, the entire amount of that bond will be used for land reclamation and treatment costs and will be covered by the treatment trust and supplemented, if necessary, by the adjustable reclamation fee. As noted above, sufficient funds exist in the site-specific bond to cover land reclamation costs. In an email dated June 18, 2013, Pennsylvania, at our request, provided the 2012 annual bond calculation, which indicated a reclamation obligation of \$10,448,389 as well as a surplus of \$74,611 at the LCN site (Administrative Record No. PA 802.89). Pennsylvania has demonstrated that its program provides suitable, enforceable funding mechanisms sufficient to guarantee the full cost of land reclamation at all sites originally permitted and bonded under the ABS, in accordance with 30 CFR 938.16(h). Therefore, the previously required amendment can be removed.

#### C. The LCN Site's Trust Fund Adequacy

PennFUTURE asserts that OSMRE cannot find that the land reclamation at the LCN site is fully guaranteed unless it also finds that perpetual treatment of the mine drainage discharge from the LCN site is fully guaranteed.

PennFUTURE states that in addition to being fully funded, a treatment trust must be adequate in amount to provide the firm guarantee of perpetual treatment required by law. Thus, in order to find that the treatment of the discharge from the LCN site is fully guaranteed (which, as explained above, is a prerequisite to finding that the reclamation of the land at the LCN site is fully guaranteed), OSMRE must determine whether Pennsylvania, in calculating the amount of the BET/LCN site trust, applied assumptions and methods that yield a dollar figure that is sufficient to provide the required firm guarantee of perpetual treatment.

PennFUTURE claims that the first complication is that Pennsylvania cannot, at this point, accurately project the treatment costs because it has yet to set the effluent limit targets that such treatment will be required to meet, much less to approve the installation of the new treatment system(s) that will be designed to meet them. PennFUTURE additionally asserts that the BET Trust CO&A estimated the present discounted value for perpetual operation and maintenance of the Mine's "New Treatment System(s)" at \$13.8 million a year before Pennsylvania produced a draft of the National Pollutant Discharge

Elimination System (NPDES) permit revision that would govern the new system's discharge. However, according to PennFUTURE, the effluent limitations in the final revision of the NPDES permit must be more stringent than those proposed in Pennsylvania's draft of the permit.

The second complication, according to PennFUTURE, is that the requirement that the amount of the trust be sufficient to provide a firm guarantee of perpetual treatment forces OSMRE to address all of the issues concerning the inadequacy of Pennsylvania treatment trusts raised in our coalition's February 27, 2009, comments on the 2008 ABS program amendment. PennFUTURE claims that OSMRE declined to address those issues in the abstract across a multitude of potential scenarios in its 2010 final rule on the ABS program amendment. 75 FR 48526. Now, however, the abstract has been made concrete and the programmatic concern has been reduced to a single, specific case. In short, PennFUTURE believes that the issues are squarely and concretely presented and OSMRE must decide them in order to rule on the adequacy of the reclamation guarantee for the LCN site.

PennFUTURE incorporates by reference all earlier comments concerning the deficiencies of Pennsylvania's trust fund calculations, along with the many exhibits supporting those comments. Issues addressed in those earlier comments included trust fund volatility, trust investment portfolio composition, treatment trust portfolio rates of return, and the 75-year recapitalization cost calculation.

*OSMRE's Response:* As we addressed in our response above, Pennsylvania's regulations require adjustment of the reclamation fee to fully fund discharge treatment costs for all ABS forfeited sites. In the event that the LCN site-specific bond is forfeited, the entire bond amount will be used for land reclamation and treatment costs will be covered by the treatment trust and supplemented by the adjustable reclamation fee, if necessary. In an email dated June 18, 2013, Pennsylvania, at our request, indicated that the 2012 bond calculation amount for the LCN site is \$10,448,389. Further, documentation was provided that indicated a surplus of \$74,611 at the site (Administrative Record No. PA 802.89). Thus, Pennsylvania has demonstrated that its program provides suitable, enforceable funding mechanisms sufficient to guarantee the full cost of land reclamation at all sites originally permitted and bonded under the ABS, in accordance with 30 CFR 938.16(h).

Therefore, the previously required amendment can be removed.

As we addressed in our findings above, Pennsylvania's submissions satisfy the requirements set forth in the previously required amendment and demonstrate the existence of sufficient funds to guarantee coverage of the full cost of land reclamation at both the LCN and CCI sites. Therefore, OSMRE is removing the previously required amendment, at subsection (h) of 30 CFR 938.16.

#### *Federal Agency Comments*

On October 5, 2010, under the Federal regulations at 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program (Administrative Record No. PA 802.73). We received a response of no comment from the Mine Safety and Health Administration on October 18, 2010 (Administrative Record No. PA 802.74). No other comments were received, with the exception noted below.

#### *Environmental Protection Agency (EPA) Concurrence and Comments*

Under 30 CFR 732.17(h)(11)(ii), we are required to obtain a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Pennsylvania proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, we received comments from EPA on November 12, 2010, regarding the submission (Administrative Record No. PA 802.76). EPA concluded that the submission was limited to land reclamation. EPA, however, mentioned that well-funded bonding programs are necessary to provide for post-mining treatment, prevent perpetual post-mining drainage problems, as well as protect the hydrologic balance and ensure compliance with water quality standards. In response to EPA's comments, OSMRE agrees that an adequately funded bonding program is crucial to prevent post-mining pollutional discharges.

#### **V. OSMRE's Decision**

Based on the above findings, we are removing the previously required amendment at 30 CFR 938.16(h). To implement this decision, we are amending the Federal regulations, at 30

CFR part 938, that codify decisions concerning the Pennsylvania program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

## VI. Procedural Determinations

### *Executive Order 12630—Takings*

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

### *Executive Order 12866—Regulatory Planning and Review*

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

### *Executive Order 12988—Civil Justice Reform*

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSMRE. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

### *Executive Order 13132—Federalism*

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be "in

accordance with" the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

### *Executive Order 13175—Consultation and Coordination With Indian Tribal Governments*

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on federally recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The basis for this determination is that our decision is on a State regulatory program and does not involve Federal regulations involving Indian lands.

### *Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy*

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

### *National Environmental Policy Act*

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

### *Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

### *Regulatory Flexibility Act*

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5

U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

### *Small Business Regulatory Enforcement Fairness Act*

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

### *Unfunded Mandates*

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

### **List of Subjects in 30 CFR Part 938**

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 22, 2015.

**Thomas D. Shope,**

*Regional Director, Appalachian Region.*

**EDITORIAL NOTE:** This document was received for publication by the Office of Federal Register on September 10, 2015.

For the reasons set out in the preamble, 30 CFR part 938 is amended as follows:

**PART 938—PENNSYLVANIA**

■ 1. The authority citation for Part 938 continues to read as follows:

*Authority:* 30 U.S.C. 1201 *et seq.*

**§ 938.16 [Amended]**

■ 2. Section 938.16 is amended by removing and reserving paragraph (h).

[FR Doc. 2015–23118 Filed 9–16–15; 8:45 am]

**BILLING CODE** 4310–05–P

**DEPARTMENT OF THE TREASURY****Fiscal Service****31 CFR Part 285**

**RIN 1530-AA02**

**Offset of Tax Refund Payments To Collect Certain Debts Owed to States**

**AGENCY:** Bureau of the Fiscal Service, Fiscal Service, Treasury.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts the interim rule, published in the **Federal Register** on January 28, 2011, concerning the collection of delinquent State unemployment compensation debts through the offset of overpayments of Federal taxes.

**DATES:** This rule is effective September 17, 2015.

**ADDRESSES:** In accordance with the U.S. government's eRulemaking Initiative, the Bureau of the Fiscal Service publishes rulemaking information on <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Thomas Kobielus, Manager, Treasury Offset Program Debt Policy Branch, Treasury Offset Program Division, Debt Collection Program Management Directorate, Debt Management Services, Bureau of the Fiscal Service, at (202) 874–6810, or Michelle M. Cordeiro, Attorney, Office of Chief Counsel, Bureau of the Fiscal Service, at (202) 874–6680.

**SUPPLEMENTARY INFORMATION:****I. Background**

This rule implements the authority added by the SSI Extension for Elderly and Disabled Refugees Act of 2008 (“2008 Act”), as amended by the Claims Resolution Act of 2010 (“2010 Act”), to offset overpayments of Federal taxes (referred to as “tax refund offset”) to collect delinquent state unemployment compensation debts. The Department of the Treasury (“Treasury”) has incorporated the procedures necessary to collect state unemployment compensation debts as part of the

Treasury Offset Program, a centralized offset program operated by Treasury's Bureau of the Fiscal Service (“Fiscal Service”).

On January 28, 2011, Fiscal Service (then, the Financial Management Service) published an interim rule with request for comments at 76 FR 5070, implementing this new authority. Specifically, this rule amended Fiscal Service regulations to include unemployment compensation debts among the types of state debts that may be collected by tax refund offset.

**II. Summary of Comments Received and Treasury's Responses**

Treasury sought comments on all aspects of the proposed rule. Treasury received comments from one private company that provides worldwide tax services. The following is a discussion of the substantive issues raised in the comments.

**1. Notice**

The commenter suggested that the rule provide guidelines to the states regarding how to notify debtor populations who may be affected by this rule. While this comment is outside the scope of this rule, Fiscal Service notes that this rule requires debtor-specific pre-offset notification (see 31 CFR 285.8(c)(3)(i)). The commenter also suggested that Fiscal Service mandate that states provide a pre-offset notice by certified mail, return receipt requested. In the 2010 Act, Congress explicitly removed this requirement in the case of unemployment compensation debt. Fiscal Service is unaware of any evidence that certified mail is more likely to reach the debtor than is regular first class mail, and notes that the cost of sending a notice by certified mail, return receipt requested, is high relative to sending a notice by regular first class mail. Therefore, Fiscal Service has not adopted this suggestion. As required by statute, however, notice must be sent by certified mail, return receipt requested prior to pursuing Federal tax refund offset to collect delinquent state income tax obligations.

The commenter also suggested that Fiscal Service mandate that the notice to the debtor include certain details about the debt. Fiscal Service notes that, prior to submitting a debt to the Treasury Offset Program for tax refund offset purposes, a state is required to certify to Fiscal Service that it has provided the debtor with sufficient due process, including identification of the debt the state seeks to collect by offset. The information that must be provided may differ with the specific circumstances, and states may provide notice beyond

what is specifically required by statute and regulation. Because identification of the debt is already required, Fiscal Service has not incorporated this suggestion.

**2. Reasonable Efforts**

The commenter suggested that this rule provide specific actions that states should take and state what documentation they should retain to demonstrate that they have made reasonable efforts to collect a debt prior to pursuing Federal tax refund offset. The rule provides detail on what a reasonable effort includes—namely, making written demand on the debtor for payment and following state law and procedure. In addition, the rule was designed to provide flexibility because what constitutes a reasonable effort may differ based on the specific circumstances. Therefore, Fiscal Service believes that providing specific actions that states should take is unnecessary and not practicable and has not adopted this suggestion.

**3. Central Repository for Information**

The commenter suggested that debtors be able to obtain information through a centralized location within the Treasury Offset Program Web site and through an automated telephone system on why their payment was offset and on state appeals processes. While this suggestion is outside the scope of this rule, Fiscal Service notes that debtors currently may access certain offset information through an automated telephone system. Fiscal Service further notes that it is exploring other self-service options that would permit debtors to obtain information about their own debts.

**4. Other Concerns**

The commenter suggested that the description of the required appeal process contain more detail. Fiscal Service is not aware of any additional detail that needs to be included and, therefore, has not made any changes to the rule based on this suggestion.

The commenter also suggested that Fiscal Service consider extending the period of dispute to 90 days because debtors are unlikely to have retained records for long periods of time. Fiscal Service notes that several other delinquent debt collection tools provide a due process period of 60 days or fewer, including the offset of Federal nontax payments to collect Federal nontax debts (31 CFR 285.5(d)(6)(ii)(A)); the offset of Federal nontax payments to collect state debts (31 CFR 285.6(e)(2)); the offset of Federal tax payments to collect Federal nontax debts (31 CFR 285.2(d)(1)(ii)(B)); and the

administrative garnishment of wages to collect Federal nontax debts (31 U.S.C. 3720D(b)(2)). Moreover, Fiscal Service believes that an additional 30 days is not likely to help debtors locate and produce such records, and is not aware of any evidence that 60 days is insufficient. Given the time period for other debt collection tools, Fiscal Service believes it would be best to leave the interim rule unchanged.

The commenter also expressed concern that lifting the 10-year time limitation will create burdens for Treasury's Internal Revenue Service, due to an increase in injured spouse claims. Fiscal Service is unaware of any evidence to support this concern. Fiscal Service further notes that the 10-year limitation was removed by statute.

#### Procedural Matters

This rule is not a significant regulatory action as defined in Executive Order 12866. Because no notice of proposed rulemaking was required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

#### Federalism

This rule has been reviewed under Executive Order 13132, federalism. This rule will not have substantial direct effects on states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Participation in the program governed by this rule is voluntary for the states; this rule only sets forth the general procedures for state participation. States already participate in offset of tax refunds to collect delinquent state income tax obligations pursuant to 31 CFR 285.8. This rule merely updates the regulations to reflect the statutory change authorizing states to submit additional debts to Treasury Offset Program for collection by tax refund offset. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

For the reasons stated above, the interim rule amending 31 CFR 285.8, published at 76 FR 5070, January 28, 2011, is adopted as final without change.

**David A. Lebryk,**

*Fiscal Assistant Secretary.*

[FR Doc. 2015-23305 Filed 9-16-15; 8:45 am]

**BILLING CODE 4810-AS-P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 86

[Docket ID: DOD-2014-OS-0009]

RIN 0790-AJ19

#### Background Checks on Individuals in DoD Child Care Services Programs

**AGENCY:** Under Secretary of Defense for Personnel and Readiness, DoD.

**ACTION:** Final rule.

**SUMMARY:** This rule establishes and updates policy, assigns responsibilities, and provides procedures to conduct criminal history checks on individuals involved in the provision of child care services for children under the age of 18 in DoD programs. The Crime Control Act of 1990 (Act) requires all individuals involved with the provision of child care services to children under the age of 18 undergo a criminal background check. "Child care services" include, but are not limited to, social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), and rehabilitative programs. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any of the services discussed above.

**DATES:** This rule is effective October 19, 2015.

**FOR FURTHER INFORMATION CONTACT:** Karen Morgan, 571-372-0859.

**SUPPLEMENTARY INFORMATION:**

#### Executive Summary

The purpose of this regulatory action is to describe requirements for criminal history background checks, including reinvestigation, and self-reporting, for individuals involved with the provision of child care services.

The legal authorities for this rule include: 5 U.S.C. 2105, 10 U.S.C. chapter 47, 42 U.S.C. 13041.

The major provisions of this regulatory action include providing procedures for requirements for criminal history background checks listing the types of background checks, and descriptions of reinvestigation and self-reporting.

This rule is intended to support the workforce mission of the DoD and implement current law that covers individuals expected to have regular contact with children in the performance of child care services on a DoD installation or DoD-sanctioned program. The estimated costs of the rule

are \$10 million annually. This cost includes administration costs; required FBI fingerprint Investigations Child Care National Agency Check and Inquiries checks (\$125/NACI); State Criminal History Repository checks (\$25/each state the individual resided in); and periodic reinvestigations. We do not believe that this rule will impose substantial direct costs on state and local governments.

This rule is part of DoD's retrospective plan, completed in August 2011, under Executive Order 13563, "Improving Regulation and Regulatory Review." DoD's full plan and updates can be accessed at: <http://www.regulations.gov/#!docketDetail;ct=FR+PR+N+O+SR;rpp=10;po=0;D=DOD-2011-OS-0036>.

#### Public Comments

The Department of Defense published a proposed rule in the **Federal Register** on October 1, 2014 (79 FR 59168-59173) for a 60-day public comment period. We received 22 comments. Five comments expressed support for the rule and no response is required. One comment was withdrawn. The remaining comments are listed below.

*Comment ID DOD-2014-OS-0009-0003:*

- The law still states that any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee. Public Law 101-647. The word may give too much flexibility in the decision making process to hiring agents in determining what to do with results of the background check. The review board may either bar employment based on the offenses listed out in the statute or excuse the background check results. Agency processes should spell out more specifically which offenses are bars and which are not.

*Response:* The commenter has referenced the summary paragraph at the beginning of the rule, which is not the rule itself. Please see § 86.6(c) for specific criteria for automatic and presumptive disqualifiers, which does not use the term, "may."

- It is imperative that a thorough review, investigation and study of different systems for background checks is completed on each organization interacting with children.

*Response:* This rule/policy was developed in collaboration with the Military Services, which are responsible for providing detailed procedures that meet the overall DoD requirements in this rule to ensure the rule/policy is implemented correctly.

*Comment ID DOD-2014-OS-0009-0004:*

- This rule includes all current employees, contractors and specific volunteers, in addition to future applicants, which is bound to create a backlog for which no solution is presented, at least in the current rule.

*Response:* This rule does not create a new system. It updates existing policy for background checks.

- This rule addresses foreign nationals in a way that could be ambiguous in its application. The definition describes a foreign national as not a citizen of the United States. This encompasses a fair amount of specific volunteers, especially in the religious ministries at overseas DoD facilities. These volunteers, innocent of any criminal wrong doing, may not fall under host country agreements and therefore be unable to continue their work. This would be an unfair outcome for those individuals and the organizations that rely on an already limited pool of volunteers. A similar outcome is possible for those foreign nationals who are military members or spouses who are not yet U.S. citizens that reside in the U.S. and work on DoD facilities.

*Response:* There are policies and procedures in place to ensure foreign nationals receive appropriate background checks or work under line-of-sight supervision (LOSS) in order to continue their work.

- The rule seems to exclude subcontractors from its application. This may be due to the potential increased burden on first line contractors to ensure all its subs are in compliance. This is frankly unacceptable as a lot of what occurs on DoD facilities, especially overseas, is accomplished by subcontractors.

*Response:* The exclusion of subcontractors has been deleted from the definition of contractors.

*Comment ID DOD-2014-OS-0009-0005:* I'm confused by the language in § 86.6(b), which references "(a)(6)(i)" and "(a)(6)(ix)" as being "in this section." I can't find the quoted section. This may be my error, or perhaps it is a clerical oversight.

*Response:* The reference should be (a)(5)(i) and (a)(5)(ix). Section 86.6(b) has been updated with the accurate reference.

*Comment ID DOD-2014-OS-0009-0006:* Why limit the background checks to individuals with "regular contact with children?" The definition of "regular contact with children" excludes those with access to children. The narrow reach of the proposed rule

seems to leave out serious threats. Limited resources could be to blame.

*Response:* It is beyond the scope of DoD to conduct a background check on any individual who has access to children. This rule/policy is intended to ensure appropriate checks of those who work in DoD-sanctioned child care services programs.

*Comment ID DOD-2014-OS-0009-0007:* Absent documented statistical research to the contrary, the Department of Defense has not established that individuals who are convicted drug felons are any more likely to threaten a child's safety than any other citizen of the United States. Please modify the proposed rule to omit the class "persons with a drug felony" from the screening process for federal jobs within the Department of Defense that serve children under the age of 18.

*Response:* Inclusion of a "felony conviction of a drug offense" as an automatic disqualifier was based on careful and objective analysis regarding how to protect children in DoD child care services programs. A felony conviction of a drug offense could adversely impact the integrity of the position and the safety and well-being of children in DoD care.

*Comment ID DOD-2014-OS-0009-0008:*

- Costs: \$10 million annually is a large amount of money. How crucial are each of the checks and investigations and how necessary is it for reinvestigations to take place every 5 years if the surfacing of derogatory information will trigger a reinvestigation anyways? I like Executive Orders 13563, and it seems to address these questions, however it states that it is not economically significant, which makes me wonder whether alternatives ways to regulate and minimize costs are properly being explored and examined. The price of each component, for example video surveillances or conspicuous marking, should be strictly scrutinized. What other programs is the use of this money being indirectly taken away from? Additionally, what process will determine that the state and local governments will not be substantially affected financially and what does substantial mean? It is great that employers and a substantial number of small entities will not be significantly impacted under the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, but how far do the costs extend to government contracts and employees within the state?

*Response:* The requirements for the initial checks and regular 5 year reinvestigations are crucial to ensuring protection of children in DoD child care

services programs. As background check systems are updated to report derogatory information more immediately, this rule/policy may be updated to revise the every 5 year requirement. The costs of the investigations are borne by the DoD, and not by the individual or his or her employer or the State. This policy update does not and cannot mandate that State, local, and tribal governments adopt new, unfunded regulatory obligations.

- Privacy and Relevancy: Those in charge of the background checks are about to look at any other available information that is relevant (listed under Adjudication). I fear that some may abuse this and unfairly use information that is not so relevant against an applicant.

*Response:* Adjudicators are trained to appropriately assess information received as part of a background checks in accordance with law and policy. Individuals who abuse their access to information are not operating in accordance with laws, regulations and policies.

- Categorizing Care Provider, Providers, and Personnel performing duties in athletic programs: The definitions for these types of jobs can easily be stretched to many things (for example, could babysitting under certain circumstances count?). Child care or youth activities could mean so many things that do not necessarily require these extensive checks. My obvious hesitancy expressed in these comments and questions comes from my concern for costs for this rule as well as unfair burdens placed on individuals that may have a poor history, but a history that is unrelated to the wrongdoings that their guilt from these tests would be impliedly accusing them of, or a history that is simply in the past and different from their present state (for example a minor criminal record or drug use that has been overcome). It is honorable to aim to protect our children, but it is also important to protect our citizens and employees who are trying to live happy lives and contribute to the economy in the best ways that they can.

*Response:* The categories of individuals who require a criminal history background check, which includes all individuals who have regular contact with children under 18 years of age in DoD-sanctioned child care services programs, was established in accordance with Public Law 101-647 in order to protect the health and well-being of children in such programs. The costs of the specific investigations required pursuant to this rule have been

budgeted and are borne by the Department of Defense and not by the individual or his or her employer or the state.

- Lastly, it concerns me that the DoD Components will evaluate the disqualifications AND ALSO oversee procedures for the appeal of unfavorable determinations. This system has the potential to be unjust.

*Response:* There is an appeals process that individuals can pursue should they feel they have been treated unjustly. The DoD Components will establish and oversee procedures for the appeal of unfavorable determinations for all categories of individuals. The procedures for civilian personnel are subject to Volume 731 of DoDI 1400.25, DoD Civilian Personnel Management System.

*Comment ID DOD-2014-OS-0009-0009:* Under § 86.4(c), not only individuals who have current DoD affiliation but also individuals who have prior DoD affiliation must undergo an IRC. I am curious why this would be necessary. If a person no longer has an affiliation with the DoD and is not going to have contact with the DoD child care service, why go through the trouble of checking all those individuals with prior affiliation?

*Response:* Section 86.4(a) has been modified to include this requirement so that it is clear the IRC is only conducted if the individual (who has a prior DoD affiliation) is undergoing a background check because he/she will have regular contact with children in DoD child care services programs.

*Comment ID DOD-2014-OS-0009-0010:*

- Section 86.4 Policy does not contain any actual policy as to why these rules are being proposed. It would be helpful if the section included something pertaining to the importance of the protection of children from known child abusers, drug users etc. A specific policy will help when looking at what is important in conducting a background check (in example, a person with a former addiction who has undergone rehabilitation who has had no adverse contact with children.) Also, the policy will help the DoD in defending any appeals from potential employees who were denied employment.

*Response:* Section 86.4 has been updated with additional language indicating why the rule is being promulgated.

- A required amount of employment for a LOSS supervisor as an extra safeguard will also help promote the policy of the proposed rules.

*Response:* The role of the LOSS supervisor is to ensure that an individual who does not yet have a completed background check remains in the line of sight of another individual who does have a completed background check. The LOSS supervisor is not necessarily supervising the performance of the other individual; the LOSS supervisor is only ensuring that individual is not left alone with children.

*Comment ID DOD-2014-OS-0009-0011:* It seems as though we should require the caregivers themselves to pay for the background checks. It is not uncommon for employers to require employees to pay the costs associated with licensing or certifications.

*Response:* Background checks should not be compared to elective licenses and certifications. The costs of the specific investigations required pursuant to this Rule have been budgeted and are borne by the Department of Defense and not by the individual or his or her employer or the state. By law, background checks are required for federal agencies that hire or contract for hire in the provision of care to children under the age of 18. Per this Rule, Office of Personnel Management (OPM) is the only authorized Investigative Service Provider (ISP) that the Military Service Components may use for background investigations. Contracted support must meet the intent of this Rule, DoD policy and the law.

*Comment ID DOD-2014-OS-0009-0012:*

- Video surveillance violates a person's "expectation of privacy." It should be re-written to comply with the 5th Amendment. The procedure may be ruled unconstitutional as it currently stands.

*Response:* Signage and monitors are placed in highly visible entryways and foyers and inform individuals that video surveillance is being conducted. Video surveillance events occurring in public space for which individuals do not have reasonable expectations of privacy. Video surveillance does not intrude upon an individual's sphere of privacy; the use of video surveillance equipment (in designated programs) supports the law's intent for Line of Sight Supervision (LOSS) for individuals whose background checks have been initiated but not completed. Surveillance equipment is also used by staff trainers and managers as a training aid for staff observations and coaching.

- Procedures: Requirements for Criminal background checks. Foreign government background checks for employees working overseas has a 5th Amendment issue. How is an overseas

employee challenge the validity of a foreign background check? There may be procedural and language barriers that prevent a fair opportunity to exonerate oneself.

*Response:* The current rule provides basic guidance regarding background checks for foreign nationals as they relate to DoD child care services programs. See DoD Instruction 5200.46 for more detailed guidance on procedures for foreign nationals.

*Comment ID DOD-2014-OS-0009-0015:* Of course children of any parentage should be protected from criminals and potential harm via their caretakers; however this cost will most likely be substantial. Please consider you taxpayers when making these choices that can seem frivolous at times.

*Response:* The costs of the investigations are borne by the DoD, and not by the individual or his or her employer or the State. When contracting for services, the contract must ensure it meets the intent of this Rule and the Crime Control Act of 1990. This Rule is a top priority for DoD to ensure the safety and well-being of all children in DoD child care services programs. By law, background checks are required for federal agencies that hire, contract for hire or use volunteers for the provision of care to children under the age of 18.

*Comment ID DOD-2014-OS-0009-0016:* The Unfunded Mandates Reform Act states there will be no additional financial expenditures required from the individual or employer while the regulatory act acknowledges potential indirect costs to small entities. If this proposed rule is passed, it would be beneficial to clearly outline what constitutes a small entity, what course of action, if any, can they take to avoid costs, and what kind of notice will they have if they are affected by this rule. When it comes to implementing the rule, if passed, there needs to be guidelines for how businesses that may incur costs can go about managing the financial change comfortably. As a DoD organization, can these small entities expect to qualify for additional funds to offset these costs (costs unspecified at this moment)? If this rule is passed, it should clearly state what the dollar figure will be, and a definite yes or no about eligibility of offsetting the expenses via government funds. If the proposed rule is passed, how immediate will the new procedures effect these small entities? The rule should be altered to include the time frame for implementing the policy and allow organizations to communicate if they need additional accommodations to be effective in its implementation.

*Response:* DoD has certified that this rule would not have a significant economic impact on a substantial number of small entities because the costs for the investigation conducted pursuant to this rule are borne by the DoD, and not by the individual or his or her employer. Furthermore, any indirect costs incurred by small businesses as a result of this rule would be minimal.

*Comment ID DOD-2014-OS-0009-00017:* Not all agencies within individual states make their records available to commercial databases, nor does the FBI make its federal or state criminal records available to commercial services. In addition, the information in commercial databases may only be updated occasionally. Some states have databases that have not been updated to determine if the individual has any arrest history, therefore when a background check is being completed on a federal level, the record may not be current, and in turn, invalid information will be received on that individual. Most states allow criminals who have paid their dues, to erase their criminal records. Currently, 12 states expunge first-time criminal offenses after ex-convicts demonstrate a law-abiding lifestyle for 10 years.

*Response:* The rule requires multiple levels of investigation in order to ensure the most accurate information possible is captured during the investigation process. The DoD uses various data sources from federal, state and local authorities to obtain information on background investigations, credentialing, suitability determination and security clearances. The primary investigations include the Child Care National Agency Check and Inquiries; the FBI Identification Records check; the State Criminal History Repository Check; the state sex offender registry; the child abuse registry and an Installations Records Check (IRC Derogatory information is identified through this multi-tier investigative process). The Department remains committed in its efforts to ensure those who work with children meet the highest standards of conduct.

*Comment ID DOD-2014-OS-0009-00018:*

- Will background checks be conducted on the current staff on hand first? Will there be a set time frame to complete the background check? For example, each person attempting to gain employment has a 4–6 month waiting period, prior to a hire date? I know firsthand that some background checks can take a very long time ranging from 4 months to 12 months depending on the individual and their circumstances.

*Response:* This rule does not create a new system. It updates existing policy for background checks. The provision to work under LOSS allows DoD to employ individuals while the background checks are being completed.

- Has the DoD considered how criminal histories are not always current or may have mistakes? A person may have committed a crime, even serious in nature, but the individual may take a plea, and with 12 months good behavior it may be expunged from their record. Are there any plans or a step to assist with this process? Has the DoD considered using public Web site searches to assist with this process such as Facebook, Instagram, YouTube, Twitter, etc. to gain more information on that particular individual? Using open source information may quickly display a person behaviors, likes, dislikes, etc., is a cheaper option, and may take only ten minutes depending on what the DoD discovers.

*Response:* DoD requirements outlined in this rule make use of available legal sources of investigative information to make determinations about individuals' suitability for employment in DoD child care services programs.

*Comment ID DOD-2014-OS-0009-00022:* I am in support of this proposed rule, but to accomplish greater safeguarding of children as intended, subcontractors should not be excluded as stated. DoD contracts are typically performed by subcontractors who actually perform work around the children, not the prime contractors.

*Response:* The exclusion of subcontractors has been deleted from the definition of contractors.

*Comment ID DOD-2014-OS-0009-00024:* The comment urges the DoD to update requirements for criminal background checks on individuals in DoD child care services programs in § 86.5, Responsibilities to align with the provisions recently enacted by the Child Care and Development Block Grant Act of 2014.

*Response:* We have carefully reviewed the requirements of the proposed rule and the requirements set forth in Public Law 113–186, the Child Care and Development Block Grant Act of 2014. This rule meets or exceeds the requirements of the Child Care and Development Block Grant Act of 2014. We have determined that, while the language of the rule differs slightly from the language of Public Law 113–186, the databases searched yield the same information.

#### Regulatory Analysis

Executive Order 12866, “Regulatory Planning and Review” and Executive

Order 13563, “Improving Regulation and Regulatory Review” direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be a significant regulatory action, although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

#### *Sec. 202, Public Law 104–4, “Unfunded Mandates Reform Act”*

DoD has reviewed the rule in accordance with the Unfunded Mandates Reform Act of 1995, and compliance with the rule would require no additional expenditures by either public or private employers. In sum, the final rule does not mandate that State, local, and tribal governments adopt new, unfunded regulatory obligations. The costs of the investigations conducted pursuant to this rule are borne by the DoD, and not by the individual or his or her employer.

#### *Public Law 96–354, “Regulatory Flexibility Act” (5 U.S.C. 601)*

We certify this rule would not have a significant economic impact on a substantial number of small entities because the costs for the investigation conducted pursuant to this rule are borne by the DoD, and not by the individual or his or her employer. Furthermore, any indirect costs incurred by small businesses as a result of this rule would be minimal. Accordingly, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

#### *Public Law 96–511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)*

This rule imposes reporting and record keeping requirements under the Paperwork Reduction Act of 1995. These requirements have been approved by the Office of Management and Budget and assigned OMB Control Number 3206–0005, “Questionnaires for National Security Positions, Standard Form 86 (SF 86),” OMB Control Number 3206–0261, “SF 85 Questionnaire for Non-Sensitive Positions,” OMB Control Number 3206–0191, “SF 85P Questionnaire for Public Trust Positions,” and OMB Control Number

0704–0516, “Child Care Development Program (CDP) Criminal History.”

*Executive Order 13132, “Federalism”*

This rulemaking was analyzed in accordance with the principles and criteria contained in Executive Order 13132 (“Federalism”). It has been determined that it does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. This rulemaking has no substantial effect on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. Nothing in this document preempts any State law or regulation. Therefore, DoD did not consult with State and local officials because it was not necessary.

**List of Subjects in 32 CFR Part 86**

Government contracts, Government employees, Infants and children, Investigations.

Accordingly, 32 CFR part 86 is revised to read as follows:

**PART 86—BACKGROUND CHECKS ON INDIVIDUALS IN DOD CHILD CARE SERVICES PROGRAMS**

Secs.

- 86.1 Purpose.
- 86.2 Applicability.
- 86.3 Definitions.
- 86.4 Policy.
- 86.5 Responsibilities.
- 86.6 Procedures.

**Authority:** 5 U.S.C. 2105, 10 U.S.C. chapter 47, and 42 U.S.C. 13041.

**§ 86.1 Purpose.**

This part establishes policy, assigns responsibilities, and provides procedures to conduct criminal history checks on individuals involved in the provision of child care services for children under the age of 18 in DoD programs.

**§ 86.2 Applicability.**

This part applies to the Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this part as the “DoD Components”).

**§ 86.3 Definitions.**

Unless otherwise noted, these terms and their definitions are for the purposes of this part.

*Adjudication.* The evaluation of pertinent data in a background investigation, as well as any other available information that is relevant and reliable, to determine whether an individual is suitable for work.

*Adult.* An individual 18 years of age or older regarded in the eyes of the law as being able to manage his or her own affairs.

*Applicant.* A person upon whom a criminal history background check is, will be, or has been conducted, including individuals who have been selected or are being considered for a position subject to a criminal history background check, and individuals undergoing a recurring criminal history background check. Includes current employees.

*Child.* A person under 18 years of age.

*Care provider.* Current or prospective individuals hired with appropriated funds (APF) and nonappropriated funds (NAFs) for education, treatment or healthcare, child care or youth activities; individuals employed under contract who work with children; and those who are certified for care. Individuals working within programs that include: Child Development Programs, DoD dependents schools, DoD-operated or -sponsored activities, foster care, private organizations on DoD installations, and youth programs.

*Child care services.* Care or services provided to children under the age of 18 in settings including child protective services (including the investigation of child abuse and neglect reports), social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), foster care, residential care, recreational or rehabilitative programs, and detention, correctional, or treatment services, as defined in 42 U.S.C. 13041.

*Class.* With regard to the designation of positions, a categorical descriptor identifying employee, contractor, provider, or volunteer positions by group rather than by individual position or title (e.g., “doctors” or “individuals supervising children in a school”).

*Contractor.* Any individual, firm, corporation, partnership, association, or other legal non-Federal entity that enters into a contract directly with DoD or a DoD Component to furnish supplies, services, or both including construction. Foreign governments or representatives of foreign governments that are engaged in selling to DoD or a DoD Component are defense contractors when acting in that context. A subcontractor is any supplier, distributor, vendor, or firm that furnishes supplies or services to or for

a prime contractor or another subcontractor.

*Covered position.* Defined in volume 731 of DoD Instruction 1400.25, “DoD Civilian Personnel Management System” (available at <http://www.dtic.mil/whs/directives/corres/pdf/140025v731.pdf>).

*Criminal history background checks.*

A review of records, investigative reports, and other investigative elements to generate criminal history background findings to be used to make fitness or suitability determinations.

*Derogatory information.* Information that may reasonably justify an unfavorable personnel suitability or fitness determination because of the nexus between the issue or conduct and the core duties of the position.

*DoD affiliation.* A prior or current association, relationship, or involvement with the DoD or any elements of DoD, including the Military Departments.

*DoD-sanctioned programs.* Any program, facility, or service funded, or operated by the DoD, a Military Department or Service, or any agency, unit, or subdivision thereof. Examples include, but are not limited to, chapel programs, child development centers, family child care (FCC) programs, medical treatment facilities, Department of Defense Education Activity (DoDEA) schools, recreation and youth programs. These do not include programs operated by other State or Federal government agencies or private organizations without the official sanction of a DoD entity.

*Duties.* Those activities performed as an employee, contractor, provider, or volunteer that involve interaction with children, including any work performed in a child development program or DoDEA school.

*Employee.* An individual, paid from funds appropriated by the Congress of the United States, or an individual employed by a NAF instrumentality in accordance with 5 U.S.C. 2105(c). Includes foreign nationals in accordance with Volume 1231 of DoD Instruction 1400.25, “DoD Civilian Personnel Management System” (available at <http://www.dtic.mil/whs/directives/corres/pdf/1400.25-V1231.pdf>), Military Service members working during their off-duty hours, and non-status, non-continuing temporary positions with specified employment periods not to exceed 1 year such as summer hires, student interns, and seasonal hires.

*FAP.* Defined in DoD Directive 6400.1, “Family Advocacy Program (FAP)” (available at <http://www.dtic.mil/whs/directives/corres/pdf/640001p.pdf>).



**FAP records check.** A review of FAP records maintained on an individual, including records maintained by the installation office and records in the Service Child and Spouse Abuse Central Registry in accordance with DoD Directive 6400.1. If the individual is the spouse or dependent of a Service member, this may entail review of records maintained on the sponsoring Service member. Installation and Service Central Registry checks are limited to identifying pending and met criteria incidents of maltreatment and do not include information related to incidents that did not meet criteria or any information contained in the clinical case record that is protected by section 1320d-6 or 5 U.S.C. 552a.

**Federal Bureau of Investigation (FBI) criminal history background check.** An FBI identification record—often referred to as a criminal history record or a “rapsheet”—is a listing of certain information taken from fingerprint submissions retained by the FBI in connection with arrests and, in some instances, federal employment, naturalization, or military service. The process of responding to an identification record request is generally known as a criminal history background check.

**FCC.** Defined in DoD Instruction 6060.2, “Child Development Programs (CDPs)” (available at <http://www.dtic.mil/whs/directives/corres/pdf/606002p.pdf>).

**FCC provider.** Defined in DoD Instruction 6060.2.

**FCC adult family members.** Any adult, 18 years of age or older, who resides in the home of an FCC provider for 30 or more consecutive days.

**Fitness.** The reference to a person’s level of character and conduct determined necessary for an individual to perform work for, or on behalf of, a Federal Agency as an employee in the excepted service (other than in a position subject to suitability) or as a contractor employee.

**Fitness determination.** A decision, based on review of criminal history background check findings, that an individual is fit to perform duties in a position subject to criminal history background check. Fitness determinations will be “favorable,” meaning that the individual is fit to perform the duties, or “unfavorable,” meaning that the individual is not.

**Foreign nationals.** Individuals who are not citizens of the United States.

**Foster care providers.** A voluntary or court-mandated program that provides 24-hour care and supportive services in a family home or group facility, within government-owned or -leased quarters,

for children and youth who cannot be properly cared for by their own family.

**Healthcare personnel.** Military, civilian, or contract staff involved in the delivery of healthcare services.

**Host-government check.** A criminal history background check conducted on foreign nationals in accordance with U.S. and host country treaties or agreements.

**Interim suitability or fitness determination.** Part of the pre-screening process in the identification and resolution of suitability or fitness issues, which occurs prior to the initiation of the required investigation. It involves the review of applications and other employment related documents. A favorable interim suitability or fitness determination is a status granted on a temporary basis, which permits individuals to work under line-of-sight supervision (LOSS) after the return of the advance FBI fingerprint check, pending completion of full investigative requirements and a final suitability determination.

**Investigative elements.** The records, reports, or other individual elements that comprise the whole of information collected during a criminal history background check and used to make a fitness or suitability determination.

**Installations records check (IRC).** A query of records maintained on an individual by programs and entities at the military installation where the individual lives, is assigned, or works, including military law enforcement and installation security records, drug and alcohol records, and FAP records for a minimum of 2 years before the date of the application.

**Investigative service provider (ISP).** The company or agency authorized to perform background investigations on personnel on behalf of the agency.

**Line of Sight Supervision (LOSS).** Continuous visual observation and supervision of an individual whose background check has not yet cleared, and has a favorable interim suitability or fitness determination, while engaged in child interactive duties, or in the presence of children in a DoD-sanctioned program or activity. The person providing supervision must have undergone a background check and received a final favorable suitability or fitness determination and be current on all periodic reinvestigations as required by this part.

**Met criteria.** Reported incident of alleged maltreatment found to meet DoD incident determination criteria for child abuse or domestic abuse and entry into the Service FAP central registry of child abuse and domestic abuse reports.

**Position.** An employee, contractor, provider, or volunteer role or function.

**Preliminary investigations.** Those investigative elements of a criminal history background check, including those specified in § 86.6(f), which must be favorably completed and reviewed before an individual may be permitted to perform duties under LOSS.

**Providers.** Individuals involved in child care services who have regular contact with children or may be alone with children in the performance of their duties. Includes FCC providers and individuals with overall management responsibility for child and youth programs.

**Regular contact with children.** Recurring and more than incidental contact with or access to children in the performance of their duties on a DoD installation, program, or as part of a DoD-sanctioned activity.

**Reinvestigation.** A criminal history background check conducted after the period of time prescribed by this part to ensure the individual remains eligible to provide child care services. Reinvestigation includes the same checks conducted for the initial investigation as outlined in § 86.6(b).

**Respite care providers.** Individuals who provide short-term care and supportive services in a family home or group facility within government-owned or -leased quarters.

**State criminal history repository (SCHR).** A repository of criminal information that lists past state convictions, current offender information, and criminal identification information (fingerprints, photographs, and other information or descriptions) that identify a person as having been the subject of a criminal arrest or prosecution. Checks of the SCHR may include the State child abuse and neglect repository and the State sex offender registry.

**Suitability determination.** A decision that a person is or is not suitable for a covered position within the DoD.

**Supervisor.** The person supervising individuals who are permitted to perform duties only under LOSS, who is not necessarily the same as an employee’s supervisor for employment purposes (e.g., ratings, assignment of duties).

**Volunteer.** There are two types of volunteers:

(1) **Specified volunteers.** Individuals who could have extensive or frequent contact with children over a period of time. They include, but are not limited to, positions involving extensive interaction alone, extended travel, or overnight activities with children or youth. Coaches and long-term

instructors are among those who fall in this category. Specified volunteers are designated by the DoD Component head. Background checks are required in accordance with § 86.6(b)(4).

(2) *Non-specified volunteers.*

Individuals who provide services that are shorter in duration than is required to perform a criminal history background check (e.g., one-day class trip, class party). Because non-specified volunteers do not receive the same level of background checks as specified volunteers, non-specified volunteers must always be in line of sight of a staff member with a complete background check.

*Youth program.* Defined in DoD Instruction 6060.4, "Department of Defense (DoD) Youth Programs (YPs)" (available at <http://www.dtic.mil/whs/directives/corres/pdf/606004p.pdf>).

**§ 86.4 Policy.**

It is DoD policy that:

(a) Individuals who have regular contact with children under 18 years of age in DoD-sanctioned child care services programs will undergo a criminal history background check in order to protect the health, safety and well-being of children in such programs.

(b) All individuals who have regular contact with children under 18 years of age in DoD-sanctioned child care services programs and who also have a current or prior DoD affiliation must also undergo an IRC.

(c) DoD Component heads are delegated the authority to make suitability determinations and take subsequent actions in cases involving applicants and appointees to covered positions as defined by 5 CFR 731.101, subject to the conditions in 5 CFR 731.103. This authority may be further delegated to authorized management officials, in writing, in accordance with volume 731 of DoD Instruction 1400.25.

(1) The DoD Consolidated Adjudications Facility is responsible for making favorable suitability determinations for civilian personnel in accordance with Deputy Assistant Secretary of Defense for Civilian Personnel and Policy Memorandum, "Responsibilities Under the Department of Defense Suitability and Fitness Adjudications for Civilian Employees Programs," August 26, 2013.

(2) Military members are not subject to suitability adjudication under Volume 731 of DoD Instruction 1400.25, "DoD Civilian Personnel Management System" (available at <http://www.dtic.mil/whs/directives/corres/pdf/140025v731.pdf>). Military members are subject to the background check requirements of DoD Instruction

5200.02, "Personnel Security Program" (available at [http://www.dtic.mil/whs/directives/corres/pdf/520002\\_2014.pdf](http://www.dtic.mil/whs/directives/corres/pdf/520002_2014.pdf)) and § 86.6.

(d) Suitability and fitness determinations for individuals subject to this part will follow the guidance of Volume 731 of DoD Instruction 1400.25 for APF employees and Subchapter 1403 of DoD Instruction 1400.25 for NAF employees. Suitability and fitness are to be applied for the child care worker population in accordance with Volume 731 of DoD Instruction 1400.25 for appropriated fund employees in covered positions as defined by 5 CFR part 731.

(e) Individuals who have received a favorable interim suitability or fitness determination based on the FBI criminal history background check are permitted to work under LOSS pursuant to 42 U.S.C. 13041(b)(3).

**§ 86.5 Responsibilities.**

(a) Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), the Assistant Secretary of Defense for Readiness and Force Management (ASD(R&FM)):

(1) Ensures the conduct of criminal history background checks complies with DoD policy and the Criminal Justice Information Services Division of the FBI's operational and security policies and procedures.

(2) Monitors DoD Component compliance with this part, applicable laws, and subsequent guidance issued by the applicable ISP.

(b) Under the authority, direction, and control of the ASD(R&FM), the Deputy Assistant Secretary of Defense for Civilian Personnel Policy (DASD(CPP)) oversees development of DoD Component policies and procedures for the background check initiation, completion, adjudication, and suitability or fitness determination process for civilian employees in accordance with this part.

(c) Under the authority, direction, and control of the ASD(R&FM), the Deputy Assistant Secretary of Defense for Military Community and Family Policy (DASD(MC&FP)) oversees development of DoD Component policies and procedures related to the background check initiation, completion, adjudication, and fitness determination process for specified volunteers, FCC providers and adults residing in their home, and others as identified in accordance with this part.

(d) Under the authority, direction, and control of the ASD(R&FM), the Deputy Assistant Secretary of Defense for Military Personnel Policy (DASD(MPP)):

(1) Implements this part for military personnel in accordance with DoD Instruction 5200.02.

(2) Institutes effective quality assurance and quality control systems for chaplains, support staff, specified volunteers, and contractors who provide support to religious programs and activities identified in § 86.6(a)(5)(v) and in accordance with this part.

(e) Under the authority, direction, and control of the Deputy Chief Management Officer (DCMO) of the Department of Defense, the Director of Administration ensures that the adjudication of background investigations of individuals who have regular contact with children under 18 years of age in DoD-sanctioned programs considers the criteria for presumptive and automatic disqualification as specified in this part.

(f) The Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) establishes policies and procedures for the background check initiation, completion, adjudication, and fitness determination process for contractors in accordance with the requirements of this part.

(g) The DoD Component heads:

(1) Ensure Component compliance with the requirements of this part, applicable laws, and guidance for civilian employees.

(2) Ensure compliance with suitability and fitness determination policies, requirements, and procedures for individuals in child care services in DoD programs as defined in 42 U.S.C. 13041 and DoD Instruction 1400.25.

(3) Ensure compliance with policies, requirements, and procedures for LOSS of individuals with a favorable interim suitability determination.

(4) Provide support and resources as required to implement this part and any Component-specific policies, requirements, and procedures, and ensure implementation.

**§ 86.6 Procedures.**

(a) *Requirements for criminal history background checks.* (1) All criminal history background checks required by this part must be initiated, tracked, and overseen by properly trained and vetted individuals who have been determined to be responsible for personnel security pursuant to DoD Instruction 5200.02 or human resource functions pursuant to Volume 731 of DoD Instruction 1400.25. Program managers, supervisors, and others not routinely performing personnel security and human resource functions are prohibited from managing the criminal history checks.

(2) All employment applications completed by individuals subject to this

part must comply with the requirements of 42 U.S.C. 13041(d).

(3) The DoD Component will ensure that only authorized ISPs are used.

(4) When permitted by the host government, foreign government checks of individuals serving on DoD installations overseas must be requested directly by the employing Military Service or agency in accordance with Volume 1231 of DoD Instruction 1400.25. As an alternative, DoD Components may request that overseas Military Service investigative elements obtain appropriate host-government checks and accept such checks if they are comparable to those required by 42 U.S.C. 13041. Where it is not possible to obtain criminal history checks comparable to those required by 42 U.S.C. 13041, foreign nationals will not be eligible for employment in child care services.

(5) Individuals subject to criminal history background checks are:

(i) All personnel employed or performing duties in DoD Child and Youth or other sanctioned child care services programs.

(ii) Individuals providing in-home FCC.

(iii) Personnel employed or performing duties in child and youth recreational and athletic programs (e.g., Morale, Welfare, and Recreation), including instructors and, when working in a facility when children and youth are present, custodial personnel.

(iv) Individuals employed or performing duties in a DoDEA school (whether or not directly involved with teaching), including but not limited to teachers, administrators, other professional staff, aides, bus drivers, janitors, cafeteria workers, nurses, and attendants.

(v) Chaplains, chaplains' assistants, religious program specialists, and other individuals employed or performing child care services duties for children under 18 years of age on a DoD installation or as part of a military-sanctioned program.

(vi) Foster and respite child care providers on a DoD installation, program, or as part of a military-sanctioned activity.

(vii) Health and mental health care personnel, employed or performing child care services duties on a DoD installation, in a DoD sanctioned program, or as part of a military-sanctioned activity, including but not limited to physicians, dentists, nurse practitioners, clinical social workers, physical therapists, speech-language pathologists, clinical support staff (including residents), registered nurses, licensed practical nurses, nursing

assistants, play therapists, and technicians.

(viii) Individuals employed or performing child care duties in social services, residential care, rehabilitation programs, detention, and correctional services on a DoD installation, program, or as part of a military-sanctioned activity.

(ix) Any other individuals reasonably expected to have regular contact with children on a DoD installation, in a DoD sanctioned program, or as part of a military-sanctioned activity, including specified volunteers and any person 18 years of age or older residing in an FCC, foster, or respite care home. Healthcare providers participating in TRICARE shall be governed by TRICARE policy.

(6) The DoD Components will also determine any other classes of positions subject to criminal history background checks, taking care to ensure that all individuals who have regular contact with children when providing child care services are investigated and the requirement must pertain to the class as a whole.

(7) Individuals designated in non-specified volunteer positions must always be under direct LOSS in accordance with paragraph (g) of this section.

(b) *Types of background checks.* Procedures for conducting a background check on individuals in paragraphs (a)(5)(i) through (ix) of this section differ based on the employment status of the individual. Military members are subject to the background check requirements of DoD Instruction 5200.02 and this section. The FBI criminal history background checks for all categories of individuals must be fingerprint-based and fingerprints must be captured using an FBI-approved system. SCHR checks may require hardcopy fingerprint submissions. State checks must include the state child abuse and neglect repository and the state sex offender registry. The Component must request a check of the state child abuse and neglect repository and the State sex offender registry if they are not automatically checked as part of the standard SCHR check.

(1) *Criminal history background checks for DoD civilian and military personnel who are investigated at the NACI or a higher level pursuant to DoD's personnel security program.* (i) DoD civilian and military personnel required by DoD Instruction 5200.02 to be investigated according to the requirements of the National Agency Check and Inquiries (NACI) or a higher level investigation and who have regular contact with children under 18 years of age in DoD-sanctioned programs will be

investigated and adjudicated in accordance with the provisions of DoD Instruction 5200.02.

(ii) These personnel will also be subject to the additional requirements of the Child Care National Agency Check and Inquiries (CNACI) and the criteria for presumptive and automatic disqualification as specified in paragraph (c) of this section.

(2) *Criminal history background checks for civilian employees (APF and NAF).* (i) In accordance with 42 U.S.C. 13041 and Volume 731 and Subchapter 1403 of DoD Instruction 1400.25, complete a CNACI, which includes an FBI criminal history background check conducted through the Criminal Justice Information Services Division of the FBI and SCHR checks through State repositories of all States that an employee or prospective employee lists as current and former residences on an employment application. Results of an advanced FBI fingerprint check must be provided before completion of the full CNACI to determine employment under LOSS.

(ii) Individuals with a prior DoD affiliation must also complete an IRC, which includes an installation law enforcement check, drug and alcohol records check, and a check of the Family Advocacy Program (FAP) records for a minimum of 2 years before the date of the application.

(3) *Criminal history background checks for FCC providers and contractors.* (i) In accordance with 42 U.S.C. 13041, complete a CNACI, which includes an FBI criminal history background check conducted through the Criminal Justice Identification Services Division of the FBI and SCHR checks through State repositories of all States that a provider or contractor or prospective provider or contractor lists as current and former residences in an employment application. Results of an advanced FBI fingerprint check must be provided before completion of the full CNACI. Results for contractors may be used to determine employment under LOSS.

(ii) Individuals with a prior DoD affiliation must also complete an IRC, including an installation law enforcement check, drug and alcohol records check, and a check of the FAP records for a minimum of 2 years before the date of the application.

(4) *Criminal history background checks for others.* (i) In accordance with 42 U.S.C. 13041, only an FBI advanced fingerprint check is required for criminal history background checks for volunteers and persons 18 years of age or older residing in an FCC, foster, or respite care home.

(ii) Individuals with a prior DoD affiliation must also complete an IRC to include: an installation law enforcement check, drug and alcohol records check, and a check of the FAP records for a minimum of 2 years before the date of the application.

(5) *Timely completion.* To ensure timely completion, the DoD Components will establish procedures to initiate or request criminal history background check results, follow up to ensure checks have been completed, and address situations where there is a delay in receiving results. In no event will an individual subject to this part be presumed to have a favorable background check merely because there has been a delay in receiving the results of the requisite background check. If no response from the state(s) is received within 60 days, determinations based upon the CNACI report may be made.

(c) *Criteria for disqualification based on results on criminal history background checks.* The ultimate decision to determine how to use information obtained from the criminal history background checks in selection for positions involving the care, treatment, supervision, or education of children must incorporate a common sense decision based upon all known facts. Adverse information is evaluated by the DoD Component who is qualified at the appropriate level of command in interpreting criminal history background checks. All information of record both favorable and unfavorable will be assessed in terms of its relevance, recentness, and seriousness. Likewise, positive mitigating factors should be considered. Final suitability decisions shall be made by that commander or designee. Criteria that will result in disqualification of an applicant require careful screening of the data. A disqualifying event may be the basis for a non-selection, withdrawal of a tentative offer of employment, ineligibility for facility access, removal from a contract, a suitability action under 5 CFR part 731, a probationary termination, an adverse action, or other appropriate action.

(1) *Criteria for automatic disqualification.* No person, regardless of circumstances, will be approved to provide child care services pursuant to this part if the background check discloses:

(i) That the individual has been convicted in either a civilian or military court (to include any general, special or summary court-martial conviction) or received non-judicial punishment (under Article 15 or chapter 47 of Title 10, U.S.C., also known and referred to in this part as “the Uniform Code of

Military Justice (UCMJ)”) for any of the following:

(A) A sexual offense.

(B) Any criminal offense involving a child victim.

(C) A felony drug offense.

(ii) That the individual has been held to be negligent in a civil adjudication or administrative proceeding concerning the death or serious injury to a child or dependent person entrusted to the individual’s care.

(2) [Reserved]

(d) *Suitability and fitness determinations for individuals involved with the provision of child care services.* Suitability and fitness determinations for individuals subject to this part will be made in accordance with Volume 731, Volume 1231, and Subchapter 1403 of DoD Instruction 1400.25, and part 1201 of 5 U.S.C., as appropriate. The following may be the basis for non-selection, withdrawal of a tentative offer of employment, ineligibility for facility access, removal from a contract, a suitability action under DoD Instruction 1400.25, a probationary termination, an adverse action, or other appropriate action.

(1) *Criteria for presumptive disqualification.* Officials charged with making determinations pursuant to this part must include in the record a written justification for any favorable determination made where background check findings include any of the following presumptively disqualifying information:

(i) A FAP record indicating that the individual met criteria for child abuse or neglect or civil adjudication that the individual committed child abuse or neglect.

(ii) Evidence of an act or acts by the individual that tend to indicate poor judgment, unreliability, or untrustworthiness in providing child care services.

(iii) Evidence or documentation of the individual’s past or present dependency on or addiction to any controlled or psychoactive substances, narcotics, cannabis, or other dangerous drug without evidence of rehabilitation.

(iv) A conviction, including any general, special, or summary court-martial conviction, or non-judicial punishment under Article 15 of the UCMJ for:

(A) A crime of violence committed against an adult.

(B) Illegal or improper use, possession, or addiction to any controlled or psychoactive substances, narcotics, cannabis, or other dangerous drug.

(v) A civil adjudication that terminated the individual’s parental

rights to his or her child, except in cases where the birth parent places his or her child for adoption.

(2) *Evaluation of presumptively disqualifying information.* The DoD Components will establish and oversee procedures for the evaluation of presumptively disqualifying information for all categories of individuals in paragraph (b) of this section. Evaluation of presumptively disqualifying information for APF and NAF personnel must be in accordance with Volume 731 and Subchapter 1403 of DoD Instruction 1400.25, respectively.

(3) *Criteria for disqualification under LOSS.* If an investigation of an individual who is currently working under LOSS subsequently results in an unfavorable determination, the DoD Components will take action to protect children by reassigning or removing the individual from employment, contract, or volunteer status.

(4) *Disputes and appeals.* The DoD Components will establish and oversee procedures for the communication of determinations and the appeal of unfavorable determinations for all categories of individuals in paragraph (b) of this section. The procedures for civilian personnel are subject to Volume 731 of DoD Instruction 1400.25 for APF employees and Subchapter 1403 of DoD Instruction 1400.25 for NAF employees.

(e) *Reinvestigation.* (1) All DoD civilian employees (both APF and NAF), contractors, military personnel, and any other individuals reasonably expected to have regular contact with children on a DoD installation, program, or as part of a military-sanctioned activity, including specified volunteers and any person 18 years of age or older residing in an FCC, foster, or respite care home, who continue to perform duties in the position for which their initial background check was conducted, must undergo a reinvestigation every 5 years. The reinvestigation must consist of the same check conducted for the initial investigation as outlined in paragraph (b) of this section.

(2) All FCC providers and adults residing in an FCC home must undergo an annual reinvestigation utilizing the Special Agreement Check (SAC) for childcare providers. The SAC reinvestigation consists of an update to the initial investigation as outlined in paragraph (b) of this section.

(3) If the reinvestigation results in an unfavorable determination, the DoD Components will take action to protect children by reassigning or removing the individual from employment, contract, or volunteer status.

(4) If derogatory information surfaces within the 5 years before the reinvestigation, the DoD Component will take action to protect children by reassigning or suspending from having contact with children, any individual, contractor or volunteer until the case is resolved.

(f) *Self-reporting.* (1) Individuals who have regular contact with children under 18 years of age in DoD-sanctioned programs who have a completed background check are required to immediately report subsequent automatic disqualification criteria under paragraph (c)(1) of this section and presumptive disqualification criteria under paragraphs (c)(2)(i), (iv), and (v) of this section.

(2) The DoD Components will establish procedures for:

(i) Informing individuals of the requirement to immediately report any incident or conviction that may invalidate their prior background check and make them ineligible to work or have contact with children.

(ii) Responding to and evaluating reports made by such individuals, and taking appropriate action until the case has been resolved or closed.

(g) *Eligibility to perform duties under LOSS.* The DoD Components will establish Component-specific procedures, policies, and requirements, subject to the requirements of this paragraph, to permit applicants for whom a criminal history background check has been initiated but not yet completed, to perform duties under LOSS upon favorable findings of preliminary investigations.

(1) *No presumption of right.* No individual will be permitted to perform duties under LOSS in a position subject to criminal history background check without authorizing policy or other written permission from a DoD Component head.

(2) *Preliminary investigations required.* No individual will be permitted to perform duties under LOSS in a position subject to criminal history background check unless the following investigative elements have been reviewed and determined favorably:

(i) An IRC, including installation law enforcement records check, drug and alcohol records, and FAP records check for a minimum of 2 years before the date of the application if the individual has a preexisting DoD affiliation.

(ii) Initial results from the advanced FBI fingerprint criminal history background check (not the full check).

(3) *Exception for non-specified volunteers.* Due to the controlled, limited duration of an activity for these individuals, an advanced FBI

fingerprint criminal history background check is not required. Non-specified volunteers will be permitted to perform duties and services under LOSS for the duration of the activity.

(4) *Supervisor requirements.* The supervisor must be a person who:

(i) Has undergone and successfully completed the required background check.

(ii) Has complied, as required, with the periodic reinvestigation requirement for a recurring criminal history background check.

(iii) Has not previously exhibited reckless disregard for an obligation to supervise an employee, contractor, or volunteer.

(5) *Video surveillance.* The use of video surveillance equipment to provide temporary oversight for individuals whose required background checks have been initiated but not completed is acceptable provided it is continuously monitored by an individual who has undergone and successfully completed all required background checks. This provision shall meet the intent of a flexible and reasonable alternative for "direct sight supervision."

(6) *Conspicuous identification of individuals subject to LOSS.* Individuals permitted to perform duties solely under LOSS must be conspicuously marked by means of distinctive clothing, badges, wristbands, or other visible and apparent markings. The purpose of such markings must be communicated to staff, customers, parents, and guardians by conspicuous posting or printed information.

(7) *Permissible performance of duties without supervision.* Individuals otherwise required to perform duties only under LOSS may perform duties without supervision if:

(i) Interaction with a child occurs in the presence of the child's parent or guardian;

(ii) Interaction with children is in a medical facility, subject to supervisory policies of the facility, and in the presence of a mandated reporter of child abuse; or

(iii) Interaction is necessary to prevent death or serious harm to the child, and supervision is impractical or unfeasible (e.g., response to a medical emergency, emergency evacuation of a child from a hazardous location).

Dated: September 11, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2015-23269 Filed 9-16-15; 8:45 am]

**BILLING CODE 5001-06-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2015-0849]

#### Drawbridge Operation Regulations; New Jersey Intracoastal Waterway, Atlantic City, NJ and Delaware River, Delair, NJ

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulations.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedules that govern the AMTRAK Bridge over Beach Thorofare, New Jersey Intracoastal Waterway, mile 68.9, at Atlantic City, NJ, and the AMTRAK Bridge over Delaware River, mile 104.6, at Delair, NJ. This deviation allows the bridges to remain in the closed-to-navigation position to facilitate the 2015 Papal Visit to Philadelphia, PA.

**DATES:** This deviation is effective from 5 a.m. on September 26, 2015, to 3 a.m. on September 28, 2015.

**ADDRESSES:** The docket for this deviation, [USCG-2015-0849], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398-6222, email [Hal.R.Pitts@uscg.mil](mailto:Hal.R.Pitts@uscg.mil). If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** The New Jersey Transit, who owns and operates the AMTRAK Bridge over Beach Thorofare and AMTRAK Bridge over Delaware River, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.733(d) and 117.716, respectively, to facilitate movement of trains during the 2015 Papal Visit to Philadelphia, PA.

Under the normal operating schedule for the AMTRAK Bridge over Beach

Thorofare, New Jersey Intracoastal Waterway, mile 68.9, at Atlantic City, NJ; the bridge shall open on signal from 11 p.m. to 6 a.m.; from 6 a.m. to 11 p.m., open on signal from 20 minutes to 30 minutes after each hour and remain open for all waiting vessels; opening of the draw may be delayed for ten minutes except as provide in 33 CFR 117.31(b); However, if a train is moving toward the bridge and has crossed the home signal for the bridge before the signal requesting the opening of the bridge is given, that train may continue across the bridge and must clear the bridge interlocks before stopping. Under the normal operating schedule for the AMTRAK Bridge over Delaware River, mile 104.6, at Delair, NJ, the bridgneed not open when there is a train in the bridge block approaching the bridge with the intention of crossing, or within five minutes of the known time of the passage of a scheduled passenger train; the opening of a bridge may not be delayed for more than 10 minutes, after the signal to open is given. The vertical clearances in the closed-to-navigation position of the AMTRAK Bridge over Beach Thorofare and AMTRAK Bridge over Delaware River are 5 feet and 49 feet, respectively, above mean high water.

Under this temporary deviation, the bridges will not be required to open on signal or within ten minutes of a signal from 5 a.m. on September 26, 2015, to 3 a.m. on September 28, 2015. Mariners requesting an opening shall provide at least one hour notice and may be required to adjust their voyage plan to transit through the bridge at a specified time. Beach Thorofare, New Jersey Intracoastal Waterway is used by a variety of vessels including small commercial fishing vessels, recreational vessels and tug and barge traffic. The Delaware River is used by a variety of vessels including deep draft ocean-going vessels, small commercial fishing vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users.

Vessels able to pass through the bridges in the closed position may do so at anytime. The bridges will be able to open for emergencies and there is no alternate route for vessels unable to pass through the bridges in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedules for these bridges so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 10, 2015.

**Hal R. Pitts,**

*Bridge Program Manager, Fifth Coast Guard District.*

[FR Doc. 2015-23342 Filed 9-16-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2015-0848]

#### Drawbridge Operation Regulations; Mantua Creek, Paulsboro, NJ and Raccoon Creek, Bridgeport, NJ

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulations.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedules that govern the S.R. 44 Bridge over Mantua Creek, mile 1.7, at Paulsboro, NJ and Route 130 Bridge over Raccoon Creek, mile 1.8, at Bridgeport, NJ. This deviation allows the bridges to remain in the closed-to-navigation position to facilitate the 2015 Papal Visit to Philadelphia, PA.

**DATES:** This deviation is effective from 7 a.m. on September 26, 2015, to 11 p.m. on September 28, 2015.

**ADDRESSES:** The docket for this deviation, [USCG-2015-0848], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398-6222, email [Hal.R.Pitts@uscg.mil](mailto:Hal.R.Pitts@uscg.mil). If you have questions on viewing the docket, call Cheryl Collins, Program

Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** The New Jersey Department of Transportation, who owns and operates the S.R. 44 Bridge and Route 130 Bridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.729 and 117.741, respectively, to facilitate movement of vehicles during the 2015 Papal Visit to Philadelphia, PA.

Under the normal operating schedule for the S.R. 44 Bridge over Mantua Creek, mile 1.7, at Paulsboro, NJ and Route 130 Bridge over Raccoon Creek, mile 1.8, at Bridgeport, NJ; the bridges shall open on signal from May 1 through October 31, from 7 a.m. to 11 p.m.; and all other times, if at least four hours notice is given. The vertical clearances in the closed-to-navigation position of the S.R. 44 Bridge and Route 130 Bridge are 25 feet and 4 feet, respectively, above mean high water.

Under this temporary deviation, the bridges will be closed to navigation from 7 a.m. to 11 p.m. each day starting September 26 through September 28, 2015, except for scheduled daily openings at 7 a.m. and 7 p.m. The bridges will operate per the normal operating schedules between 11 p.m. and 7 a.m. Mantua Creek and Raccoon Creek are used by a variety of vessels including small commercial fishing vessels and recreational vessels. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users.

Vessels able to pass through the bridges in the closed position may do so at anytime. The bridges will be able to open for emergencies and there is no alternate route for vessels unable to pass through the bridges in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedules for these bridges so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 10, 2015.

**Hal R. Pitts,**

*Bridge Program Manager, Fifth Coast Guard District.*

[FR Doc. 2015-23341 Filed 9-16-15; 8:45 am]

**BILLING CODE 9110-04-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 117**

[Docket No. USCG–2015–0850]

**Drawbridge Operation Regulations; Delaware River, Burlington County, NJ**

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedules that govern the Tacony-Palmyra (Route 73) Bridge over Delaware River, mile 107.2, between Tacony, PA and Palmyra, NJ and Burlington-Bristol (Route 413) Bridge over Delaware River, mile 117.8, between Burlington, NJ and Bristol, PA. This deviation allows the bridges to remain in the closed-to-navigation position to facilitate the 2015 Papal Visit to Philadelphia, PA.

**DATES:** This deviation is effective from 6 a.m. on September 26, 2015, to 9 p.m. on September 27, 2015.

**ADDRESSES:** The docket for this deviation, [USCG–2015–0850], is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH”. Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6222, email [Hal.R.Pitts@uscg.mil](mailto:Hal.R.Pitts@uscg.mil). If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:** The Burlington County Bridge Commission, who owns and operates the Tacony-Palmyra (Route 73) Bridge over Delaware River and Burlington-Bristol (Route 413) Bridge over Delaware River, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.716 to facilitate movement of vehicles during the 2015 Papal Visit to Philadelphia, PA.

Under the normal operating schedule for Tacony-Palmyra (Route 73) Bridge over Delaware River, mile 107.2, between Tacony, PA and Palmyra, NJ and Burlington-Bristol (Route 413) Bridge over Delaware River, mile 117.8, between Burlington, NJ and Bristol, PA; opening of the bridge may not be delayed more than five minutes after the signal to open is given. The vertical clearances in the closed-to-navigation position of the Tacony-Palmyra (Route 73) Bridge over Delaware River and Burlington-Bristol (Route 413) Bridge over Delaware River are 53 feet and 62 feet, respectively, above mean high water.

Under this temporary deviation, the bridges will remain in the closed-to-navigation position from 6 a.m. to 9 p.m. on September 26 and September 27, 2015, except for scheduled daily openings at 12 noon and 6 p.m. Vessels signaling an intention to transit through both bridges during a scheduled opening will receive openings at both bridges. The bridges will operate as required per 33 CFR 117.716 from 9 p.m. on September 26 to 6 a.m. on September 27, 2015. The Delaware River is used by a variety of vessels including deep draft ocean-going vessels, small commercial fishing vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users.

Vessels able to pass through the bridges in the closed position may do so at anytime. The bridges will be able to open for emergencies and there is no alternate route for vessels unable to pass through the bridges in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedules for these bridges so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 10, 2015.

**Hal R. Pitts,***Bridge Program Manager, Fifth Coast Guard District.*

[FR Doc. 2015–23343 Filed 9–16–15; 8:45 am]

**BILLING CODE 9110–04–P****DEPARTMENT OF VETERANS AFFAIRS****38 CFR Part 36**

RIN 2900–AO70

**Loan Guaranty—Specially Adapted Housing Assistive Technology Grant Program**

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

**SUMMARY:** This rule adopts as final, without change, a proposed rule of the Department of Veterans Affairs (VA) to amend its regulations to provide grants for the development of new assistive technologies for use in specially adapted housing for eligible veterans or servicemembers. The Veterans’ Benefits Act of 2010 authorizes VA to provide grants of up to \$200,000 per fiscal year to persons or entities to encourage the development of specially adapted housing assistive technologies. This final rule implements changes to VA regulations to clarify the process, the criteria, and the priorities relating to the award of these research and development grants.

**DATES:** *Effective Date:* This rule is effective October 19, 2015.

**FOR FURTHER INFORMATION CONTACT:** John Bell III, Assistant Director for Loan Policy and Valuation (262), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–8786. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:****The September 8, 2014 Proposed Rule**

On September 8, 2014, VA published a proposed rule in the **Federal Register** at 79 FR 53146, implementing VA’s statutory authority to provide grants for the development of new assistive technologies for use in specially adapted housing for eligible veterans or servicemembers. Section 203 of the Veterans’ Benefits Act of 2010 (the Act) amended chapter 21, title 38, United States Code, to establish the Specially Adapted Housing Assistive Technology Grant Program. Veterans’ Benefits Act of 2010, Public Law 111–275, section 203, 124 Stat. 2874 (2010). The Act authorizes VA to provide grants of up to \$200,000 per fiscal year, through September 30, 2016, to a “person or entity” for the development of specially adapted housing assistive technologies and limits to \$1 million the aggregate amount of such grants VA may award in any fiscal year. *Id.*

The public comment period for the proposed rule closed on November 7,

2014. VA received one comment. The comment received on the proposed rule is discussed below. VA adopts without substantive change the proposed rule that implements the grant program to encourage the development of specially adapted housing assistive technologies. As explained below, however, VA is making one administrative correction to the proposed delegation of authority.

VA received one public comment on the proposed rule from an individual. The commenter expressed support for the proposed rule, but believed the application scoring criteria should be revised. The commenter explained that the prioritization of the criteria outlined in the proposed rule should be changed to reflect “those characteristics that make the project most likely to produce a successful and impactful result.” The commenter recommended changing the maximum point values that may be awarded for certain scoring criteria, with a feasible implementation plan being eligible for the highest number of maximum possible points and innovation and minority or economic status being eligible for the lowest number of maximum possible points. Additionally, the commenter proposed that “empirical research” should be added as a distinct scoring criterion utilized in the review process.

VA is publishing the scoring criteria set forth in proposed 38 CFR 36.4412(f) without change because VA believes that the criteria as proposed effectively carry out Congress’s intent for the Grant program and satisfy the commenter’s interest in successful and impactful results. Specifically, in regard to the legislative history of the Act, the preamble to the proposed rule explained that “House Report 111–109 also explained that there are many emerging technologies that could improve home adaptations or otherwise enhance a veteran or servicemember’s ability to live independently, such as voice-recognition and voice-command operations, living environment controls, and adaptive feeding equipment.” 79 FR 53147. In its scoring criteria, VA provided that a new advancement’s innovation and ability to meet an unmet need may be awarded the maximum possible points because it understood a central goal of the law to be the development of original, potentially groundbreaking technologies. VA also prioritized a new advancement’s promotion of independent living in the scoring criteria based on Congress’s statement that emerging technologies (as supported through this Grant program) could enhance the ability for veterans or servicemembers to live independently. See 79 FR 53148. Additionally, to

ensure that these advancements may be feasibly developed and effectively utilized by eligible individuals, VA’s proposed scoring criteria also include a description of the new assistive technology’s concept, size, and scope and an implementation plan for bringing the technology to the marketplace. See *id.* Accordingly, VA is maintaining its scoring criteria as set forth in the proposed rule because this prioritization effectively carries out congressional intent while addressing the commenter’s stated interest in successful and impactful results.

Additionally, VA is publishing the scoring criteria set forth in proposed 38 CFR 36.4412(f) without change because the criteria provide VA flexibility to ensure that grant awards are made based on the identified priorities and/or needs of veterans and VA at the time the Notice of Funds Availability (NoFA) is published. See 79 FR 53147, 53148. Specifically, in setting out the scoring criteria and maximum points that may be awarded for each criterion, VA explained that “the scoring framework would allow the Secretary to make awards based on priorities of veterans and VA, while also ensuring that taxpayer funds are used responsibly.” 79 FR 53148. As explained in the preamble to the proposed rule, while the regulation text sets forth the maximum number of points that may be awarded based on any one criterion, each NoFA would explain the specific scoring priorities for that grant application cycle. *Id.* This change in priorities would not introduce new scoring criteria, but would instead help technology grant applicants understand how the scores will be weighted and provide them an opportunity to tailor their responses accordingly. *Id.*

The preamble to the proposed rule also provides an example to illustrate VA’s flexibility to emphasize certain criterion in each NoFA. It explains that VA might emphasize in one grant cycle the need for innovation, and as a result, explain in the NoFA that innovation will be a top priority. A technology grant applicant would then know to concentrate on how innovative its product would be. In reviewing the application, the Secretary might award all 50 allowable points to the technology grant applicant who best satisfies that criterion. In the next grant cycle, the Secretary might determine that a particular need has gone unmet among eligible individuals who are adapting their homes. The Secretary might choose to place more emphasis on meeting that need than on general innovation. As a result, the published NoFA for that grant cycle would explain

the Secretary’s new priorities. A technology grant applicant would then know that its application would have more success if it were to focus on how the product would meet the need. When reviewing applications, the Secretary could choose to award all 50 points for that criterion, while only scoring the most innovative product 30 points. *Id.* Accordingly, VA believes this flexibility to weigh criteria based on the identified needs and priorities of veterans and VA at the time a NoFA is published will ensure grant awards successfully carry out program goals and positively impact eligible individuals.

Finally, the commenter suggested adding “empirical research” as a criterion to be evaluated when scoring grant applications. VA understands empirical research to be defined as “originating in or based on observation or experience” (<http://www.merriam-webster.com/dictionary/empirical>). VA’s scoring criteria anticipate VA’s consideration of empirical research in evaluating applications and determining points awarded for each criterion. For example, an application for a new assistive technology may utilize empirical research surrounding currently-available technologies on the market to demonstrate the advancement’s level of innovation. Or, a successful description of how the new advancement is specifically designed to promote the ability of eligible individuals to live independently may utilize empirical research to explain, for example, the most common disabilities among eligible individuals, the critical factors that affect an eligible individual’s ability to live independently, and how the new assistive technology may enable individuals to overcome barriers to independent living. VA will consider the presence of empirical research in its review of applications and determination of points to be awarded. As empirical research may be utilized to support applications and impact application scoring under the existing criteria, it does not need to be added as a stand-alone factor for evaluation.

#### Administrative Correction

The proposed rule included a delegation of authority to various officials in the Department. The title of the Deputy Under Secretary for Economic Opportunity was incorrectly listed as the Deputy Under Secretary for Economic Development. This rule corrects the error. The change is only for administrative accuracy and has no substantive effect on the rule.



**Executive Orders 12866 and 13563**

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Orders 12866 or 13563. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published from FY 2004 Through Fiscal Year to Date.”

**Regulatory Flexibility Act**

The Secretary hereby certifies that this final rule will not have a significant

economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. There will be no significant economic impact on any small entities because grant applicants are not required to provide matching funds to receive the maximum grant amount of \$200,000. The assistive technology grant program will not impact a substantial number of small entities because VA may only award a maximum of \$1 million in aggregate grant funds per fiscal year, and VA’s authority to award these grants expires September 30, 2016. On this basis, the Secretary certifies that the final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, under 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

**Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

**Paperwork Reduction Act**

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number. 5 CFR 1320.8(b)(1) and (3)(vi).

This final rule will impose the following new information collection requirements. Section 36.4412(d) of title 38 CFR will require applicants for an SAH Assistive Technology grant to submit VA Form 26–0967, “Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion,” and to provide statements addressing the scoring criteria for grant awards. The information provided under this collection of information is necessary for a complete SAH Assistive Technology grant application. The information will be used by VA in deciding whether an applicant meets the requirements and satisfies the

scoring criteria for award of an SAH Assistive Technology grant under 38 U.S.C. 2108. As required by the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3507(d)), VA has submitted these information collections to OMB for its review. OMB approved these new information collection requirements associated with the final rule and assigned OMB control number 2900–0821.

**Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance program numbers and titles for the programs affected by this document are 64.106, Specially Adapted Housing for Disabled Veterans and 64.118, Veterans Housing—Direct Loans for Certain Disabled Veterans.

**Signing Authority**

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on September 11, 2015, for publication.

**List of Subjects in 38 CFR Part 36**

Condominiums, Housing, Indians, Individuals with disabilities, Loan programs—housing and community development, Loan programs—Indians, Loan programs—veterans, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements, Veterans.

Dated: September 11, 2015.

**Michael P. Shores,**

*Chief Impact Analyst, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.*

For the reasons set out in the preamble, VA amends 38 CFR part 36, subpart C to read as follows:

**PART 36—LOAN GUARANTY**

- 1. The authority citation for part 36 continues to read as follows:

**Authority:** 38 U.S.C. 501 and as otherwise noted.

- 2. Add § 36.4412 to read as follows:

**§ 36.4412 Specially Adapted Housing Assistive Technology Grant Program.**

(a) *General.* (1) The Secretary will make grants for the development of new assistive technologies for specially adapted housing.

(2) A person or entity may apply for, and receive, a grant pursuant to this section.

(3)(i) All technology grant recipients, including individuals and entities formed as for-profit entities, will be subject to the rules on Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, as found at 2 CFR part 200.

(ii) Where the Secretary determines that 2 CFR part 200 is not applicable or where the Secretary determines that additional requirements are necessary due to the uniqueness of a situation, the Secretary will apply the same standard applicable to exceptions under 2 CFR 200.102.

(b) *Definitions.* To supplement the definitions contained in § 36.4401, the following terms are herein defined for purposes of this section:

(1) A *technology grant applicant* is a person or entity that applies for a grant pursuant to 38 U.S.C. 2108 and this section to develop new assistive technology or technologies for specially adapted housing.

(2) A *new assistive technology* is an advancement that the Secretary determines could aid or enhance the ability of an eligible individual, as defined in 38 CFR 36.4401, to live in an adapted home.

(c) *Grant application solicitation.* As funds are available for the program, VA will publish in the **Federal Register** a Notice of Funds Availability (NoFA), soliciting applications for the grant program and providing information on applications.

(d) *Application process and requirements.* Upon publication of the NoFA, a technology grant applicant must submit an application to the Secretary via [www.Grants.gov](http://www.Grants.gov). Applications must consist of the following:

(1) Standard Form 424 (Application for Federal Assistance) with the box labeled "application" marked;

(2) VA Form 26–0967 (Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion) to ensure that the technology grant applicant has not been debarred or suspended and is eligible to participate in the VA grant process and receive Federal funds;

(3) Statements addressing the scoring criteria in paragraph (f) of this section; and

(4) Any additional information as deemed appropriate by VA.

(e) *Threshold requirements.* The NoFA will set out the full and specific procedural requirements for technology grant applicants.

(f) *Scoring criteria.* (1) The Secretary will score technology grant applications

based on the scoring criteria in paragraph (f)(2) of this section. Although there is not a cap on the maximum aggregate score possible, a technology grant application must receive a minimum aggregate score of 70 points to be considered for a technology grant.

(2) The scoring criteria and maximum points are as follows:

(i) A description of how the new assistive technology is innovative (up to 50 points);

(ii) An explanation of how the new assistive technology will meet a specific, unmet need among eligible individuals (up to 50 points);

(iii) An explanation of how the new assistive technology is specifically designed to promote the ability of eligible individuals to live more independently (up to 30 points);

(iv) A description of the new assistive technology's concept, size, and scope (up to 30 points);

(v) An implementation plan with major milestones for bringing the new assistive technology into production and to the market. Such milestones must be meaningful and achievable within a specific timeframe (up to 30 points); and

(vi) An explanation of what uniquely positions the technology grant applicant in the marketplace. This can include a focus on characteristics such as the economic reliability of the technology grant applicant, the technology grant applicant's status as a minority or veteran-owned business, or other characteristics that the technology grant applicant wants to include to show how it will help protect the interests of, or further the mission of, VA and the program (up to 20 points).

(g) *Application deadlines.* Deadlines for technology grant applications will be established in the NoFA.

(h) *Awards process.* Decisions for awarding technology grants under this section will be made in accordance with guidelines (covering such issues as timing and method of notification) described in the NoFA. The Secretary will provide written approvals, denials, or requests for additional information. The Secretary will conduct periodic audits of all approved grants under this program to ensure that the actual project size and scope are consistent with those outlined in the proposal and that established milestones are achieved.

(i) *Delegation of authority.* (1) Each VA employee appointed to or lawfully fulfilling any of the following positions is hereby delegated authority, within the limitations and conditions prescribed by law, to exercise the powers and functions of the Secretary with respect

to the grant program authorized by 38 U.S.C. 2108:

- (i) Under Secretary for Benefits.
- (ii) Deputy Under Secretary for Economic Opportunity.
- (iii) Director, Loan Guaranty Service.
- (iv) Deputy Director, Loan Guaranty Service.

(2) [Reserved]

(j) *Miscellaneous.* (1) The grant offered by this chapter is not a veterans' benefit. As such, the decisions of the Secretary are final and not subject to the same appeal rights as decisions related to veterans' benefits.

(2) The Secretary does not have a duty to assist technology grant applicants in obtaining a grant.

(Authority: 38 U.S.C. 2108)

(The Office of Management and Budget has approved the information collection requirements in this section under control numbers 4040–0004 and 2900–0821.)

[FR Doc. 2015–23280 Filed 9–16–15; 8:45 am]

BILLING CODE 8320–01–P

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## POSTAL SERVICE

### 39 CFR Part 957

#### Rules of Practice Before the Judicial Officer

**AGENCY:** Postal Service.

**ACTION:** Final rule.

**SUMMARY:** This document contains the final revisions to the rules of practice before the Judicial Officer in proceedings relative to debarment from contracting.

**DATES:** *Effective:* September 17, 2015.

**ADDRESSES:** Written inquiries may be directed to: Postal Service Judicial Officer Department, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078.

**FOR FURTHER INFORMATION CONTACT:** Associate Judicial Officer Gary E. Shapiro, (703) 812–1910.

**SUPPLEMENTARY INFORMATION:**

#### A. Executive Summary

On July 1, 2015, the Judicial Officer Department published for comment proposed revisions to the rules of practice before the Judicial Officer for proceedings relative to debarment from contracting (80 FR 37565–7). The period for comments closed on July 31, 2015, and no comments were received. The Judicial Officer has made no further revisions to the original proposed rules, which are adopted as final. The new rules completely replace the former rules of 39 CFR part 957.

## B. Background

The rules of practice in proceedings relative to debarment from contracting are set forth in 39 CFR part 957. This authority is delegated by the Postmaster General. The rules are being changed to effectuate the Postal Service's present debarment procedures, at 39 CFR part 601, and the Judicial Officer's role in those procedures.

In 2007, the Postal Service changed its procurement regulations regarding suspension and debarment from contracting. See 72 FR 58252 (October 15, 2007). Whereas prior to that change, the Judicial Officer conducted hearings and rendered final agency decisions regarding suspension and debarment from contracting, the revised procurement regulations at 39 CFR 601.113 eliminated any role of the Judicial Officer from suspensions, and reserved final agency action regarding debarments to the Vice President, Supply Management. The remaining role of the Judicial Officer relative to debarment from contracting is set forth in paragraphs (g)(2) and (h)(2) of § 601.113. Those paragraphs provide that the Vice President, Supply Management, may request the Judicial Officer to conduct fact-finding hearings to resolve questions of material facts involving a debarment, and will consider those findings when deciding the matter. Under paragraph (h)(2) of § 601.113, fact-finding hearings will be governed by rules of procedure promulgated by the Judicial Officer. These new rules of procedure satisfy that requirement.

### List of Subjects in 39 CFR Part 957

Administrative practice and procedure, Government contracts.

Accordingly, for the reasons stated, the Postal Service revises 39 CFR part 957 to read as follows:

## PART 957—RULES OF PRACTICE IN PROCEEDINGS RELATIVE TO DEBARMENT FROM CONTRACTING

Sec.

- 957.1 Authority for rules.
- 957.2 Scope of rules.
- 957.3 Definitions.
- 957.4 Authority of the Hearing Officer.
- 957.5 Case initiation.
- 957.6 Filing documents for the record.
- 957.7 Failure to appear at the hearing.
- 957.8 Hearings.
- 957.9 Appearances.
- 957.10 Conduct of the hearing.
- 957.11 Witness fees.
- 957.12 Transcript.
- 957.13 Proposed findings of fact.
- 957.14 Findings of fact.
- 957.15 Computation of time.
- 957.16 Official record.

- 957.17 Public information.
- 957.18 Ex parte communications.

**Authority:** 39 U.S.C. 204, 401.

### § 957.1 Authority for rules.

The rules in this part are issued by the Judicial Officer of the Postal Service pursuant to authority delegated by the Postmaster General (39 U.S.C. 204, 401).

### § 957.2 Scope of rules.

The rules in this part apply to proceedings initiated pursuant to paragraphs (g)(2) or (h)(2) of § 601.113 of this subchapter.

### § 957.3 Definitions.

(a) *Vice President* means the Vice President, Supply Management, or the Vice President's representative for the purpose of carrying out the provisions of § 601.113 of this subchapter.

(b) *General Counsel* includes the Postal Service's General Counsel and any designated representative within the Office of the General Counsel.

(c) *Judicial Officer* includes the Postal Service's Judicial Officer, Associate Judicial Officer, and Acting Judicial Officer.

(d) *Debarment* has the meaning given by paragraph (b)(2) of § 601.113 of this subchapter.

(e) *Respondent* means any individual, firm or other entity which has been served a written notice of proposed debarment pursuant to § 601.113(h), or which previously has been debarred, as provided in § 601.113(g)(2) of this subchapter.

(f) *Hearing Officer* means the judge assigned to the case by the Judicial Officer. The Hearing Officer may be the Judicial Officer, Associate Judicial Officer, Administrative Law Judge or an Administrative Judge who is a member of the Postal Service Board of Contract Appeals.

(g) *Recorder* means the Recorder of the Judicial Officer Department of the United States Postal Service, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201-3078. The Recorder's telephone number is (703) 812-1900, fax number is (703) 812-1901, and the Judicial Officer's Web site is <http://www.about.usps.com/who-we-are/judicial/welcome.htm>.

### § 957.4 Authority of the Hearing Officer.

The Hearing Officer's authority includes, but is not limited to, the following:

(a) Ruling on all motions or requests by the parties.

(b) Issuing notices, orders, or memoranda to the parties concerning the hearing proceedings.

(c) Conducting conferences with the parties. The Hearing Officer will prepare

a Memorandum of Conference, which will be transmitted to both parties and which serves as the official record of that conference.

(d) Determining whether an oral hearing will be conducted, and setting the place, date, and time for such a hearing.

(e) Administering oaths or affirmations to witnesses.

(f) Conducting the proceedings and the hearing in a manner to maintain discipline and decorum while ensuring that relevant, reliable and probative evidence is elicited, but irrelevant, immaterial or repetitious evidence is excluded. The Hearing Officer in his or her discretion may examine witnesses to ensure that a satisfactory record is developed.

(g) Establishing the record. The weight to be attached to evidence will rest within the discretion of the Hearing Officer. Except as the Hearing Officer may otherwise order, no proof shall be received in evidence after completion of a hearing. The Hearing Officer may require either party, with appropriate notice to the other party, to submit additional evidence on any relevant matter.

(h) Granting reasonable time extensions or other relief for good cause shown, in the Hearing Officer's sole discretion.

(i) Issuing findings of fact. The Hearing Officer will issue findings of fact to the Vice President within 30 days from the close of the record, to the extent practicable.

### § 957.5 Case initiation.

(a) Upon receipt of a request or referral from the Vice President, the Recorder will docket a case under this Part. Following docketing, the Judicial Officer will assign a Hearing Officer. The Hearing Officer will establish the schedule for the proceeding, perform all judicial duties under this Part and render Findings of Fact. Whenever practicable, a hearing should be conducted within 30 days of the date of docketing.

(b) The request or referral from the Vice President shall include the notice of proposed debarment and the information or argument submitted by the Respondent pursuant to paragraphs (g) or (h) of § 601.113 of this subchapter.

### § 957.6 Filing documents for the record.

The parties shall file documents, permitted by the rules in this part or required by the Hearing Officer, in the Judicial Officer Department's electronic filing system. The Web site for electronic filing is <https://uspsjoe.justware.com/justiceweb>.

Documents submitted using that system are considered filed as of the date and time (Eastern Time) reflected in the system. Orders issued by the Hearing Officer shall be considered received by the parties on the date posted to the electronic filing system.

**§ 957.7 Failure to appear at the hearing.**

If a party fails to appear at the hearing, the Hearing Officer may proceed with the hearing, receive evidence and issue findings of fact without requirement of further notice to the absent party.

**§ 957.8 Hearings.**

Hearings ordinarily will be conducted in the Judicial Officer Department courtroom at 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201-3078. However, the Hearing Officer, in his or her discretion, may order the hearing to be conducted at another location, or by another means such as by video.

**§ 957.9 Appearances.**

(a) An individual Respondent may appear in his or her own behalf, a corporation may appear by an officer thereof, a partnership or joint venture may appear by a member thereof, or any of these may appear by a licensed attorney.

(b) After a request for a hearing has been filed pursuant to the rules in this part, the General Counsel shall designate a licensed attorney as counsel assigned to handle the case.

(c) All counsel, or a self-represented Respondent, shall register in the electronic filing system, and request to be added to the case. Counsel also promptly shall file notices of appearance.

(d) An attorney for any party who has filed a notice of appearance and who wishes to withdraw must file a motion requesting withdrawal, explaining the reasons supporting the motion, and identifying the name, email address, mailing address, telephone number, and fax number of the person who will assume responsibility for representation of the party in question.

**§ 957.10 Conduct of the hearing.**

The Hearing Officer may approve or disapprove witnesses in his or her discretion. All testimony will be taken under oath or affirmation, and subject to cross-examination. The Hearing Officer may exclude evidence to avoid unfair prejudice, confusion of the issues, undue delay, waste of time, or presentation of irrelevant, immaterial, or cumulative evidence. Although the Hearing Officer will consider the Federal Rules of Evidence for guidance

regarding admissibility of evidence and other evidentiary issues, he or she is not bound by those rules. The weight to be attached to evidence presented in any particular form will be within the discretion of the Hearing Officer, taking into consideration all the circumstances of the particular case. Stipulations of fact agreed upon by the parties may be accepted as evidence at the hearing. The parties may stipulate the testimony that would be given by a witness if the witness were present. The Hearing Officer may in any case require evidence in addition to that offered by the parties. A party requiring the use of a foreign language interpreter allowing testimony to be taken in English for itself or witnesses it proffers is responsible for making all necessary arrangements and paying all costs and expenses associated with the use of an interpreter.

**§ 957.11 Witness fees.**

Each party is responsible for the fees and costs for its own witnesses.

**§ 957.12 Transcript.**

Testimony and argument at hearings shall be reported verbatim, unless the Hearing Officer otherwise orders. Transcripts of the proceedings will be made available or provided to the parties.

**§ 957.13 Proposed findings of fact.**

(a) The Hearing Officer may direct the parties to submit proposed findings of fact and supporting explanations within 15 days after the delivery of the official transcript to the Recorder who shall notify both parties of the date of its receipt. The filing date for proposed findings shall be the same for both parties.

(b) Proposed findings of fact shall be set forth in numbered paragraphs and shall state with particularity all evidentiary facts in the record with appropriate citations to the transcript or exhibits supporting the proposed findings.

**§ 957.14 Findings of fact.**

The Hearing Officer shall issue written findings of fact, and transmit them to the Vice President. Copies will be sent to the parties.

**§ 957.15 Computation of time.**

A designated period of time under the rules in this part excludes the day the period begins, and includes the last day of the period unless the last day is a Saturday, Sunday, or legal holiday, in which event the period runs until the close of business on the next business day.

**§ 957.16 Official record.**

The transcript of testimony together with all pleadings, orders, exhibits, briefs, and other documents filed in the proceeding shall constitute the official record of the proceeding.

**§ 957.17 Public information.**

The Postal Service shall maintain for public inspection copies of all findings of fact issued under this Part, and make them available through the Postal Service Web site. The Recorder maintains the complete official record of every proceeding.

**§ 957.18 Ex parte communications.**

The provisions of 5 U.S.C. 551(14), 556(d), and 557(d) prohibiting ex parte communications are made applicable to proceedings under these rules of practice.

**Stanley F. Mires,**

*Attorney, Federal Compliance.*

[FR Doc. 2015-23314 Filed 9-16-15; 8:45 am]

**BILLING CODE 7710-12-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2014-0574; FRL-9933-00]

**Halosulfuron-methyl; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of halosulfuron-methyl in or on the pome fruit group 11-10 and a tolerance with regional registration for residues of halosulfuron-methyl in or on the small vine climbing fruit, except fuzzy kiwifruit, subgroup 13-07F. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 17, 2015. Objections and requests for hearings must be received on or before November 16, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0574, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William

Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfrNotices@epa.gov](mailto:RDfrNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0574 in the subject line on the first page of your submission. All objections and requests for a hearing

must be in writing, and must be received by the Hearing Clerk on or before November 16, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0574, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8297) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, Suite 201 W, 500 College Road East, Princeton, NJ 08540. The petition requested that 40 CFR 180.479 be amended by establishing tolerances for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylamino-sulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the raw agricultural commodities: Fruit, pome, group 11-10 at 0.05 parts per million (ppm), and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.05 ppm (associated with a regional registration). That document referenced a summary of

the petition prepared by the Canyon Group, c/o Gowan Company, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received on the notice of filing.

Based upon available data, EPA is establishing tolerances as requested.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for halosulfuron-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with halosulfuron-methyl follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

With repeated dosing, the available data on halosulfuron-methyl did not demonstrate a target organ or tissue in any of the test animals. Reduction in body weight was seen in the 90-day and 1-year oral toxicity studies in dogs. Reduced body weights were also seen in

rat studies at higher dose levels than those seen in dogs. An effect on the hematological parameters was detected in the dog studies, but the magnitude of changes was slight and the effect was considered to be marginal. Thus, the slight hematological changes were not considered to be adverse.

In the prenatal developmental toxicity study in rats, increases in resorptions, soft tissue (dilation of the lateral ventricles) and skeletal variations, and decreases in body weights were seen in the fetuses compared to clinical signs and decreases in body weights and food consumption in the maternal animals at a similar dose level. In the rabbit developmental toxicity study, increases in resorptions and post-implantation losses and decreases in mean litter size were observed in the presence of decreases in body weight and food consumption in maternal animals. The fetal effects seen in developmental toxicity studies in rats and rabbits represented a qualitative increase in susceptibility. However, a clear no-observed-adverse-effect-level (NOAEL) for these effects was established in both rat and rabbit developmental toxicity studies. No quantitative susceptibility was found in studies following pre-and/or post-natal exposures. Halosulfuron-methyl did not produce any effects on reproductive parameters in the 2-generation reproduction study in rats. No neurotoxic effects were observed in the acute or subchronic neurotoxicity studies up to 2,000 mg/kg or 760 mg/kg/day, respectively. In addition, no adverse effect was found in a 21-day dermal toxicity study at doses up to the limit dose (1,000 mg/kg/day).

Halosulfuron-methyl is negative for mutagenicity in a battery of genotoxicity studies and is classified as “not likely to be carcinogenic to humans” based on lack of evidence for carcinogenicity in mice and rats following long-term dietary administration.

Specific information on the studies received and the nature of the adverse effects caused by halosulfuron-methyl as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Halosulfuron-Methyl. Human Health Risk Assessment for a Proposed Use on Pome Fruit Crop Group 11–10 and Small Fruit Vine Climbing Subgroup, Except Fuzzy Kiwifruit, Subgroup 13–07F” at page 28 in docket ID number EPA–HQ–OPP–2014–0574.

### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for halosulfuron used for human risk assessment is discussed in Unit III. B. of the final rule published in the **Federal Register** of December 3, 2012 (77 FR 71555) (FRL–9370–6). However, there is one change to the prior toxicity endpoint and point of departure selections for halosulfuron-methyl discussed in the 2012 document. The previous toxicity endpoint for dermal exposure assessments was based on the results of a 21-day dermal toxicity study, where the no observed effect level (NOEL) and lowest observed effect level (LOEL) were established at 100 and 1,000 mg/kg/day, respectively. The LOEL was based on “total body weight gains in males.” However, following a reevaluation of this study according to the current evaluation standard, there was only 4% reduction in absolute body weight in the affected 1,000 mg/kg/day males. This reduction was not considered to be adverse and no other adverse effect was reported in this study. No LOAEL could be established, and the NOAEL was 1,000 mg/kg/day. Based on this re-evaluation, halosulfuron-methyl did not cause adverse effects at the limit dose (1,000

mg/kg/day), and no toxicity endpoint could be established for the dermal exposure scenario. In addition, no quantitative susceptibility was found in studies following pre-and/or post-natal exposures. Hence, no dermal exposure assessment was necessary.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to halosulfuron-methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing halosulfuron-methyl tolerances in 40 CFR 180.479. EPA assessed dietary exposures from halosulfuron-methyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for halosulfuron-methyl. Exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID). This software uses 2003–2008 food consumption data from the United States Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that halosulfuron-methyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for halosulfuron-methyl. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for halosulfuron-methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport

characteristics of halosulfuron-methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of halosulfuron-methyl for acute exposures are estimated to be 59.2 parts per billion (ppb) for surface water and 0.065 ppb for ground water and for chronic exposures are estimated to be 59.2 ppb for surface water and 0.065 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 59.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 59.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Halosulfuron-methyl is currently registered for use by residential handlers on residential turf. EPA reassessed residential exposure for aggregate risk assessment reflecting the removal of the dermal POD. EPA assessed short-term (1–30 days) exposure to halosulfuron-methyl for residential handlers (inhalation exposure) and children 1 to < 2 years old (post-application incidental oral exposures).

The residential exposure scenario used in the adult aggregate assessment reflects inhalation exposure from mixing/loading/applying halosulfuron-methyl via backpack sprayer or manually pressurized handwand to turf.

The residential exposure scenario used in the children 1 to <2 years old aggregate assessment reflects hand-to-mouth incidental oral exposures from post-application exposure to treated turf.

Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found halosulfuron-methyl to share a common mechanism of toxicity with any other substances, and halosulfuron-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that halosulfuron-methyl does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no quantitative evidence of increased susceptibility following pre- and/or post-natal exposure to halosulfuron-methyl. Qualitative susceptibility was seen in the prenatal developmental toxicity study in rats and in rabbits; however, this qualitative susceptibility was of low concern because (1) in both studies, there were clear NOAELs/LOAELs for developmental and maternal toxicities; (2) the developmental effects were seen in the presence of maternal toxicity; and (3) the effects were only seen at the high dose levels. In rats, the developmental effects were seen at a dose (750 mg/kg/day) which was approaching the limit-dose (1,000 mg/kg/day). Furthermore, the PODs for risk assessment are

protective of the effects which occur at high doses.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for halosulfuron-methyl is considered complete.

ii. There is no indication that halosulfuron-methyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There was no quantitative evidence of increased susceptibility following pre- and/or post-natal exposure and the qualitative susceptibility observed in the developmental toxicity studies in rats and rabbits was of low concern for the reasons outlined in section III.D.2.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to halosulfuron-methyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by halosulfuron-methyl.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to halosulfuron-methyl will occupy <1% of the aPAD for females 13–49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to halosulfuron-methyl from food and water will utilize

5.7% of the cPAD for children 1–2 years old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of halosulfuron-methyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Halosulfuron-methyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to halosulfuron-methyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 25,000 for adults and 1,800 for children 1 to < 2 years old. Because EPA's level of concern for halosulfuron-methyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, halosulfuron-methyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for halosulfuron-methyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, halosulfuron-methyl is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to halosulfuron-methyl residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) thermionic-specific detection (TSD, nitrogen specific)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for halosulfuron-methyl for any of the crops covered by this Final Rule.

#### V. Conclusion

Therefore, a tolerance is established for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonylamino-sulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the fruit, pome, group 11–10 at 0.05 ppm, and a tolerance with regional registration is established for fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.05 ppm. In addition, the existing tolerance for the commodity “Apple” in paragraph (a)(2) of § 180.479 is removed since it is covered by the newly established fruit, pome, group 11–10 tolerance.

#### VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the

Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary



consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 4, 2015.

**Susan Lewis,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.479:

- a. Remove the entry for “Apple” from the table in paragraph (a)(2);
- b. Add alphabetically the entry for “Fruit, pome, group 11–10” to the table in paragraph (a)(2), and
- c. Revise paragraph (c).

The additions and revision read as follows:

**§ 180.479 Halosulfuron-methyl; tolerances for residues.**

- (a) \* \* \*
- (2) \* \* \*

Commodity	Parts per million
* * * *	
Fruit, pome, group 11–10 .....	0.05
* * * *	

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide halosulfuron-methyl, methyl 5-[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonylamino-sulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, including its metabolites and

degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only halosulfuron-methyl.

Commodity	Parts per million
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F .....	0.05
* * * *	

[FR Doc. 2015–23298 Filed 9–16–15; 8:45 am]  
**BILLING CODE 6560–50–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 64**

[Docket ID FEMA–2015–0001: Internal Agency Docket No. FEMA–8399]

**Suspension of Community Eligibility**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA’s Community Status Book (CSB).

**DATES:** The effective date of each community’s scheduled suspension is the third date (“Susp.”) listed in the third column of the following tables.

**ADDRESSES:** The CSB is available at <http://www.fema.gov/fema/csb.shtm>.

**FOR FURTHER INFORMATION CONTACT:** If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Bret Gates, Federal Insurance and Mitigation

Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4133.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA’s initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed

in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

*National Environmental Policy Act.* This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

*Regulatory Flexibility Act.* The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42

U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

*Regulatory Classification.* This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

*Executive Order 13132, Federalism.* This rule involves no policies that have federalism implications under Executive Order 13132.

*Executive Order 12988, Civil Justice Reform.* This rule meets the applicable standards of Executive Order 12988.

*Paperwork Reduction Act.* This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

**List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

**PART 64—[AMENDED]**

■ 1. The authority citation for Part 64 continues to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

**§ 64.6 [Amended]**

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
<b>Region I</b>				
Rhode Island:				
Central Falls, City of, Providence County.	445394	November 6, 1970, Emerg; May 28, 1971, Reg; October 2, 2015, Susp	October 2, 2015	October 2, 2015
Coventry, Town of, Kent County .....	440004	November 21, 1973, Emerg; September 1, 1978, Reg; October 2, 2015, Susp	.....do .....	Do.
Cranston, City of, Providence County ...	445396	September 11, 1970, Emerg; August 27, 1971, Reg; October 2, 2015, Susp	.....do .....	Do.
Cumberland, Town of, Providence County.	440016	July 15, 1975, Emerg; December 16, 1980, Reg; October 2, 2015, Susp	.....do .....	Do.
East Greenwich, Town of, Kent County	445397	July 16, 1971, Emerg; February 9, 1973, Reg; October 2, 2015, Susp	.....do .....	Do.
East Providence, City of, Providence County.	445398	June 5, 1970, Emerg; May 18, 1973, Reg; October 2, 2015, Susp	.....do .....	Do.
Johnston, Town of, Providence County	440018	August 1, 1975, Emerg; September 1, 1978, Reg; October 2, 2015, Susp	.....do .....	Do.
Lincoln, Town of, Providence County ...	445400	May 5, 1972, Emerg; November 30, 1973, Reg; October 2, 2015, Susp	.....do .....	Do.
North Providence, Town of, Providence County.	440020	October 6, 1972, Emerg; December 15, 1977, Reg; October 2, 2015, Susp	.....do .....	Do.
North Smithfield, Town of, Providence County.	440021	May 6, 1975, Emerg; August 1, 1978, Reg; October 2, 2015, Susp	.....do .....	Do.
Pawtucket, City of, Providence County	440022	January 15, 1971, Emerg; July 16, 1971, Reg; October 2, 2015, Susp	.....do .....	Do.
Providence, City of, Providence County	445406	September 11, 1970, Emerg; December 11, 1970, Reg; October 2, 2015, Susp	.....do .....	Do.
Scituate, Town of, Providence County ..	440024	January 13, 1975, Emerg; January 2, 1981, Reg; October 2, 2015, Susp	.....do .....	Do.
Smithfield, Town of, Providence County	440025	December 17, 1971, Emerg; March 1, 1977, Reg; October 2, 2015, Susp	.....do .....	Do.
Warwick, City of, Kent County .....	445409	June 19, 1970, Emerg; April 6, 1973, Reg; October 2, 2015, Susp	.....do .....	Do.
West Greenwich, Town of, Kent County	440037	October 10, 1975, Emerg; January 3, 1986, Reg; October 2, 2015, Susp	.....do .....	Do.
West Warwick, Town of, Kent County ..	440007	September 1, 1972, Emerg; February 1, 1978, Reg; October 2, 2015, Susp	.....do .....	Do.
<b>Region III</b>				
Maryland:				
Carroll County Unincorporated Areas ...	240015	December 22, 1972, Emerg; August 1, 1978, Reg; October 2, 2015, Susp	.....do .....	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Hampstead, Town of, Carroll County ....	240090	November 27, 1973, Emerg; January 7, 1983, Reg; October 2, 2015, Susp	.....do .....	Do.
Manchester, Town of, Carroll County ...	240107	July 27, 2006, Emerg; N/A, Reg; October 2, 2015, Susp	.....do .....	Do.
Mount Airy, Town of, Carroll and Frederick Counties.	240200	N/A, Emerg; May 27, 2014, Reg; October 2, 2015, Susp	.....do .....	Do.
New Windsor, Town of, Carroll County	240149	August 5, 1975, Emerg; February 16, 1979, Reg; October 2, 2015, Susp	.....do .....	Do.
Sykesville, Town of, Carroll County .....	240016	May 1, 1973, Emerg; September 30, 1977, Reg; October 2, 2015, Susp	.....do .....	Do.
Union Bridge, Town of, Carroll County	240017	April 16, 1973, Emerg; August 1, 1977, Reg; October 2, 2015, Susp	.....do .....	Do.
Westminster, City of, Carroll County .....	240018	June 25, 1973, Emerg; December 1, 1977, Reg; October 2, 2015, Susp	.....do .....	Do.
<b>Region V</b>				
Wisconsin:				
Prairie du Sac, Village of, Sauk County	550401	September 29, 2000, Emerg; March 7, 2001, Reg; October 2, 2015, Susp	.....do .....	Do.
Reedsburg, City of, Sauk County .....	550402	May 21, 1975, Emerg; March 4, 1985, Reg; October 2, 2015, Susp	.....do .....	Do.
Sauk City, Village of, Sauk County .....	550404	May 7, 1975, Emerg; March 7, 2001, Reg; October 2, 2015, Susp	.....do .....	Do.
Sauk County Unincorporated Areas .....	550391	September 7, 1973, Emerg; September 17, 1980, Reg; October 2, 2015, Susp	.....do .....	Do.
<b>Region VII</b>				
Nebraska:				
Bloomfield, City of, Knox County .....	310351	N/A, Emerg; June 18, 2007, Reg; October 2, 2015, Susp	.....do .....	Do.
Crofton, City of, Knox County .....	310361	July 9, 1976, Emerg; September 1, 1986, Reg; October 2, 2015, Susp	.....do .....	Do.
Knox County Unincorporated Areas .....	310451	N/A, Emerg; November 14, 2005, Reg; October 2, 2015, Susp	.....do .....	Do.

\*-do- = Ditto.  
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp—Suspension.

Dated: August 31, 2015.

**Roy E. Wright,**

*Deputy Associate Administrator, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.*

[FR Doc. 2015–23303 Filed 9–16–15; 8:45 am]

**BILLING CODE 9110–12–P**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 1**

[MD Docket No. 15–121; FCC 15–108]

**Assessment and Collection of Regulatory Fees for Fiscal Year 2015**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document the Commission revises its Schedule of Regulatory Fees to recover an amount of \$339,844,000 that Congress has required the Commission to collect for fiscal year 2015. Section 9 of the Communications

Act of 1934, as amended, provides for the annual assessment and collection of regulatory fees under sections 9(b)(2) and 9(b)(3), respectively, for annual “Mandatory Adjustments” and “Permitted Amendments” to the Schedule of Regulatory Fees.

**DATES:** Effective September 17, 2015. To avoid penalties and interest, regulatory fees should be paid by the due date of September 24, 2015.

**FOR FURTHER INFORMATION CONTACT:** Roland Helvajian, Office of Managing Director at (202) 418–0444.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Report and Order (R&O), FCC 15–108, MD Docket No. 15–121, adopted on September 1, 2015 and released on September 2, 2015.

**I. Administrative Matters**

*A. Final Regulatory Flexibility Analysis*

1. As required by the Regulatory Flexibility Act of 1980 (RFA),<sup>1</sup> the

<sup>1</sup> See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996

Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) relating to this Report and Order. The FRFA is contained towards the end of this document.

*B. Final Paperwork Reduction Act of 1995 Analysis*

2. This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

*C. Congressional Review Act*

3. The Commission will send a copy of this Report and Order to Congress and the Government Accountability

(SBREFA), Public Law 104–121, Title II, 110 Stat. 847 (1996). The SBREFA was enacted as Title II of the Contract with America Advancement Act of 1996 (CWAAA).

Office pursuant to the Congressional Review Act. 5 U.S.C. 801(a)(1)(A).

## II. Introduction and Executive Summary

4. This *Report and Order* adopts a schedule of regulatory fees to assess and collect \$339,844,000 in regulatory fees for Fiscal Year (FY) 2015, pursuant to Section 9 of the Communications Act of 1934, as amended (the Act or Communications Act) and the Commission's FY 2015 Appropriation.<sup>2</sup> The schedule of regulatory fees for FY 2015 adopted here is attached in Table C. These regulatory fees are due in September 2015.

5. The FY 2015 regulatory fees are based on the proposals in the *FY 2015 NPRM*,<sup>3</sup> considered in light of the comments received and Commission analysis. The FY 2015 regulatory fee schedule includes the following noteworthy changes from prior years: (1) A reduction in regulatory fees for the submarine cable/terrestrial and satellite bearer circuit (IBC) category relative to other fee categories in the International Bureau; (2) the first fee rate for Direct Broadcast Satellite (DBS) as a subcategory of the cable television and Internet Protocol Television (IPTV) regulatory fee category; (3) the first fee rate for toll free numbers; and (4) the elimination of the regulatory fee component of two fee categories: amateur radio Vanity Call Signs and General Mobile Radio Service (GMRS).<sup>4</sup> In addition, for FY 2015, in calculating the fee schedule, the Commission also reallocated four International Bureau full time employees (FTEs)<sup>5</sup> from direct to indirect.

<sup>2</sup> Section 9 regulatory fees are mandated by Congress and collected to recover the regulatory costs associated with the Commission's enforcement, policy and rulemaking, user information, and international activities. 47 U.S.C. 159(a). Public Law 113-235, Consolidated and Further Continuing Appropriation Act of 2015 (*FY 2015 Appropriation*) ("Provided further, That \$339,844,000 of offsetting collections shall be assessed and collected pursuant to section 9 of title I of the Communications Act of 1934, shall be retained and used for necessary expenses and shall remain available until expended.")

<sup>3</sup> *Assessment and Collection of Regulatory Fees for Fiscal Year 2015*, Notice of Proposed Rulemaking, Report and Order, and Order, 30 FCC Rcd 5354 (2015) (*FY 2015 NPRM, FY 2015 Fee Reform Report and Order*).

<sup>4</sup> See *FY 2015 Fee Reform Report and Order*, 30 FCC Rcd at 5361-62, paras. 19-22. As required by section 9(b)(4)(B) of the Act, "permitted amendment" letters were mailed June 4, 2015 and these amendments will take effect 90 days after congressional notification, *i.e.*, September 3, 2015.

<sup>5</sup> One FTE, a "Full Time Equivalent" or "Full Time Employee," is a unit of measure equal to the work performed annually by a full time person (working a 40 hour workweek for a full year) assigned to the particular job, and subject to agency personnel staffing limitations established by the U.S. Office of Management and Budget.

## III. Background

6. Congress adopted a regulatory fee schedule in 1993<sup>6</sup> and authorized the Commission to assess and collect annual regulatory fees pursuant to the schedule, as amended by the Commission.<sup>7</sup> As a result, the Commission annually reviews the regulatory fee schedule, proposes changes to the schedule to reflect changes in the amount of its appropriation, and proposes increases or decrease to the schedule of regulatory fees.<sup>8</sup> The Commission makes changes to the regulatory fee schedule "if the Commission determines that the schedule requires amendment to comply with the requirements"<sup>9</sup> of section 9(b)(1)(A) of the Act.<sup>10</sup> The Commission may also add, delete, or reclassify services in the fee schedule to reflect additions, deletions, or changes in the nature of its services "as a consequence of Commission rulemaking proceedings or changes in law." Thus, for each fiscal year, the proposed fee schedule in the annual Notice of Proposed Rulemaking (NPRM) will reflect changes in the amount appropriated for the performance of the FCC's regulatory activities, changes in the industries represented by the regulatory fee payers, changes in Commission FTE levels, and any other issues of relevance to the proposed fee schedule.<sup>11</sup> After receipt and review of comments, the Commission issues a Report and Order adopting the fee schedule for the fiscal year and sets out the procedures for payment of fees.

7. The Commission calculates the fees by first determining the FTE number of employees performing the regulatory activities specified in section 9(a), "adjusted to take into account factors that are reasonably related to the benefits provided to the payor of the fee by the Commission's activities . . ." <sup>12</sup> FTEs are categorized as "direct" if they are performing regulatory activities in one of the "core" bureaus, *i.e.*, the

<sup>6</sup> 47 U.S.C. 159 (g) (showing original fee schedule prior to Commission amendment).

<sup>7</sup> 47 U.S.C. 159.

<sup>8</sup> 47 U.S.C. 159(b)(1)(B).

<sup>9</sup> 47 U.S.C. 159(b)(2).

<sup>10</sup> 47 U.S.C. 159(b)(1)(A).

<sup>11</sup> Section 9(b)(2) discusses mandatory amendments to the fee schedule and Section 9(b)(3) discusses permissive amendments to the fee schedule. Both mandatory and permissive amendments are not subject to judicial review. 47 U.S.C. 159(b)(2) and (3).

<sup>12</sup> 47 U.S.C. 159(b)(1)(A). When section 9 was adopted, the total FTEs were to be calculated based on the number of FTEs in the Private Radio Bureau, Mass Media Bureau, and Common Carrier Bureau. (The names of these bureaus were subsequently changed.) Satellites and submarine cable were regulated through the Common Carrier Bureau before the International Bureau was created.

Wireless Telecommunications Bureau, Media Bureau, Wireline Competition Bureau, and part of the International Bureau. All other FTEs are considered "indirect."<sup>13</sup> The total FTEs for each fee category is calculated by counting the number of direct FTEs in the core bureau that regulates that category, plus a proportional allocation of indirect FTEs. Next, the Commission allocates the total amount to be collected among the various regulatory fee categories. This allocation is based on the number of FTEs assigned to work in each regulatory fee category. Each regulatee within a fee category pays its proportionate share based on an objective measure, *e.g.*, revenues, number of subscribers, or licenses.<sup>14</sup>

8. As part of its annual review, the Commission regularly seeks to improve its regulatory fee analysis.<sup>15</sup> For example, in the *FY 2013 Report and Order*, the Commission adopted updated FTE allocations to more accurately reflect the number of FTEs working on regulation and oversight of the regulatees in the various fee categories,<sup>16</sup> combined the UHF and VHF television stations into one regulatory fee category,<sup>17</sup> and created a fee category to include IPTV.<sup>18</sup> Subsequently, in the *FY 2014 Report and Order and FNPRM*, the Commission adopted a new fee category for toll free numbers,<sup>19</sup> increased the de minimis threshold,<sup>20</sup> and eliminated several categories from the regulatory fee

<sup>13</sup> The indirect FTEs are the employees from the International Bureau (in part), Enforcement Bureau, Consumer & Governmental Affairs Bureau, Public Safety & Homeland Security Bureau, Chairman and Commissioners' offices, Office of the Managing Director, Office of General Counsel, Office of the Inspector General, Office of Communications Business Opportunities, Office of Engineering and Technology, Office of Legislative Affairs, Office of Strategic Planning and Policy Analysis, Office of Workplace Diversity, Office of Media Relations, and Office of Administrative Law Judges, totaling 1,041 indirect FTEs.

<sup>14</sup> See *Assessment and Collection of Regulatory Fees*, Notice of Proposed Rulemaking, 27 FCC Rcd 8458, 8461-62, paras. 8-11 (2012) (*FY 2012 NPRM*).

<sup>15</sup> See *Assessment and Collection of Regulatory Fees for Fiscal Year 2008*, MD Docket No. 08-65, Report and Order and Further Notice of Proposed Rulemaking, 24 FCC Rcd 6388 (2008) (*FY 2008 Further Notice*).

<sup>16</sup> *Assessment and Collection of Regulatory Fees for Fiscal Year 2013*, MD Docket No. 08-65, Report and Order, 28 FCC Rcd 12351, 12354-58, paras. 10-20 (2013) (*FY 2013 Report and Order*).

<sup>17</sup> *FY 2013 Report and Order*, 28 FCC Rcd at 12361-62, paras. 29-31.

<sup>18</sup> *Id.*, 28 FCC Rcd at 12362-63, paras. 32-33.

<sup>19</sup> *Assessment and Collection of Regulatory Fees for Fiscal Year 2014*, Report and Order and Further Notice of Proposed Rulemaking, 29 FCC Rcd 10767, 10777-79, paras. 25-28 (2014) (*FY 2014 Report and Order and FNPRM*).

<sup>20</sup> *FY 2014 Report and Order and FNPRM*, 29 FCC Rcd at 10774-76, paras. 18-21.

schedule.<sup>21</sup> Earlier this year, in our *FY 2015 Fee Reform Report and Order*, we added a subcategory for DBS providers in the cable television and IPTV regulatory fee category.<sup>22</sup>

9. In our *FY 2015 NPRM*, we proposed to collect \$339,844,000 in regulatory fees and included a detailed, proposed fee schedule. We also sought comment on (1) a proposal revising the apportionment between the submarine cable/terrestrial and satellite bearer circuits fee category and the space station/earth station fee category; (2) revising an apportionment of regulatory fees among broadcasters; (3) a request for relief from regulatory fee assessments for radio stations in Puerto Rico filed by the Puerto Rico Broadcasters Association (PRBA);<sup>23</sup> (4) raising earth station regulatory fees relative to space station fees;<sup>24</sup> (5) a new regulatory fee for toll free numbers; (6) a new regulatory fee for DBS (as a subcategory in the cable television and IPTV regulatory fee category); and (7) whether certain FTEs should be allocated as direct instead of indirect.<sup>25</sup> We received 13 comments and eight reply comments. The list of commenters is attached in Table A.

#### IV. Report And Order

##### A. Discussion

##### 1. FY 2015 Regulatory Fees

10. In this Report and Order, we adopt a regulatory fee schedule for FY 2015, pursuant to Section 9 of the Communications Act and our FY 2015 appropriation statute in order to collect \$339,844,000 in regulatory fees.<sup>26</sup> Of this amount, we project approximately \$18.56 million (5.45 percent of the total FTE allocation) in fees from the International Bureau regulatees;<sup>27</sup> \$69.07 million (20.28 percent of the

total FTE allocation) in fees from the Wireless Telecommunications Bureau regulatees;<sup>28</sup> \$132.81 million (38.99 percent of the total FTE allocation) from Wireline Competition Bureau regulatees;<sup>29</sup> and \$120.15 million (35.28 percent of the total FTE allocation) from the Media Bureau regulatees.<sup>30</sup> These regulatory fees are due in September 2015. The schedule of regulatory fees for FY 2015 adopted here is attached as Table C.

##### 2. Toll Free Numbers

11. In the *FY 2014 Report and Order and FNPRM*,<sup>31</sup> we adopted a regulatory fee category for each toll free number managed by a RespOrg.<sup>32</sup> In the *FY 2015 NPRM*, we sought comment on a regulatory fee of 12 cents per toll free number.<sup>33</sup> In this *Report and Order*, we

<sup>28</sup> Includes Commercial Mobile Radio Service (CMRS), CMRS messaging, Broadband Radio Service/Local Multipoint Distribution Service (BRS/LMDS), and multi-year wireless licensees.

<sup>29</sup> Includes Interstate Telecommunications Service Providers (ITSP) and toll free numbers.

<sup>30</sup> Includes AM radio, FM radio, television, low power/FM, cable and IPTV, DBS, and Cable Television Relay Service (CARS) licenses.

<sup>31</sup> *FY 2014 Report and Order and FNPRM*, 29 FCC Rcd at 10777–79, paras. 25–28. We adopted this category for working, assigned, and reserved toll free numbers and for toll free numbers that are in the “transit” status, or any other status as defined in section 52.103 of the Commission’s rules. The regulatory fee, assessed on RespOrgs, for toll free numbers is limited to toll free numbers that are accessible within the United States.

<sup>32</sup> A Responsible Organization or RespOrg is a company that manages toll free telephone numbers for subscribers. They use the SMS/800 data base to verify the availability of specific numbers and to reserve the numbers for subscribers. See 47 CFR 52.101(b). ITTA contends that “it makes no sense to collect this fee from entities that already pay regulatory fees as ITSPs.” ITTA Comments at 7–8. In the *FY 2014 Report and Order and FNPRM*, 29 FCC Rcd 10767, 10777–79, paras. 25–28, we explained the issue in some detail. In particular, we noted that there may be many toll free numbers controlled or managed by entities, Responsible Organizations or RespOrgs, that in some cases are not carriers. As a result, the Commission adopted a regulatory fee on Resp Orgs, for each toll free number, because there appears to be many toll free numbers controlled or managed by Resp Orgs that are not carriers, and therefore, have not been paying regulatory fees. Commission FTEs in the Wireline Competition Bureau and the Enforcement Bureau work on toll free numbering issues and other related activities. Because Commission FTEs work on toll free number regulation, we adopted a regulatory fee category for toll free numbers to recover the associated costs. It is also important to note that the amount assessed for toll free numbers reduces the total regulatory fee assessment for ITSPs. In the *FY 2014 Report and Order and FNPRM*, we stated that: “Based on evaluation, the FTEs involved in toll free issues are primarily from the Wireline Competition Bureau. . . . Accordingly, a regulatory fee assessed on toll free numbers reduces the ITSP regulatory fee total.” *FY 2014 Report and Order and FNPRM*, 29 FCC Rcd at 10778, para. 27 (footnote omitted).

<sup>33</sup> *FY 2015 NPRM*, 30 FCC Rcd at 5358, para. 10.

adopt the proposed fee of 12 cents per toll free number.

##### 3. Submarine Cable

12. In the *FY 2014 Report and Order and FNPRM*, we concluded that the regulatory fee assessment for the submarine cable/terrestrial and satellite bearer circuits fee category did not fairly take into account the Commission’s minimal oversight and regulation of the international bearer circuit (IBC) industry. Accordingly, we reduced the total regulatory fee apportionment for submarine cable/terrestrial and satellite bearer circuits by five percent and stated that we would revisit the issue to determine if additional adjustment is warranted.<sup>34</sup> Subsequently, in the *FY 2015 NPRM*, we sought comment on further reducing the regulatory fee allocation for the submarine cable/terrestrial and satellite bearer circuit fee category.<sup>35</sup> In particular, we observed that after the initial licensing process, the regulatory activity concerning submarine cable/terrestrial and satellite bearer circuit systems is primarily limited to reviewing the Circuit Capacity Reports<sup>36</sup> and quarterly reports filed by licensees.<sup>37</sup> Based on our tentative conclusion that the fee remained excessive relative to the minimal Commission oversight and regulation of this industry, we proposed another five percent decrease in fees.<sup>38</sup>

13. NASCA, representing submarine cable operators,<sup>39</sup> argues that the proposed fee remains excessive because the industry would be responsible for 27.6 percent of all International Bureau regulatory fees.<sup>40</sup> Commenters also contend that the apportionment of regulatory fees for submarine cable operators and terrestrial and satellite bearer circuits remains too high due to the small number of FTEs working on

<sup>34</sup> See *FY 2014 Report and Order and FNPRM*, 29 FCC Rcd at 10772, para. 11.

<sup>35</sup> See *FY 2014 Report and Order and FNPRM*, 29 FCC Rcd at 10772, para. 11.

<sup>36</sup> See 47 CFR 43.62(a)(2); *Reporting Requirements for U.S. Providers of International Telecommunications Services; Amendment of Part 43 of the Commission’s Rules*, IB Docket No. 04–112, Second Report and Order, 28 FCC Rcd 575, 601–08, paras. 89–108 (2013) (*Second Report and Order*); *id.* at 604, para. 98 (noting that submarine cable capacity holders will report circuit capacity, rather than circuit status, going forward), *recon. dismissed*, Order, DA 15–711 (Int’l Bur. rel. June 17, 2015).

<sup>37</sup> See 47 CFR 1.767(l).

<sup>38</sup> *FY 2015 NPRM*, 30 FCC Rcd at 5358–59, para. 12.

<sup>39</sup> NASCA Comments at 2–3. (NASCA represents operators with 30 of the 42 active systems landing in the United States.)

<sup>40</sup> NASCA Comments at 9.

<sup>21</sup> *Id.*, 29 FCC Rcd at 10776–77, paras. 22–24.

<sup>22</sup> *FY 2015 Fee Reform Report and Order*, 30 FCC Rcd at 5364–5373, paras. 28–41. We also eliminated two additional fee categories. See *id.*, 30 FCC Rcd at 5361–62, paras. 19–22.

<sup>23</sup> See Letter from Messrs. Francisco Montero, Esq. and Jonathan R. Markman, Esq., Counsel for the Puerto Rico Broadcasters Association, filed in Docket No. 14–92, to Marlene Dortch, Secretary, Federal Communications Commission (Dec. 10, 2014) (PRBA Letter).

<sup>24</sup> Earth station fees were previously increased by 7.5 percent. See *FY 2014 Report and Order*, 29 FCC Rcd at 10772–73, para. 12.

<sup>25</sup> This issue was raised previously. See, e.g., *FY 2014 NPRM*, 29 FCC Rcd at 6425–27, paras. 22–27.

<sup>26</sup> Section 9 regulatory fees are mandated by Congress and collected to recover the regulatory costs associated with the Commission’s enforcement, policy and rulemaking, user information, and international activities. 47 U.S.C. 159(a).

<sup>27</sup> Includes satellites, earth stations, and international bearer circuits (submarine cable systems and satellite and terrestrial bearer circuits).

those services.<sup>41</sup> Some commenters observe as well that the high regulatory fees imposed on the submarine cable operators can place the United States at a competitive disadvantage because Canada and Mexico have much lower fees and the submarine cable industry may choose to land new cables in those countries instead.<sup>42</sup> Commenters suggest that this could pose national security issues if the submarine cable operators choose to build out in Canada and Mexico, because those facilities would not be subject to the Communications Assistance for Law Enforcement Act, commonly known as CALEA.<sup>43</sup> EchoStar contends that we have not supported our proposal to reduce the IBC fees with sufficient facts.<sup>44</sup>

14. In 2009, the Commission adopted a new regulatory fee methodology for submarine cable based on a proposal by a large group of submarine cable operators.<sup>45</sup> Under this methodology, after we apportion the IBC revenue requirement between the terrestrial and satellite facilities and submarine cable, we assess the submarine cable systems on a per cable landing license basis, with higher fees for larger systems and lower fees for smaller systems (the regulatory fees for terrestrial and satellite facilities are still assessed on a per bearer circuit basis).<sup>46</sup> The regulatory fees that are now paid by the submarine cable operators cover the services provided to common carriers using the submarine cable circuits in addition to the services that the International Bureau provides to submarine cable operators. The International Bureau's regulatory activity concerning submarine cable includes licensing,<sup>47</sup> reviewing the Circuit Capacity Reports<sup>48</sup> and filed quarterly reports.<sup>49</sup> In addition, all

International Bureau services provided to common carriers using the submarine cable circuits, such as benchmarks enforcement,<sup>50</sup> protection from anticompetitive actions by foreign carriers, foreign ownership rulings (Petitions for Declaratory Rulings, or PDRs), section 214 authorizations, and bilateral and multilateral negotiations and representation of U.S. interests at international organizations, are all provided by the International Bureau on behalf of the common carriers using submarine cable circuits. Upon this further analysis, we conclude that our previous estimate of two FTEs working on IBC issues discussed in *FY 2014 Report and Order*, did not take these issues into account.<sup>51</sup> Nevertheless, as we have discussed previously in the *FY 2013 NPRM*, *FY 2014 NPRM*, and the *FY 2015 NPRM*,<sup>52</sup> the oversight and regulation of the IBC industry may warrant additional adjustment to the fee allocation. For the reasons discussed above, we reduce the regulatory fee apportionment for submarine cable/terrestrial and satellite bearer circuits by 7.5 percent to more accurately reflect the regulation and oversight for the industry.<sup>53</sup> This analysis reflects both the direct work on submarine cable/terrestrial and satellite bearer circuit issues and other common carrier issues by International Bureau FTEs and the indirect FTEs that devote their time to International Bureau regulatees as a whole. We find that this decrease in the regulatory fees paid by IBCs more accurately reflects the level of regulation and oversight for this industry. Also, we reject the speculation that failure to reduce regulatory fees as much as the submarine cable operators might prefer could lead to a change in the cable landing locations. We also reject EchoStar's statement that our proposal lacked factual support. As noted above, the regulatory oversight of this fee category has been explained in detail in

publishes annual industry analysis reports based on that data.

<sup>50</sup> See, e.g., *International Settlement Rates*, IB Docket No. 96-261, Report and Order, FCC 97-280, 12 FCC Rcd 19806 (1997) (*Benchmarks Order*); Report and Order on Reconsideration and Order Lifting Stay, 14 FCC Rcd 9256 (1999) (*Benchmarks Reconsideration Order*); *aff'd sub nom. Cable & Wireless*, 166 F.3d 1224.

<sup>51</sup> *FY 2014 Report and Order*, 29 FCC Rcd at 10772, para. 11.

<sup>52</sup> *FY 2013 NPRM*, 28 FCC Rcd at 7800-7803, paras. 24-29; *FY 2014 NPRM*, 29 FCC Rcd at 6427-28, para. 28; *FY 2015 NPRM*, 30 FCC Rcd at 5358-59, para. 12.

<sup>53</sup> The actual decrease is higher than 7.5 percent due to the reallocation of four direct FTEs, discussed in paragraph 25, because the submarine cable percentage of International Bureau regulatory fees was 31.36 percent in FY 2014 and will be 24.85 percent in 2015, a reduction of more than 20 percent.

this, and prior proceedings,<sup>54</sup> and has been the subject of comments by submarine cable operators for a number of years.

#### 4. Earth Stations

15. In the *FY 2014 NPRM*, the Commission recognized that the International Bureau's oversight and regulation of the satellite industry involves FTEs working on legal, technical, and policy issues pertaining to both space station and earth station operations and is therefore interdependent to some degree.<sup>55</sup> For that reason, we sought comment on whether we should increase the earth station regulatory fee allocation in order to reflect more appropriately the number of FTEs devoted to the regulation and oversight of the earth station portion of the satellite industry.<sup>56</sup> In the FY 2014 regulatory fee proceeding, we increased the regulatory fees paid by earth station licensees by approximately 7.5 percent based on our analysis and review of the record.<sup>57</sup>

16. In the *FY 2015 NPRM*, we sought comment on whether to raise the earth station regulatory fees again.<sup>58</sup> We find, however, that this issue requires further analysis. In particular, due to comments suggesting that we adopt different regulatory fees for different types of earth stations and an ongoing proceeding concerning Part 25 (Satellite Communications) of the Commission's rules which may affect the distribution of FTE work, we plan to further examine and consider this issue for FY 2016.<sup>59</sup> In doing so, we intend to seek comment on EchoStar's proposal to assess different levels of regulatory fees on different types of earth station licenses.<sup>60</sup>

#### 5. FTE Reallocations

17. As explained above in paragraph five, we calculate regulatory fees by classifying FTEs either as direct or indirect. FTEs classified as direct are further associated with one of the core bureaus. The Commission now updates FTE allocations on an annual basis to more accurately reflect the number of FTEs working on regulation and oversight of the regulatees in the various fee categories.<sup>61</sup> The Commission has

<sup>54</sup> See *FY 2013 NPRM*, 28 FCC Rcd at 7800-7803, paras. 24-29; *FY 2014 NPRM*, 29 FCC Rcd at 6427-28, para. 28; *FY 2015 NPRM*, 30 FCC Rcd at 5358-59, para. 12.

<sup>55</sup> *FY 2014 NPRM*, 29 FCC Rcd at 6428, para. 29.

<sup>56</sup> *Id.*, 29 FCC Rcd at 6428, para. 29.

<sup>57</sup> See *FY 2014 Report and Order*, 29 FCC Rcd at 10772-73, para. 12.

<sup>58</sup> *FY 2015 NPRM*, 30 FCC Rcd at 5360, para. 14.

<sup>59</sup> See EchoStar July 20, 2015 ex parte.

<sup>60</sup> See EchoStar July 20, 2015 ex parte.

<sup>61</sup> *FY 2013 Report and Order*, 28 FCC Rcd at 12355-56, para. 14.

<sup>41</sup> NASCA Comments at 11-13; Coalition Comments at 4-7 & Reply Comments at 3. (The Coalition consists of Cedar Cable Ltd., Columbus Networks USA, Inc., GlobeNet Cabos Submarinos America, Inc., and GU Holdings Inc.).

<sup>42</sup> Coalition Comments at 8.

<sup>43</sup> Coalition Comments at 8.

<sup>44</sup> EchoStar Comments at 5.

<sup>45</sup> *Assessment and Collection of Regulatory Fees for Fiscal Year 2008*, Second Report and Order, 24 FCC Rcd 4208 (2009) (*Submarine Cable Order*).

<sup>46</sup> *Submarine Cable Order*, 24 FCC Rcd at 4214-17, paras. 13-22.

<sup>47</sup> The International Bureau reviews, processes, analyzes, and grants applications for submarine cable landing license applications, transfers, assignments, and modifications. The bureau also coordinates processing of submarine cable landing license applications with the relevant Executive Branch agencies.

<sup>48</sup> See *Second Report and Order*, 28 FCC Rcd at 601-08, paras. 89-108.

<sup>49</sup> See 47 CFR 1.767(l). The International Bureau reviews Part 43 submarine cable circuit capacity and traffic and revenue filings, and compiles and

also previously determined that some of the International Bureau FTEs should be considered indirect instead of direct.<sup>62</sup> We find that apart from the unique nature of the International Bureau FTEs, the work of all the FTEs in a core bureau contributes to the cost of regulating and overseeing the licensees of that bureau. Therefore, we may reasonably expect that the work of the FTEs in the core bureaus would remain focused on the industry segment regulated by each of those bureaus. The work of the FTEs in the remaining (*i.e.*, indirect) bureaus and offices benefits the Commission and the telecommunications industry and is not specifically focused on the licensees of a particular core bureau. Given the significant implications of reassignment of FTEs in our fee calculation, we make changes to FTE classifications only after performing considerable analysis and finding the clearest case for reassignment.<sup>63</sup>

#### a. Request To Characterize Indirect FTEs as Direct FTEs

18. SIA and EchoStar propose that we consider FTEs working in certain divisions of the Enforcement Bureau and the Consumer & Governmental Affairs Bureau and the Office of Engineering & Technology (*i.e.*, indirect FTEs) as direct FTEs, associated with a core bureau for purposes of regulatory fee calculation.<sup>64</sup> SIA contends that the work in the Market Disputes Resolution Division “is limited to complaints against common carriers and pole attachment disputes”<sup>65</sup> and the “Telecommunications Consumers Division focuses on protecting consumers from fraudulent, misleading, and other harmful practices involving telecommunications, such as slamming.”<sup>66</sup> SIA’s description of these two Enforcement Bureau divisions underestimates the range of issues that they investigate.<sup>67</sup> EchoStar argues that the Office of Engineering &

Technology’s regulatory work suggests that “no more than 7 percent of the applicable FTEs for the OET should be allocated to space-related IB licensees.”<sup>68</sup> This proposal raised by SIA and EchoStar involves more than an analysis of two divisions and one office but rather would require an assessment of how all work done by FTEs in a bureau or office not classified as a core bureau could be associated with the work of a core bureau, such that additional FTEs could be allocated to the core bureau. However, FTEs are assigned as indirect in our regulatory fee calculation where the FTEs work on a variety of issues that cannot be attributed to one particular type of industry or regulatee at this time.

19. The Enforcement Bureau and Consumer & Governmental Affairs FTEs and other indirect FTEs, such as those in the Office of Engineering & Technology, work on a wide range of matters, not all directly assignable to a particular core bureau. We recognize that before the Enforcement Bureau was created, the core bureaus each had an enforcement division and those FTEs would have been assigned to those core bureaus. Currently, however, most enforcement activity is consolidated into the Enforcement Bureau, therefore the FTEs may work on a range of issues and many of their investigations cannot be assigned to a specific core bureau, *e.g.*, investigations that involve more than one service. While SIA suggests that we might track informal complaints filed in the Consumer & Governmental Affairs Bureau and associate them with a core licensing bureau based on the number of informal complaints in each category over a certain time period,<sup>69</sup> we find that this would not be feasible at this time because the types of informal complaints can vary considerably and often cover areas that are not specifically correlated with one core bureau, *e.g.*, billing issues for bundled services. For these reasons, we conclude that reallocating indirect FTEs as direct as suggested by EchoStar and SIA is not feasible at this time. However, we will continue to analyze this issue in future regulatory fee proceedings.

#### b. Request To Associate Direct FTEs With a Different Core Bureau

20. NAB notes that the FTEs in the Media Bureau who work on issues pertaining to the upcoming spectrum

incentive auction to repurpose broadcast television spectrum to wireless use should be reallocated to the Wireless Telecommunications Bureau for regulatory fee purposes.<sup>70</sup> SIA asks us to “re-evaluate whether it is appropriate to exclude auction FTEs in assessing direct costs.”<sup>71</sup> FTE time devoted to developing and implementing the upcoming spectrum incentive auction—direct and indirect costs—is not included in the calculation of fees and is not offset by the collection of regulatory fees. Instead, time devoted to developing and implementing the incentive auction is tracked separately from other work performed by Media Bureau and other FTEs and is offset by the auction proceeds that the Commission is permitted to retain pursuant to section 309(j)(8) of the Communications Act and the Commission’s annual appropriation statute.<sup>72</sup> Thus, the Commission is unable, as a legal matter, to implement these proposals.

#### 6. DBS Rate Issues

21. In the *FY 2015 NPRM*, we sought comment on setting the initial rate for DBS regulatory fees, as a subset of the cable television and IPTV category, at 12 cents per year, or one cent per month.<sup>73</sup> Several commenters contend that we should require DBS operators to pay the same rate as cable television and IPTV.<sup>74</sup> DBS commenters contend that paying the same rate as cable television/IPTV would cause “rate shock” and if we adopt a fee it should be 12 cents as proposed.<sup>75</sup>

22. When adopting the new regulatory fee subcategory for DBS within the cable and IPTV category, we determined a variety of regulatory developments have increased the amount of regulatory activity by the Media Bureau FTEs involving regulation and oversight of MVPDs, including DBS providers.<sup>76</sup> For example, DBS providers (and cable television operators) are permitted to file program access complaints<sup>77</sup> and complaints seeking relief under the retransmission consent good faith

<sup>62</sup> *FY 2013 Report and Order*, 28 FCC Rcd at 12356, para. 14.

<sup>63</sup> *FY 2013 Report and Order*, 28 FCC Rcd at 12357, para. 19. The Commission observed that the International Bureau was a “singular case” because the work of those FTEs “primarily benefits licensees regulated by other bureaus.” *Id.*, 28 FCC Rcd at 12355, para. 14.

<sup>64</sup> SIA Comments at 8–11; EchoStar Comments at 3–4. CTIA observes that excluding one type of licensee, such as satellite providers, from contributing to indirect costs would threaten the administrability of the regulatory fee program. CTIA Reply Comments at 5. We interpret this proposal as asking us to determine how many indirect FTEs work on issues pertaining to all core bureau licensees.

<sup>65</sup> SIA Comments at 8.

<sup>66</sup> SIA Comments at 8.

<sup>67</sup> For a brief description of the Enforcement Bureau divisions, see <https://www.fcc.gov/encyclopedia/enforcement-bureau-organization>.

<sup>68</sup> EchoStar Comments at 4. We note that currently International Bureau licensees are 5.43% of the direct FTEs and therefore 5.43% of the indirect FTEs are assigned to the International Bureau licensees, which is lower than the 7% EchoStar is proposing.

<sup>69</sup> SIA Comments at 10.

<sup>71</sup> SIA Comments at 12.

<sup>72</sup> See, *e.g.* the FCC’s FY 2015 appropriation statute, the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, 128 Stat. 2130 (2014).

<sup>73</sup> *FY 2015 NPRM*, 30 FCC Rcd at 5358, para. 9.

<sup>74</sup> NCTA & ACA Comments at 2–6 & Reply Comments at 4–6; ITTA Comments at 5–7.

<sup>75</sup> DIRECTV Comments at 3–5 & Reply Comments at 3–4 (arguing that if we adopt a fee it should be the 12 cents proposed); DISH Reply Comments at 4–5.

<sup>76</sup> See *FY 2015 Fee Reform Report and Order*, 30 FCC Rcd at 5367–68, para. 31.

<sup>77</sup> 47 U.S.C. 548; 47 CFR 76.1000–1004.

rules.<sup>78</sup> In addition, DBS providers are subject to MVPD requirements such as those pertaining to program carriage<sup>79</sup> and the requirement to negotiate retransmission consent in good faith.<sup>80</sup> More recently, the Commission adopted a host of requirements that apply to all MVPDs and thus equally apply to DBS providers as part of its implementation of the Commercial Advertisement Loudness Mitigation Act (CALM Act),<sup>81</sup> the Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA),<sup>82</sup> as well as the Satellite Television Extension and Localism Act (STELA) Reauthorization Act of 2014 (STELAR).<sup>83</sup> Moreover, we recognize that FY 2015 would be the first time the Commission would be applying this regulatory fee subcategory for DBS. Thus, for the above reasons, we find that for FY 2015 the proposed rate of 12 cents per subscriber per year is a sensible fee supported by data and analysis.<sup>84</sup> In the FY 2016 regulatory fee proceeding, we will update this rate for future years, based on relevant information, as necessary for ensuring an appropriate level of regulatory parity and considering the resources dedicated to this new regulatory fee subcategory.<sup>85</sup>

#### 7. Other Rate Issues

**23. Aviation Ground Licenses.** In the FY 2015 NPRM, we proposed an increase in regulatory fees for aviation ground licenses. Commenters contend that we have proposed an unjustified and disproportionate fee increase for

aviation ground licensees.<sup>86</sup> The Aviation Joint Commenters disagree with our contention that the payment units should be adjusted and they observe that we failed to explain why the revenue requirement was increased.<sup>87</sup> These commenters observe that despite no increase in regulation of this industry, the Commission has significantly increased the regulatory fees in FY 2014 and FY 2015.<sup>88</sup> We agree with the Aviation Joint Commenters and, after reviewing additional information, have adjusted the payment units and rate accordingly based on current fiscal year renewals.

**24. Satellite.** Several commenters have raised issues pertaining to the proposed space station fees. SIA and EchoStar object to the proposed increase in fees, contending that we should cap any increases at 7.5 percent.<sup>89</sup> These commenters argue that we should adopt the same cap we adopted for FY 2013. In FY 2013, the 7.5% cap was instituted to address the initial changes in the FTE allocations (not fee rate changes resulting from changes in the unit counts) as a result of GAO recommendations.<sup>90</sup> Such FTE allocation changes could have caused some regulatory fee rates to increase dramatically. To address this issue, the Commission capped the fee rate increase to 7.5% from the prior year. In the current proceeding, some satellite commenters requested that the Commission adopt a 7.5% cap on FY 2015 regulatory fee increases as the Commission did in FY 2013 with respect to the Non-Geostationary Space Station fee category. Although the circumstances in which we instituted the cap in FY 2013 are different than now, any discussion of imposing a cap at this time is not necessary because the satellite fee rate in the FY 2015 Report and Order is nearly the same or slightly lower than in FY 2014. We therefore decline to adopt a cap in this instance.

25. Intelsat asks that we take satellite application fees<sup>91</sup> into consideration in calculating our regulatory fees.<sup>92</sup> We are

required to assess and collect \$339,844,000 in regulatory fees for FY 2015, pursuant to Section 9 of the Communications Act and the Commission's FY 2015 Appropriation.<sup>93</sup> Thus, we are not able to collect less than mandated by Congress in order to take into account section 8 application fees, as Intelsat requests.

26. In addition, Intelsat argues that U.S.-licensed satellite operators should not have to subsidize the non-U.S.-licensed satellite operators' ability to serve the U.S. market.<sup>94</sup> We have sought comment previously on this issue because the number of International Bureau FTEs working on non-U.S.-licensed space stations increases the regulatory fees for the International Bureau regulatees.<sup>95</sup> We also note that non-U.S.-licensed space stations that have been granted access to the U.S. market will eventually communicate with earth stations in the United States, and therefore aspects of the interrelated communications system are apportioned to earth station licensees when accounting for FTE time spent processing requests to access the non-U.S. licensed space station. We conclude that due to: (i) The time spent by International Bureau FTEs in working on these issues; and (ii) the significant number of requests to access the U.S. market by non-U.S.-licensed space stations, the FTEs working on petitions or other matters involving non-U.S.-licensed space stations should be removed from the regulatory fee assessments for U.S.-licensed space stations and considered indirect for regulatory fee purposes. Non-U.S.-licensed space stations granted access to the market in the United States provide a variety of services. Attributing such FTE work as indirect appropriately attributes the regulatory fee burden to the wider telecommunications industry that benefits from such grants of market access. We have reviewed the number of FTEs working on the non-U.S.-licensed space stations and have determined that approximately four FTEs are devoted to this work at this time, therefore, we are reallocating four International Bureau FTEs as indirect FTEs for regulatory fee purposes.<sup>96</sup>

<sup>78</sup> 47 U.S.C. 325(b)(1), (3)(C)(ii); 47 CFR 76.65(b).

<sup>79</sup> 47 U.S.C. 536; 47 CFR 76.1300–1302.

<sup>80</sup> 47 U.S.C. 325(b)(3)(C)(iii); 47 CFR 76.65(a)–(b).

<sup>81</sup> See *Implementation of the Commercial Advertisement, Loudness Mitigation (CALM) Act*, Report and Order, 26 FCC Rcd 17222 (2011) (*CALM Act Report and Order*).

<sup>82</sup> Public Law 111–260, 124 Stat. 2751 (2010). See also *Amendment of Twenty-First Century Communications and Video Accessibility Act of 2010*, Public Law 111–265, 124 Stat. 2795 (2010) (making corrections to the CVAA); 47 CFR part 79.

<sup>83</sup> The STELA Reauthorization Act of 2014 (STELAR), 102, Public Law 113–200, 128 Stat. 2059, 2060–62 (2014) (codified at 47 U.S.C. 338(1)). The STELAR was enacted on Dec. 4, 2014 (H.R. 5728, 113th Cong.). *Implementation of Section 102 of the STELA Reauthorization Act of 2014*, Notice of Proposed Rulemaking, MB Docket No. 15–71, FCC 15–34 (released Mar. 26, 2015) proposes satellite television “market modification” rules to implement section 102 of STELAR.

<sup>84</sup> See *FY 2015 Fee Reform Report and Order*, 30 FCC Rcd at 5367–5373, paras. 31 to 41. The agency is not required to calculate its costs with “scientific precision.” *Central & Southern Motor Freight Tariff Ass'n v. United States*, 777 F.2d 722, 736 (D.C. Cir. 1985). Reasonable approximations will suffice. *Id.*; *Mississippi Power & Light*, 601 F.2d at 232; *National Cable Television Ass'n v. FCC*, 554 F.2d 1094, 1105 (D.C. Cir. 1976); 36 Comp. Gen. 75 (1956).

<sup>85</sup> See *FY 2015 Fee Reform Report and Order*, 30 FCC Rcd at 5371–72, para. 38

<sup>86</sup> Aviation Joint Comments at 4–12.

<sup>87</sup> Aviation Joint Comments at 5–6.

<sup>88</sup> Aviation Joint Comments at 6–9.

<sup>89</sup> SIA Comments at 6–7; EchoStar Comments at 6–8.

<sup>90</sup> General Accountability Office, “Federal Communications Commission, Regulatory Fee Process Needs to be Updated”, GAO 12–686, August 2012, p. 1, 8–11.

<sup>91</sup> Application fees are assessed under Section 8 of the Communications Act. 47 U.S.C. 158 and are paid directly into the general fund of the U.S. Treasury. 47 U.S.C. 158(e). The Commission is not authorized to retain receipts from application fees for its own use or to use application fees to offset its appropriation.

<sup>92</sup> Intelsat Comments at 1–2.

<sup>93</sup> Section 9 regulatory fees are mandated by Congress and collected to recover the regulatory costs associated with the Commission's enforcement, policy and rulemaking, user information, and international activities. 47 U.S.C. 159(a).

<sup>94</sup> Intelsat Comments at 3–4.

<sup>95</sup> See *FY 2014 NPRM*, 29 FCC Rcd at 6434, para. 50.

<sup>96</sup> The number of market access requests can vary; however, four FTEs is appropriate at this point.



## 8. Puerto Rico Broadcasters Association Petition

27. In the *FY 2015 NPRM*, we sought comment on the petition filed by the Puerto Rico Broadcaster's Association (PRBA) seeking regulatory fee relief.<sup>97</sup> We recognize the challenging circumstances described in the PRBA petition. Due to the complexities of this proposal and time constraints imposed by the annual regulatory fee process, additional time is needed to further consider this petition. We intend to address the PRBA petition in a separate proceeding outside of the regulatory fee rulemaking process. We understand that PRBA is contending that the costs associated with preparing and filing a waiver request would be overly burdensome.<sup>98</sup> We do not agree that PRBA's assertion, that requesting a waiver is a burden, eliminates that option. Our waiver process,<sup>99</sup> is available to PRBA members and any aggrieved party seeking a waiver of our rules.<sup>100</sup>

## 9. Effective Date of Elimination of the Vanity Call Sign and General Mobile Radio Service Regulatory Fee

28. In the Commission's *FY 2015 Fee Reform Report and Order*,<sup>101</sup> the Commission eliminated the regulatory fee component of two fee categories: amateur radio Vanity Call Signs<sup>102</sup> and General Mobile Radio Service (GMRS).<sup>103</sup> The elimination of regulatory fee categories constitutes a "permitted amendment" as defined in section 9(b)(3) of the Act. As required by section 9(b)(4)(B) of the Act, "permitted amendment" letters dated June 4, 2015 were mailed to congressional officials informing them of the elimination of these two fee categories and adoption of the new DBS fee category. Consistent with section 9(b)(4)(B) of the Act, these

<sup>97</sup> *FY 2015 NPRM*, 30 FCC Rcd at 5360–61, paras. 15–18. One commenter addressed the issues in the PRBA petition and suggests that we adopt our second proposal and create a separate fee category for Puerto Rico at a lower rate. ARSO Comments at 6–8.

<sup>98</sup> PRBA Comments at 2.

<sup>99</sup> 47 U.S.C. 159(d); 47 CFR 1.1166.

<sup>100</sup> See the Commission's regulatory fee waiver fact sheet, available at <https://www.fcc.gov/document/fy-2014-regulatory-fees-waiver-fact-sheet>.

<sup>101</sup> *FY 2015 Fee Reform Report and Order*, 30 FCC Rcd at 5361–62, paras. 19–22.

<sup>102</sup> Call signs assigned to newly licensed stations, *i.e.*, a sequential call sign, are assigned based on the licensee's mailing address and class of operator license. 47 CFR 97.17(d). The licensee can request a specific unassigned but assignable call sign, known as a vanity call sign. 47 CFR 97.19. There is no fee for the sequential call sign.

<sup>103</sup> GMRS (formerly Class A of the Citizens Radio Service) is a personal radio service available for the conduct of an individual's personal and family communications. See 47 CFR 95.1.

amendments will take effect 90 days after congressional notification of the permitted amendment letter, dated June 4, 2015. Thus, effective September 3, 2015, the Vanity Call Sign and GMRS regulatory fee categories will be eliminated and licensees will not be required to pay additional regulatory fees for these licenses.<sup>104</sup> Regulatees are still responsible for the payment of all application fees associated with these licenses.

## V. Procedural Matters

### A. Payment of Regulatory Fees

#### 1. Payments by Check Will Not Be Accepted for Payment of Annual Regulatory Fees

29. Pursuant to an Office of Management and Budget (OMB) directive,<sup>105</sup> the Commission is moving towards a paperless environment, extending to disbursement and collection of select federal government payments and receipts.<sup>106</sup> The initiative to reduce paper and curtail check payments for regulatory fees is expected to produce cost savings, reduce errors, and improve efficiencies across government. Accordingly, the Commission will no longer accept checks (including cashier's checks and money orders) and the accompanying hardcopy forms (*e.g.*, Forms 159, 159–B, 159–E, 159–W) for the payment of regulatory fees. This new paperless procedure will require that all payments be made by online ACH payment, online credit card, or wire transfer. Any other form of payment (*e.g.*, checks, cashier's checks, or money orders) will be rejected. For payments by wire, a Form 159–E should still be transmitted via fax so that the Commission can associate the wire payment with the correct regulatory fee information. This change will affect all payments of regulatory fees.<sup>107</sup>

#### 2. Revised Credit Card Transaction Levels

##### 30. In accordance with U.S. Treasury Announcement No. A–2014–04 (July

<sup>104</sup> The letter dated June 4, 2015 also includes the establishment of a DBS regulatory fee which will also be effective September 3, 2015.

<sup>105</sup> Office of Management and Budget (OMB) Memorandum M–10–06, Open Government Directive, Dec. 8, 2009; see also <http://www.whitehouse.gov/the-press-office/2011/06/13/executive-order-13576-delivering-efficient-effective-and-accountable-gov>.

<sup>106</sup> See U.S. Department of the Treasury, Open Government Plan 2.1, Sept. 2012.

<sup>107</sup> Payors should note that this change will mean that to the extent certain entities have to date paid both regulatory fees and application fees at the same time via paper check, they will no longer be able to do so as the regulatory fees payment via paper check will no longer be accepted.

2014), the amount that can be charged on a credit card for transactions with federal agencies has been reduced to \$24,999.99.<sup>108</sup> Previously, the credit card limit was \$49,999.99. This lower transaction amount is effective June 1, 2015. Transactions greater than \$24,999.99 will be rejected. This limit applies to single payments or bundled payments of more than one bill. Multiple transactions to a single agency in one day may be aggregated and treated as a single transaction subject to the \$24,999.99 limit. Customers who wish to pay an amount greater than \$24,999.99 should consider available electronic alternatives such as Visa or MasterCard debit cards, Automated Clearing House (ACH) debits from a bank account, and wire transfers. Each of these payment options is available after filing regulatory fee information in Fee Filer. Further details will be provided regarding payment methods and procedures at the time of FY 2015 regulatory fee collection in Fact Sheets, available at <https://www.fcc.gov/regfees>.

#### 3. Lock Box Bank

31. During the fee season for collecting FY 2015 regulatory fees, regulatees can pay their fees by credit card through Pay.gov,<sup>109</sup> ACH, debit card,<sup>110</sup> or by wire transfer. Additional payment instructions are posted at <http://transition.fcc.gov/fees/regfees.html>.

#### 4. Receiving Bank for Wire Payments

32. The receiving bank for all wire payments is the Federal Reserve Bank, New York, New York (TREAS NYC). When making a wire transfer, regulatees must fax a copy of their Fee Filer generated Form 159–E to the Federal Communications Commission at (202) 418–2843 at least one hour before initiating the wire transfer (but on the

<sup>108</sup> Customers who owe an amount on a bill, debt, or other obligation due to the federal government are prohibited from splitting the total amount due into multiple payments. Splitting an amount owed into several payment transactions violates the credit card network and Fiscal Service rules. An amount owed that exceeds the Fiscal Service maximum dollar amount, \$24,999.99, may not be split into two or more payment transactions in the same day by using one or multiple cards. Also, an amount owed that exceeds the Fiscal Service maximum dollar amount may not be split into two or more transactions over multiple days by using one or more cards.

<sup>109</sup> In accordance with U.S. Treasury Financial Manual Announcement No. A–2014–04 (July 2014), the amount that may be charged on a credit card for transactions with federal agencies has been reduced to \$24,999.99.

<sup>110</sup> In accordance with U.S. Treasury Financial Manual Announcement No. A–2012–02, the maximum dollar-value limit for debit card transactions is eliminated. It should also be noted that only Visa and MasterCard branded debit cards are accepted by Pay.gov.

same business day) so as not to delay crediting their account. Regulatees should discuss arrangements (including bank closing schedules) with their bankers several days before they plan to make the wire transfer to allow sufficient time for the transfer to be initiated and completed before the deadline. Complete instructions for making wire payments are posted at <http://transition.fcc.gov/fees/wiretran.html>.

#### 5. De Minimis Regulatory Fees

33. Regulatees whose total FY 2015 annual regulatory fee liability, including all categories of fees for which payment is due, is \$500 or less are exempt from payment of FY 2015 regulatory fees. The *de minimis* threshold applies only to filers of annual regulatory fees (not regulatory fees paid through multi-year filings), and it is not a permanent exemption. Rather, each regulatee will need to reevaluate their total fee liability each fiscal year to determine whether they meet the *de minimis* exemption.

#### 6. Standard Fee Calculations and Payment Dates

34. The Commission will accept fee payments made in advance of the window for the payment of regulatory fees. The responsibility for payment of fees by service category is as follows:

- *Media Services*: Regulatory fees must be paid for initial construction permits that were granted on or before October 1, 2014 for AM/FM radio stations, VHF/UHF full service television stations, and satellite television stations. Regulatory fees must be paid for all broadcast facility licenses granted on or before October 1, 2014. For providers of Direct Broadcast Service (DBS) service, regulatory fees should be paid based on a subscriber count on or about December 31, 2014. In instances where a permit or license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the permit or license as of the fee due date.

- *Wireline (Common Carrier) Services*: Regulatory fees must be paid for authorizations that were granted on or before October 1, 2014. In instances where a permit or license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the permit or license as of the fee due date. Audio bridging service providers are included in this category.<sup>111</sup> For Responsible Organizations (RespOrgs) that manage Toll Free Numbers (TFN), regulatory

<sup>111</sup> Audio bridging services are toll teleconferencing services.

fees should be paid on all working, assigned, and reserved toll free numbers, including those toll free numbers that are in transit status, or any other status as defined in section 52.103 of the Commission's rules. The unit count should be based on toll free numbers managed by RespOrgs on or about December 31, 2014.

- *Wireless Services*: CMRS cellular, mobile, and messaging services (fees based on number of subscribers or telephone number count): Regulatory fees must be paid for authorizations that were granted on or before October 1, 2014. The number of subscribers, units, or telephone numbers on December 31, 2014 will be used as the basis from which to calculate the fee payment. In instances where a permit or license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the permit or license as of the fee due date.

- *Wireless Services, Multi-year fees*: The first eight regulatory fee categories in our Schedule of Regulatory Fees pay "small multi-year wireless regulatory fees." Entities pay these regulatory fees in advance for the entire amount period covered by the five-year or ten-year terms of their initial licenses, and pay regulatory fees again only when the license is renewed or a new license is obtained. We include these fee categories in our rulemaking (see Table B) to publicize our estimates of the number of "small multi-year wireless" licenses that will be renewed or newly obtained in FY 2015.

- *Multichannel Video Programming Distributor Services (cable television operators and CARS licensees)*: Regulatory fees must be paid for the number of basic cable television subscribers as of December 31, 2014.<sup>112</sup> Regulatory fees also must be paid for CARS licenses that were granted on or before October 1, 2014. In instances where a permit or license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the permit or license as of the fee due date.

- *International Services*: Regulatory fees must be paid for (1) earth stations and (2) geostationary orbit space

<sup>112</sup> Cable television system operators should compute their number of basic subscribers as follows: Number of single family dwellings + number of individual households in multiple dwelling unit (apartments, condominiums, mobile home parks, etc.) paying at the basic subscriber rate + bulk rate customers + courtesy and free service. Note: Bulk-Rate Customers = Total annual bulk-rate charge divided by basic annual subscription rate for individual households. Operators may base their count on "a typical day in the last full week" of December 2014, rather than on a count as of December 31, 2014.

stations and non-geostationary orbit satellite systems that were licensed and operational on or before October 1, 2014. In instances where a permit or license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the permit or license as of the fee due date.

- *International Services: (Submarine Cable Systems)*: Regulatory fees for submarine cable systems are to be paid on a per cable landing license basis based on circuit capacity as of December 31, 2014. In instances where a license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the license as of the fee due date. For regulatory fee purposes, the allocation in FY 2015 will remain at 87.6 percent for submarine cable and 12.4 percent for satellite/terrestrial facilities.

- *International Services: (Terrestrial and Satellite Services)*: Regulatory fees for Terrestrial and Satellite International Bearer Circuits are to be paid by facilities-based common carriers that have active (used or leased) international bearer circuits as of December 31, 2014 in any terrestrial or satellite transmission facility for the provision of service to an end user or resale carrier. When calculating the number of such active circuits, the facilities-based common carriers must include circuits used by themselves or their affiliates. In addition, non-common carrier satellite operators must pay a fee for each circuit they and their affiliates hold and each circuit sold or leased to any customer, other than an international common carrier authorized by the Commission to provide U.S. international common carrier services. For these purposes, "active circuits" include backup and redundant circuits as of December 31, 2014. Whether circuits are used specifically for voice or data is not relevant for purposes of determining that they are active circuits.<sup>113</sup> In instances where a permit or license is transferred or assigned after October 1, 2014, responsibility for payment rests with the holder of the permit or license as of the fee due date. For regulatory fee purposes, the allocation in FY 2015 will remain at 87.6 percent for submarine cable and 12.4 percent for satellite/terrestrial facilities.<sup>114</sup>

<sup>113</sup> We encourage terrestrial and satellite service providers to seek guidance from the International Bureau's Policy Division to verify their IBC reporting processes to ensure that their calculation methods comply with our rules.

<sup>114</sup> We remind facilities-based common carriers to review their reporting processes to ensure that they accurately calculate and report IBCs. As we recently have done with submarine cable capacity holders,

*B. Commercial Mobile Radio Service (CMRS) Cellular and Mobile Services Assessments*

35. The Commission will compile data from the Numbering Resource Utilization Forecast (NRUF) report that is based on “assigned” telephone number (subscriber) counts that have been adjusted for porting to net Type 0 ports (“in” and “out”).<sup>115</sup> This information of telephone numbers (subscriber count) will be posted on the Commission’s electronic filing and payment system (Fee Filer) along with the carrier’s Operating Company Numbers (OCNs).

36. A carrier wishing to revise its telephone number (subscriber) count can do so by accessing Fee Filer and follow the prompts to revise their telephone number counts. Any revisions to the telephone number counts should be accompanied by an explanation or supporting documentation.<sup>116</sup> The Commission will then review the revised count and supporting documentation and either approve or disapprove the submission in Fee Filer. If the submission is disapproved, the Commission will contact the provider to afford the provider an opportunity to discuss its revised subscriber count and/or provide additional supporting documentation. If we receive no response from the provider, or we do not reverse our initial disapproval of the provider’s revised count submission, the fee payment must be based on the number of subscribers listed initially in Fee Filer. Once the timeframe for revision has passed, the telephone number counts are final and are the basis upon which CMRS regulatory fees are to be paid. Providers can view their final telephone counts online in Fee Filer. A final CMRS assessment letter will not be mailed out.

37. Because some carriers do not file the NRUF report, they may not see their telephone number counts in Fee Filer. In these instances, the carriers should compute their fee payment using the standard methodology that is currently in place for CMRS Wireless services (*i.e.*, compute their telephone number counts as of December 31, 2014), and submit their fee payment accordingly. Whether a carrier reviews its telephone

we will review the processes for reporting IBCs in the near future to ensure that all carriers are reporting IBCs in the same manner, consistent with our rules.

<sup>115</sup> See *FY 2005 Report and Order*, 20 FCC Rcd at 12264, paras. 38–44.

<sup>116</sup> In the supporting documentation, the provider will need to state a reason for the change, such as a purchase or sale of a subsidiary, the date of the transaction, and any other pertinent information that will help to justify a reason for the change.

number counts in Fee Filer or not, the Commission reserves the right to audit the number of telephone numbers for which regulatory fees are paid. In the event that the Commission determines that the number of telephone numbers that are paid is inaccurate, the Commission will bill the carrier for the difference between what was paid and what should have been paid.

*C. Enforcement*

38. To be considered timely, regulatory fee payments must be made electronically by the payment due date for regulatory fees. Section 9(c) of the Act requires us to impose a late payment penalty of 25 percent of the unpaid amount to be assessed on the first day following the deadline for filing these fees.<sup>117</sup> Failure to pay regulatory fees and/or any late penalty will subject regulatees to sanctions, including those set forth in section 1.1910 of the Commission’s rules,<sup>118</sup> which generally requires the Commission to withhold action on “applications, including on a petition for reconsideration or any application for review of a fee determination, or requests for authorization by any entity found to be delinquent in its debt to the Commission” and in the DCIA.<sup>119</sup> We also assess administrative processing charges on delinquent debts to recover additional costs incurred in processing and handling the debt pursuant to the DCIA and section 1.1940(d) of the Commission’s rules.<sup>120</sup> These administrative processing charges will be assessed on any delinquent regulatory fee, in addition to the 25 percent late charge penalty. In the case of partial payments (underpayments) of regulatory fees, the payor will be given credit for the amount paid, but if it is later determined that the fee paid is incorrect or not timely paid, then the 25 percent late charge penalty (and other charges and/or sanctions, as appropriate) will be assessed on the portion that is not paid in a timely manner.

39. Pursuant to the “red light rule,” we will withhold action on any applications or other requests for

<sup>117</sup> 47 U.S.C. 159(c).

<sup>118</sup> See 47 CFR 1.1910.

<sup>119</sup> Delinquent debt owed to the Commission triggers the “red light rule,” which places a hold on the processing of pending applications, fee offsets, and pending disbursement payments. 47 CFR 1.1910, 1.1911, 1.1912. In 2004, the Commission adopted rules implementing the requirements of the DCIA. See *Amendment of Parts 0 and 1 of the Commission’s Rules*, MD Docket No. 02–339, Report and Order, 19 FCC Rcd 6540 (2004); 47 CFR part 1, subpart O, Collection of Claims Owed the United States.

<sup>120</sup> 47 CFR 1.1940(d).

benefits filed by anyone who is delinquent in any non-tax debts owed to the Commission (including regulatory fees) and will ultimately dismiss those applications or other requests if payment of the delinquent debt or other satisfactory arrangement for payment is not made.<sup>121</sup> Failure to pay regulatory fees can also result in the initiation of a proceeding to revoke any and all authorizations held by the entity responsible for paying the delinquent fee(s).<sup>122</sup> Pursuant to a pilot program, we have initiated procedures to transfer debt to the Centralized Receivables Service at the U.S. Treasury, as described below.

*D. Transfers of Unpaid Debt to Centralized Receivables Service, U.S. Treasury*

40. Under section 9 of the Act, Commission’s rules, and federal debt collection laws, a licensee’s regulatory fee is due on the first day of the fiscal year and payable at a date established in the Commission’s annual regulatory fee Report and Order. Beginning on or after October 1, 2015, under revised procedures, the Commission will begin transferring unpaid regulatory fee receivables directly to the CRS at the U.S. Treasury instead of working to collect the debt and then transferring the remaining unpaid debts to Treasury. The Commission can transfer delinquent debt to Treasury for further collection action within 120 days after the date of delinquency.<sup>123</sup> We anticipate that the transfer of FY 2015 debts to Treasury will occur much sooner than our current process. Regulatees, however, will not likely see any substantial change in the current procedures of how past due debts are to be paid, except that the debts will be handled by CRS (U.S. Treasury) rather than by the Commission.

*E. Effective Date*

41. Providing a 30 day period after **Federal Register** publication before this *Report and Order* becomes effective as required by 5 U.S.C. 553(d) will not allow sufficient time for the Commission to collect the FY 2015 fees before FY 2015 ends on September 30, 2015. For this reason, pursuant to 5 U.S.C. 553(d)(3), the Commission finds there is good cause to waive the requirements of section 553(d), and this *Report and Order and Further Notice of Proposed Rulemaking* will become effective upon publication in the

<sup>121</sup> See 47 CFR 1.1161(c), 1.1164(f)(5), and 1.1910.

<sup>122</sup> 47 U.S.C. 159.

<sup>123</sup> See 31 U.S.C. 3711(g); 31 CFR 285.12; 47 CFR 1.1917.

**Federal Register.** Because payments of the regulatory fees will not actually be due until the middle of September,

persons affected by this *Report and Order* will still have a reasonable period in which to make their payments and

thereby comply with the rules established herein.

**VI. Additional Tables**

TABLE A

Commenter	Abbreviation
<b>List of Commenters—Initial Comments</b>	
ARSO Radio Corporation .....	ARSO.
Aviation Spectrum Resources, Inc., Airlines for America, Aircraft Owners and Pilots Association, Delta Airlines, Harris Corporation, Rockwell-Collins Information Management Services, Southwest Airlines Co., The Boeing Company, and SITA OnAir.	Aviation Joint Commenters.
DIRECTV, LLC .....	DIRECTV.
DISH Network, L.L.C. ....	DISH.
EchoStar Satellite Operating Corporation and Hughes Network Systems, LLC .....	EchoStar.
Intelsat Licensee, LLC .....	Intelsat.
ITTA—The Voice of Mid-Size Communications Companies .....	ITTA.
National Association of Broadcasters .....	NAB.
National Cable & Telecommunications Association and the American Cable Association .....	NCTA & ACA.
North American Submarine Cable Association .....	NASCA.
Puerto Rico Broadcasters Association, International Broadcasting Corporation, Eastern Television Corporation, America-CV Stations Group, Inc., R & F Broadcasting, Inc..	PRBA.
Satellite Industry Association .....	SIA.
Submarine Cable Coalition .....	Coalition.
<b>List of Commenters—Reply Comments</b>	
CTIA—The Wireless Association® .....	CTIA.
DIRECTV, LLC .....	DIRECTV.
DISH Network, L.L.C .....	DISH.
EchoStar Satellite Operating Corporation and Hughes Network Systems, LLC .....	EchoStar.
National Cable & Telecommunications Association and the American Cable Association .....	NCTA & ACA.
North American Submarine Cable Association .....	NASCA.
SES Americom, Inc., Inmarsat, Inc., Telesat Canada .....	Satellite Parties.
Submarine Cable Coalition .....	Coalition.

TABLE B—CALCULATION OF FY 2015 REVENUE REQUIREMENTS AND PRO-RATA FEES

[The first seven regulatory fees listed below are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.]

Fee category	FY 2015 payment units	Years	FY 2014 revenue estimate	Pro-rated FY 2015 revenue requirement	Computed FY 2015 regulatory fee	Rounded FY 2015 regulatory fee	Expected FY 2015 revenue
PLMRS (Exclusive Use) .....	1,820	10	595,000	589,899	32	30	546,000
PLMRS (Shared use) .....	31,000	10	3,000,000	2,822,788	9	10	3,100,000
Microwave .....	12,600	10	2,550,000	2,780,552	22	20	2,520,000
Marine (Ship) .....	6,300	10	780,000	927,085	15	15	945,000
Aviation (Aircraft) .....	4,200	10	420,000	420,954	10	10	420,000
Marine (Coast) .....	490	10	165,000	168,241	34	35	171,500
Aviation (Ground) .....	900	10	153,000	168,241	19	20	180,000
AM Class A <sup>4</sup> .....	65	1	274,700	280,935	4,322	4,325	281,125
AM Class B <sup>4</sup> .....	1,505	1	3,410,900	3,483,012	2,314	2,325	3,499,125
AM Class C <sup>4</sup> .....	889	1	1,212,750	1,245,750	1,401	1,400	1,244,600
AM Class D <sup>4</sup> .....	1,492	1	4,033,300	4,120,475	2,762	2,750	4,103,000
FM Classes A, B1 & C3 <sup>4</sup> .....	3,132	1	8,466,575	8,641,905	2,759	2,700	8,613,000
FM Classes B, C, C0, C1 & C2 <sup>4</sup> .....	3,143	1	10,437,175	10,595,484	3,371	3,375	10,607,625
AM Construction Permits <sup>1</sup> .....	29	1	17,700	17,110	590	590	17,110
FM Construction Permits <sup>1</sup> .....	182	1	138,750	136,500	750	750	136,500
Satellite TV .....	127	1	196,850	199,675	1,572	1,575	200,025
Digital TV Markets 1–10 .....	134	1	6,161,700	6,274,824	46,827	46,825	6,274,550
Digital TV Markets 11–25 .....	137	1	5,809,800	5,918,646	43,202	43,200	5,918,400
Digital TV Markets 26–50 .....	181	1	4,909,450	5,001,220	27,631	27,625	5,001,125
Digital TV Markets 51–100 .....	283	1	4,424,000	4,608,775	16,285	16,275	4,605,825
Digital TV Remaining Markets .....	379	1	1,805,000	1,834,853	4,841	4,850	1,838,150
Digital TV Construction Permits <sup>1</sup> .....	2	1	23,750	9,700	4,850	4,850	9,700
LPTV/Translators/Boosters/Class A TV .....	3,640	1	1,570,300	1,592,900	438	440	1,601,600
CARS Stations .....	300	1	196,625	197,876	660	660	198,000
Cable TV Systems, including IPTV ...	64,500,000	1	64,746,000	61,618,439	.955532	.96	61,920,000
Direct Broadcast Satellite (DBS) .....	34,000,000	1	.....	4,115,811	.1211	.12	4,080,000
Interstate Telecommunication Service Providers .....	\$38,800,000,000	1	131,369,000	128,607,682	0.0033146	0.00331	128,428,000
Toll Free Numbers .....	36,500,000	1	.....	4,419,018	0.12069	0.12	4,380,000
CMRS Mobile Services (Cellular/Public Mobile) .....	354,000,000	1	60,300,000	60,506,881	0.1737	0.17	60,180,000
CMRS Messag. Services .....	2,600,000	1	232,000	208,000	0.0800	0.080	208,000

TABLE B—CALCULATION OF FY 2015 REVENUE REQUIREMENTS AND PRO-RATA FEES—Continued

[The first seven regulatory fees listed below are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.]

Fee category	FY 2015 payment units	Years	FY 2014 revenue estimate	Pro-rated FY 2015 revenue requirement	Computed FY 2015 regulatory fee	Rounded FY 2015 regulatory fee	Expected FY 2015 revenue
BRS <sup>2</sup> .....	890	1	643,500	564,064	634	635	565,150
LMDS .....	375	1	135,850	237,667	634	635	238,125
Per 64 kbps Int'l Bearer Circuits .....	21,900,000	1	941,640	658,593	.0301	.03	657,000
Terrestrial (Common) & Satellite (Common & Non-Common) <sup>5</sup> .....							
Submarine Cable Providers (see chart in Appendix C) <sup>3,5</sup> .....	40,563	1	6,586,731	4,652,639	114,702	114,700	4,652,576
Earth Stations <sup>5</sup> .....	3,300	1	1,003,000	1,022,890	310	310	1,023,000
Space Stations (Geostationary) <sup>5</sup> .....	96	1	11,505,600	11,437,435	119,140	119,150	11,438,400
Space Stations (Non-Geostationary) <sup>5</sup> .....	6	1	797,100	792,693	132,116	132,125	792,750
***** Total Estimated Revenue to be Collected .....			339,847,246	341,879,214			340,593,961
***** Total Revenue Requirement .....			339,844,000	339,844,000			339,844,000
Difference .....			3,246	2,035,214			749,961

Notes on Table B

<sup>1</sup>The AM and FM Construction Permit revenues and the Digital (VHF/UHF) Construction Permit revenues were adjusted, respectively, to set the regulatory fee to an amount no higher than the lowest licensed fee for that class of service. Reductions in the Digital (VHF/UHF) Construction Permit revenues were also offset by increases in the revenue totals for various Digital television stations by market size, respectively.

<sup>2</sup>MDS/MMDS category was renamed Broadband Radio Service (BRS). See Amendment of Parts 1, 21, 73, 74 and 101 of the Commission's Rules to Facilitate the Provision of Fixed and Mobile Broadband Access, Educational and Other Advanced Services in the 2150–2162 and 2500–2690 MHz Bands, Report & Order and Further Notice of Proposed Rulemaking, 19 FCC Rcd 14165, 14169, para. 6 (2004).

<sup>3</sup>The chart at the end of Table C lists the submarine cable bearer circuit regulatory fees (common and non-common carrier basis) that resulted from the adoption of the FY 2008 Further Notice, 24 FCC Rcd 6388 and the Submarine Cable Order, 24 FCC Rcd 4208.

<sup>4</sup>The fee amounts listed in the column entitled "Rounded New FY 2015 Regulatory Fee" constitute a weighted average media regulatory fee by class of service. The actual FY 2015 regulatory fees for AM/FM radio station are listed on a grid located at the end of Table C.

<sup>5</sup>As a continuation of our regulatory fee reform for the submarine cable and bearer circuit fee categories, the allocation percentage for these two categories, in relation to the satellite (GSO and NGSO) and earth station fee categories, was reduced by approximately 7.5 per cent proportionally between the submarine cable and bearer circuit fee categories. This allocation reduction of 7.5 per cent resulted in an increase in the allocation for the satellite and earth station fee categories. In addition, four (4) International Bureau FTEs were changed from "direct" to "indirect", thereby reducing the International Bureau's overall FTE allocation percentage.

TABLE C—FY 2015 SCHEDULE OF REGULATORY FEES

[The first eight regulatory fees listed below are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.]

Fee category	Annual regulatory fee (U.S. \$'s)
PLMRS (per license) (Exclusive Use) (47 CFR part 90) .....	30
Microwave (per license) (47 CFR part 101) .....	20
Marine (Ship) (per station) (47 CFR part 80) .....	15
Marine (Coast) (per license) (47 CFR part 80) .....	35
Rural Radio (47 CFR part 22) (previously listed under the Land Mobile category) .....	10
PLMRS (Shared Use) (per license) (47 CFR part 90) .....	10
Aviation (Aircraft) (per station) (47 CFR part 87) .....	10
Aviation (Ground) (per license) (47 CFR part 87) .....	20
CMRS Mobile/Cellular Services (per unit) (47 CFR parts 20, 22, 24, 27, 80 and 90) .....	.17
CMRS Messaging Services (per unit) (47 CFR parts 20, 22, 24 and 90) .....	.08
Broadband Radio Service (formerly MMDS/MDS) (per license) (47 CFR part 27) .....	635
Local Multipoint Distribution Service (per call sign) (47 CFR, part 101) .....	635
AM Radio Construction Permits .....	590
FM Radio Construction Permits .....	750
Digital TV (47 CFR part 73) VHF and UHF Commercial:	
Markets 1–10 .....	46,825
Markets 11–25 .....	43,200
Markets 26–50 .....	27,625
Markets 51–100 .....	16,275
Remaining Markets .....	4,850
Construction Permits .....	4,850
Satellite Television Stations (All Markets) .....	1,575
Low Power TV, Class A TV, TV/FM Translators & Boosters (47 CFR part 74) .....	440
CARS (47 CFR part 78) .....	660
Cable Television Systems (per subscriber) (47 CFR part 76), Including IPTV .....	.96
Direct Broadcast Service (DBS) (per subscriber) (as defined by section 602(13) of the Act) .....	.12
Interstate Telecommunication Service Providers (per revenue dollar) .....	.00331
Toll Free (per toll free subscriber) (47 C.F.R. section 52.101 (f) of the rules) .....	.12
Earth Stations (47 CFR part 25) .....	310
Space Stations (per operational station in geostationary orbit) (47 CFR part 25) also includes DBS Service (per operational station) (47 CFR part 100) .....	119,150

TABLE C—FY 2015 SCHEDULE OF REGULATORY FEES—Continued

[The first eight regulatory fees listed below are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.]

Fee category	Annual regulatory fee (U.S. \$'s)
Space Stations (per operational system in non-geostationary orbit) (47 CFR part 25) .....	132,125
International Bearer Circuits—Terrestrial/Satellites (per 64KB circuit) .....	.03
Submarine Cable Landing Licenses Fee (per cable system) .....	See Table Below

FY 2015 SCHEDULE OF REGULATORY FEES:  
[Continued]

FY 2015 RADIO STATION REGULATORY FEES

Population served	AM Class A	AM Class B	AM Class C	AM Class D	FM Classes A, B1 & C3	FM Classes B, C, C0, C1 & C2
<=25,000 .....	\$775	\$645	\$590	\$670	\$750	\$925
25,001–75,000 .....	1,550	1,300	900	1,000	1,500	1,625
75,001–150,000 .....	2,325	1,625	1,200	1,675	2,050	3,000
150,001–500,000 .....	3,475	2,750	1,800	2,025	3,175	3,925
500,001–1,200,000 .....	5,025	4,225	3,000	3,375	5,050	5,775
1,200,001–3,000,00 .....	7,750	6,500	4,500	5,400	8,250	9,250
>3,000,000 .....	9,300	7,800	5,700	6,750	10,500	12,025

FY 2015 SCHEDULE OF REGULATORY FEES  
[International Bearer Circuits—Submarine Cable.]

Submarine Cable Systems (capacity as of December 31, 2014)	Fee amount
<2.5 Gbps .....	\$7,175
2.5 Gbps or greater, but less than 5 Gbps .....	14,350
5 Gbps or greater, but less than 10 Gbps .....	28,675
10 Gbps or greater, but less than 20 Gbps .....	57,350
20 Gbps or greater .....	114,700

**Table D—Sources of Payment Unit Estimates for FY 2015**

In order to calculate individual service fees for FY 2015, we adjusted FY 2014 payment units for each service to more accurately reflect expected FY 2015 payment liabilities. We obtained our updated estimates through a variety of means. For example, we used Commission licensee data bases, actual prior year payment records and industry and trade association projections when available. The databases we consulted include our Universal Licensing System (ULS), International Bureau Filing System (IBFS), Consolidated Database

System (CDBS) and Cable Operations and Licensing System (COALS), as well as reports generated within the Commission such as the Wireless Telecommunications Bureau's *Numbering Resource Utilization Forecast* report.

We sought verification for these estimates from multiple sources and, in all cases, we compared FY 2015 estimates with actual FY 2014 payment units to ensure that our revised estimates were reasonable. Where appropriate, we adjusted and/or rounded our final estimates to take into consideration the fact that certain variables that impact on the number of

payment units cannot yet be estimated with sufficient accuracy. These include an unknown number of waivers and/or exemptions that may occur in FY 2015 and the fact that, in many services, the number of actual licensees or station operators fluctuates from time to time due to economic, technical, or other reasons. When we note, for example, that our estimated FY 2015 payment units are based on FY 2014 actual payment units, it does not necessarily mean that our FY 2015 projection is exactly the same number as in FY 2014. We have either rounded the FY 2015 number or adjusted it slightly to account for these variables.

Fee category	Sources of payment unit estimates
Land Mobile (All), Microwave, Marine (Ship & Coast), Aviation (Aircraft & Ground), Domestic Public Fixed.	Based on Wireless Telecommunications Bureau (WTB) projections of new applications and renewals taking into consideration existing Commission licensee data bases. Aviation (Aircraft) and Marine (Ship) estimates have been adjusted to take into consideration the licensing of portions of these services on a voluntary basis.
CMRS Cellular/Mobile Services .....	Based on WTB projection reports, and FY 14 payment data.
CMRS Messaging Services .....	Based on WTB reports, and FY 14 payment data.
AM/FM Radio Stations .....	Based on CDBS data, adjusted for exemptions, and actual FY 2014 payment units.
Digital TV Stations (Combined VHF/UHF units) .....	Based on CDBS data, adjusted for exemptions, and actual FY 2014 payment units.
AM/FM/TV Construction Permits .....	Based on CDBS data, adjusted for exemptions, and actual FY 2014 payment units.

Fee category	Sources of payment unit estimates
LPTV, Translators and Boosters, Class A Television .....	Based on CDBS data, adjusted for exemptions, and actual FY 2014 payment units.
BRS (formerly MDS/MMDS) .....	Based on WTB reports and actual FY 2014 payment units.
LMDS .....	Based on WTB reports and actual FY 2014 payment units.
Cable Television Relay Service ("CARS") Stations .....	Based on data from Media Bureau's COALS database and actual FY 2013 payment units.
Cable Television System Subscribers, Including IPTV Subscribers.	Based on publicly available data sources for estimated subscriber counts and actual FY 2014 payment units.
Interstate Telecommunication Service Providers .....	Based on FCC Form 499-Q data for the four quarters of calendar year 2014, the Wireline Competition Bureau projected the amount of calendar year 2014 revenue that will be reported on 2015 FCC Form 499-A worksheets in April, 2015.
Earth Stations .....	Based on International Bureau ("IB") licensing data and actual FY 2014 payment units.
Space Stations (GSOs & NGSOs) .....	Based on IB data reports and actual FY 2014 payment units.
International Bearer Circuits .....	Based on IB reports and submissions by licensees, adjusted as necessary.
Submarine Cable Licenses .....	Based on IB license information.

**Table E—Factors, Measurements, and Calculations That Determines Station Signal Contours and Associated Population Coverages**

**AM Stations**

For stations with nondirectional daytime antennas, the theoretical radiation was used at all azimuths. For stations with directional daytime antennas, specific information on each day tower, including field ratio, phase, spacing, and orientation was retrieved, as well as the theoretical pattern root-mean-square of the radiation in all directions in the horizontal plane (RMS) figure (milliVolt per meter (mVm) @1 km) for the antenna system. The standard, or augmented standard if pertinent, horizontal plane radiation pattern was calculated using techniques and methods specified in sections 73.150 and 73.152 of the Commission's rules. Radiation values were calculated for each of 360 radials around the transmitter site. Next, estimated soil conductivity data was retrieved from a

database representing the information in FCC Figure R3. Using the calculated horizontal radiation values, and the retrieved soil conductivity data, the distance to the principal community (5 mVm) contour was predicted for each of the 360 radials. The resulting distance to principal community contours were used to form a geographical polygon. Population counting was accomplished by determining which 2010 block centroids were contained in the polygon. (A block centroid is the center point of a small area containing population as computed by the U.S. Census Bureau.) The sum of the population figures for all enclosed blocks represents the total population for the predicted principal community coverage area.

**FM Stations**

The greater of the horizontal or vertical effective radiated power (ERP) (kW) and respective height above average terrain (HAAT) (m) combination was used. Where the antenna height

above mean sea level (HAMSL) was available, it was used in lieu of the average HAAT figure to calculate specific HAAT figures for each of 360 radials under study. Any available directional pattern information was applied as well, to produce a radial-specific ERP figure. The HAAT and ERP figures were used in conjunction with the Field Strength (50–50) propagation curves specified in 47 CFR 73.313 of the Commission's rules to predict the distance to the principal community (70 dBu (decibel above 1 microVolt per meter) or 3.17 mVm) contour for each of the 360 radials. The resulting distance to principal community contours were used to form a geographical polygon. Population counting was accomplished by determining which 2010 block centroids were contained in the polygon. The sum of the population figures for all enclosed blocks represents the total population for the predicted principal community coverage area.

**TABLE F—FY 2014 SCHEDULE OF REGULATORY FEES**

[The first eleven regulatory fees listed below are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed]

Fee category	Annual regulatory fee (U.S. \$'s)
PLMRS (per license) (Exclusive Use) (47 CFR part 90) .....	35
Microwave (per license) (47 CFR part 101) .....	15
218–219 MHz (Formerly Interactive Video Data Service) (per license) (47 CFR part 95) .....	80
Marine (Ship) (per station) (47 CFR part 80) .....	15
Marine (Coast) (per license) (47 CFR part 80) .....	55
General Mobile Radio Service (per license) (47 CFR part 95) .....	5
Rural Radio (47 CFR part 22) (previously listed under the Land Mobile category) .....	10
PLMRS (Shared Use) (per license) (47 CFR part 90) .....	10
Aviation (Aircraft) (per station) (47 CFR part 87) .....	10
Aviation (Ground) (per license) (47 CFR part 87) .....	30
Amateur Vanity Call Signs (per call sign) (47 CFR part 97) .....	2.14
CMRS Mobile/Cellular Services (per unit) (47 CFR parts 20, 22, 24, 27, 80 and 90) .....	.18
CMRS Messaging Services (per unit) (47 CFR parts 20, 22, 24 and 90) .....	.08
Broadband Radio Service (formerly MMDS/MDS) (per license) (47 CFR part 27) .....	715
Local Multipoint Distribution Service (per call sign) (47 CFR, part 101) .....	715
AM Radio Construction Permits .....	590
FM Radio Construction Permits .....	750

TABLE F—FY 2014 SCHEDULE OF REGULATORY FEES—Continued

[The first eleven regulatory fees listed below are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed]

Fee category	Annual regulatory fee (U.S. \$'s)
Digital TV (47 CFR part 73) VHF and UHF Commercial:	
Markets 1–10 .....	44,650
Markets 11–25 .....	42,100
Markets 26–50 .....	26,975
Markets 51–100 .....	15,600
Remaining Markets .....	4,750
Construction Permits .....	4,750
Satellite Television Stations (All Markets) .....	1,550
Construction Permits—Satellite Television Stations .....	1,300
Low Power TV, Class A TV, TV/FM Translators & Boosters (47 CFR part 74) .....	410
Broadcast Auxiliaries (47 CFR part 74) .....	10
CARS (47 CFR part 78) .....	605
Cable Television Systems (per subscriber) (47 CFR part 76), Including IPTV .....	.99
Interstate Telecommunication Service Providers (per revenue dollar) .....	.00343
Earth Stations (47 CFR part 25) .....	295
Space Stations (per operational station in geostationary orbit) (47 CFR part 25) also includes DBS Service (per operational station) (47 CFR part 100) .....	122,400
Space Stations (per operational system in non-geostationary orbit) (47 CFR part 25) .....	132,850
International Bearer Circuits—Terrestrial/Satellites (per 64KB circuit) .....	.21
International Bearer Circuits—Submarine Cable .....	See Table Below

FY 2014 SCHEDULE OF REGULATORY FEES: MAINTAIN ALLOCATION

FY 2014 Radio Station Regulatory Fees						
Population served	AM Class A	AM Class B	AM Class C	AM Class D	FM Classes A, B1 & C3	FM Classes B, C, C0, C1 & C2
<=25,000 .....	\$775	\$645	\$590	\$670	\$750	\$925
25,001–75,000 .....	1,550	1,300	900	1,000	1,500	1,625
75,001–150,000 .....	2,325	1,625	1,200	1,675	2,050	3,000
150,001–500,000 .....	3,475	2,750	1,800	2,025	3,175	3,925
500,001–1,200,000 .....	5,025	4,225	3,000	3,375	5,050	5,775
1,200,001–3,000,000 .....	7,750	6,500	4,500	5,400	8,250	9,250
>3,000,000 .....	9,300	7,800	5,700	6,750	10,500	12,025

FY 2014 SCHEDULE OF REGULATORY FEES

[International Bearer Circuits—Submarine Cable]

Submarine cable systems (capacity as of December 31, 2013)	Fee amount
<2.5 Gbps .....	\$10,250
2.5 Gbps or greater, but less than 5 Gbps .....	20,500
5 Gbps or greater, but less than 10 Gbps .....	40,975
10 Gbps or greater, but less than 20 Gbps .....	81,950
20 Gbps or greater .....	163,900

VII. Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),<sup>124</sup> an Initial Regulatory Flexibility Analysis (IRFA) was included in the *Notice of Proposed Rulemaking*.<sup>125</sup> The Commission sought

written public comment on these proposals including comment on the IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the IRFA.<sup>126</sup>

A. Need for, and Objectives of, the Report and Order

2. In this Report and Order, we conclude the Assessment and Collection of Regulatory Fees for Fiscal Year (FY) 2015 proceeding to collect \$339,844,000 in regulatory fees for FY 2015, pursuant to section 9 of the Communications Act of 1934, as amended.<sup>127</sup> These regulatory fees will be due in September 2015. Under section 9 of the

<sup>124</sup> 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612 has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 847 (1996).

<sup>125</sup> *Assessment and Collection of Regulatory Fees for Fiscal Year 2015*, Notice of Proposed

Rulemaking, Report and Order, and Order, MD Docket No. 15–121, 30 FCC Rcd 5354 (2015) (FY 2015 NPRM).

<sup>126</sup> 5 U.S.C. 604.

<sup>127</sup> 47 U.S.C. 159.



Communications Act, regulatory fees are mandated by Congress and collected to recover the regulatory costs associated with the Commission's enforcement, policy and rulemaking, user information, and international activities in an amount that can be reasonably expected to equal the amount of the Commission's annual appropriation.<sup>128</sup>

3. This FY 2015 Report and Order adopts a regulatory fee schedule that includes the following noteworthy changes from prior years: (1) A reduction in regulatory fees for the submarine cable/terrestrial and satellite bearer circuit category relative to other fee categories in the International Bureau; (2) the first fee rate for Direct Broadcast Satellite (DBS) as a subcategory of the cable television and Internet Protocol Television (IPTV) regulatory fee category; (3) the first fee rate for toll free numbers; and (4) the elimination of the regulatory fee component of two fee categories: Amateur Radio Vanity Call Signs and General Mobile Radio Service (GMRS). In addition, in calculating the FY 2015 fee schedule, the Commission also reallocated four International Bureau full time employees (FTEs) as indirect.

4. With respect to the submarine cable/terrestrial and satellite bearer circuit fee category, after additional review, the Commission concluded that the fee assessed on the submarine cable/terrestrial and satellite bearer circuit fee category was excessive relative to the Commission's oversight and regulation of this industry. As a result, the Commission reduced the percentage of total fees paid by this fee category by 7.5 percent. With respect to the DBS fee category, the Commission instituted the DBS fee after realizing that Media Bureau resources were being used to address DBS and MVPD issues, but these costs were not being recovered from DBS providers. Therefore, the DBS fee is instituted to recover the cost of Media Bureau resources that is spent on MVPD and DBS issues. Similarly, a toll free number regulatory fee is instituted to recover the cost of resources expended by the Wireline Bureau on issues relating to toll free numbers. With respect to Amateur Radio Vanity Call Signs and General Mobile Radio Service (GMRS), the Commission concluded that the administrative costs of processing, reviewing, and enforcing the thousands of Vanity Call Sign and GMRS licenses far exceeds the \$21.40 and \$25 per license regulatory fee rate that is collected, respectively. Many of the Amateur Radio Vanity Call Signs and GMRS licensees are small businesses

and/or individuals. Finally, in calculating the FY 2015 fee schedule, the Commission reallocated four International Bureau full time employees (FTEs) as indirect to reflect work performed by International Bureau staff on non-U.S.-licensed space stations, who are not required to pay regulatory fees.

*B. Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA*

5. None.

*C. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply*

6. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and policies, if adopted.<sup>129</sup> The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."<sup>130</sup> In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.<sup>131</sup> A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.<sup>132</sup> Nationwide, there are a total of approximately 27.9 million small businesses, according to the SBA.<sup>133</sup>

1. Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as "establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities

that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry."<sup>134</sup> The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees.<sup>135</sup> Census data for 2007 shows that there were 3,188 firms that operated that year. Of this total, 3,144 operated with less than 1,000 employees.<sup>136</sup> Thus, under this size standard, the majority of firms in this industry can be considered small.

2. Local Exchange Carriers (LECs). Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable NAICS Code category is Wired Telecommunications Carriers as defined in paragraph 6 of this FRFA. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees.<sup>137</sup> According to Commission data, census data for 2007 shows that there were 3,188 firms that operated that year. Of this total, 3,144 operated with fewer than 1,000 employees.<sup>138</sup> The Commission therefore estimates that most providers of local exchange carrier service are small entities that may be affected by the rules adopted.

3. Incumbent LECs. Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. The closest applicable NAICS Code category is Wired Telecommunications Carriers as defined in paragraph 6 of this FRFA. Under that size standard, such a business is small if it has 1,500 or fewer employees.<sup>139</sup> According to Commission data, 3,188 firms operated in that year. Of this total, 3,144 operated

<sup>129</sup> 5 U.S.C. 603(b)(3).

<sup>130</sup> 5 U.S.C. 601(6).

<sup>131</sup> 5 U.S.C. 601(3) (incorporating by reference the definition of "small-business concern" in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**."

<sup>132</sup> 15 U.S.C. 632.

<sup>133</sup> See SBA, Office of Advocacy, "Frequently Asked Questions," [http://www.sba.gov/sites/default/files/FAQ\\_Sept\\_2012.pdf](http://www.sba.gov/sites/default/files/FAQ_Sept_2012.pdf).

<sup>134</sup> <http://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

<sup>135</sup> See 13 CFR 120.201, NAICS Code 517110.

<sup>136</sup> [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\\_2007\\_US\\_51SSSZ5&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5&prodType=table).

<sup>137</sup> 13 CFR 121.201, NAICS code 517110.

<sup>138</sup> [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\\_2007\\_US\\_51SSSZ5&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5&prodType=table).

<sup>139</sup> 13 CFR 121.201, NAICS code 517110.

<sup>128</sup> 47 U.S.C. 159(a).

with fewer than 1,000 employees.<sup>140</sup> Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by the rules and policies adopted. Three hundred and seven (307) Incumbent Local Exchange Carriers reported that they were incumbent local exchange service providers.<sup>141</sup> Of this total, an estimated 1,006 have 1,500 or fewer employees.<sup>142</sup>

4. Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers. Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate NAICS Code category is Wired Telecommunications Carriers, as defined in paragraph 6 of this FRFA. Under that size standard, such a business is small if it has 1,500 or fewer employees.<sup>143</sup> U.S. Census data for 2007 indicate that 3,188 firms operated during that year. Of that number, 3,144 operated with fewer than 1,000 employees.<sup>144</sup> Based on this data, the Commission concludes that the majority of Competitive LECs, CAPs, Shared-Tenant Service Providers, and Other Local Service Providers, are small entities. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services.<sup>145</sup> Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees.<sup>146</sup> In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees.<sup>147</sup> Also, 72 carriers have reported that they are Other Local Service Providers.<sup>148</sup> Of this total, 70 have 1,500 or fewer employees.<sup>149</sup> Consequently, based on internally researched FCC data, the Commission estimates that most

providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities that may be affected by the rules adopted.

5. Interexchange Carriers (IXCs). Neither the Commission nor the SBA has developed a definition for Interexchange Carriers. The closest NAICS Code category is Wired Telecommunications Carriers as defined in paragraph 6 of this FRFA. The applicable size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees.<sup>150</sup> U.S. Census data for 2007 indicates that 3,188 firms operated during that year. Of that number, 3,144 operated with fewer than 1,000 employees.<sup>151</sup> According to internally developed Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services.<sup>152</sup> Of this total, an estimated 317 have 1,500 or fewer employees.<sup>153</sup> Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by the rules adopted.

6. Prepaid Calling Card Providers. Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. The appropriate NAICS Code category for prepaid calling card providers is Telecommunications Resellers. This industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Mobile virtual networks operators (MVNOs) are included in this industry.<sup>154</sup> Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees.<sup>155</sup> U.S. Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000 employees.<sup>156</sup> Thus, under this category

and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities. According to Commission data, 193 carriers have reported that they are engaged in the provision of prepaid calling cards.<sup>157</sup> All 193 carriers have 1,500 or fewer employees.<sup>158</sup> Consequently, the Commission estimates that the majority of prepaid calling card providers are small entities that may be affected by the rules adopted.

7. Local Resellers. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees.<sup>159</sup> Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000 employees.<sup>160</sup> Under this category and the associated small business size standard, the majority of these local resellers can be considered small entities. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services.<sup>161</sup> Of this total, an estimated 211 have 1,500 or fewer employees.<sup>162</sup> Consequently, the Commission estimates that the majority of local resellers are small entities that may be affected by the rules adopted.

8. Toll Resellers. The Commission has not developed a definition for Toll Resellers. The closest NAICS Code Category is Telecommunications Resellers, and the SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees.<sup>163</sup> Census data for 2007 show that 1,523 firms provided resale services during that year. Of that number, 1,522 operated with fewer than 1,000 employees.<sup>164</sup> Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are

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<sup>157</sup> See *Trends in Telephone Service*, at Table 5.3.

<sup>158</sup> *Id.*

<sup>159</sup> 13 CFR 121.201, NAICS code 517911.

<sup>160</sup> *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\_2007\_US\_51SSSZ5&prodType=table.*

<sup>161</sup> See *Trends in Telephone Service*, at Table 5.3.

<sup>162</sup> *Id.*

<sup>163</sup> *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\_2007\_US\_51SSSZ5&prodType=table.*

<sup>164</sup> *Id.*

<sup>140</sup> *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\_2007\_US\_51SSSZ5&prodType=table.*

<sup>141</sup> See *Trends in Telephone Service*, Federal Communications Commission, Wireline Competition Bureau, Industry Analysis and Technology Division at Table 5.3 (Sept. 2010) (*Trends in Telephone Service*).

<sup>142</sup> *Id.*

<sup>143</sup> 13 CFR 121.201, NAICS code 517110.

<sup>144</sup> *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\_2007\_US\_51SSSZ5&prodType=table.*

<sup>145</sup> See *Trends in Telephone Service*, at Table 5.3.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> 13 CFR 121.201, NAICS code 517110.

<sup>151</sup> *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\_2007\_US\_51SSSZ5&prodType=table.*

<sup>152</sup> See *Trends in Telephone Service*, at Table 5.3.

<sup>153</sup> *Id.*

<sup>154</sup> *http://www.census.gov/cgi-bin/ssd/naics/naicsrch.*

<sup>155</sup> 13 CFR 121.201, NAICS code 517911.

<sup>156</sup> *http://factfinder.census.gov/faces/tableservices/jsf/pages/*

engaged in the provision of toll resale services.<sup>165</sup> Of this total, an estimated 857 have 1,500 or fewer employees.<sup>166</sup> Consequently, the Commission estimates that the majority of toll resellers are small entities that may be affected by the rules adopted.

9. Other Toll Carriers. Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable NAICS Code category is for Wired Telecommunications Carriers as defined in paragraph 6 of this FRFA. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees.<sup>167</sup> Census data for 2007 shows that there were 3,188 firms that operated that year. Of this total, 3,144 operated with fewer than 1,000 employees.<sup>168</sup> Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small. According to internally developed Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage.<sup>169</sup> Of these, an estimated 279 have 1,500 or fewer employees.<sup>170</sup> Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by the rules and policies adopted.

10. Wireless Telecommunications Carriers (except Satellite). This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves, such as cellular services, paging services, wireless internet access, and wireless video services.<sup>171</sup> The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, Census data for 2007 show that there were 1,383 firms that operated for the entire year. Of this total, 1,368 firms had fewer than 1,000 employees. Thus under this category and the associated size standard, the Commission estimates

that the majority of wireless telecommunications carriers (except satellite) are small entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) services.<sup>172</sup> Of this total, an estimated 261 have 1,500 or fewer employees.<sup>173</sup> Consequently, the Commission estimates that approximately half of these firms can be considered small. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

11. Cable Television and Other Subscription Programming.<sup>174</sup> Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers. That category is defined as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks.

<sup>172</sup> *Trends in Telephone Service*, at Table 5.3

<sup>173</sup> *Id.*

<sup>174</sup> In 2014, "Cable and Other Subscription Programming," NAICS Code 515210, replaced a prior category, now obsolete, which was called "Cable and Other Program Distribution." Cable and Other Program Distribution, prior to 2014, was placed under NAICS Code 517110, Wired Telecommunications Carriers. Wired Telecommunications Carriers is still a current and valid NAICS Code Category. Because of the similarity between "Cable and Other Subscription Programming" and "Cable and other Program Distribution," we will, in this proceeding, continue to use Wired Telecommunications Carrier data based on the U.S. Census. The alternative of using data gathered under Cable and Other Subscription Programming (NAICS Code 515210) is unavailable to us for two reasons. First, the size standard established by the SBA for Cable and Other Subscription Programming is annual receipts of \$38.5 million or less. Thus to use the annual receipts size standard would require the Commission either to switch from existing employee based size standard of 1,500 employees or less for Wired Telecommunications Carriers, or else would require the use of two size standards. No official approval of either option has been granted by the Commission as of the time of the release of the *FY 2015 NPRM*. Second, the data available under the size standard of \$38.5 million dollars or less is not applicable at this time, because the only currently available U.S. Census data for annual receipts of all businesses operating in the NAICS Code category of 515210 (Cable and other Subscription Programming) consists only of total receipts for all businesses operating in this category in 2007 and of total annual receipts for all businesses operating in this category in 2012. The data do not provide any basis for determining, for either year, how many businesses were small because they had annual receipts of \$38.5 million or less. See [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\\_2012\\_US\\_5112&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2012_US_5112&prodType=table).

Transmission facilities may be based on a single technology or a combination of technologies."<sup>175</sup> The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees.<sup>176</sup> Census data for 2007 shows that there were 3,188 firms that operated that year. Of this total, 3,144 had fewer than 1,000 employees.<sup>177</sup> Thus under this size standard, the majority of firms offering cable and other program distribution services can be considered small and may be affected by rules adopted.

12. Cable Companies and Systems. The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a "small cable company" is one serving 400,000 or fewer subscribers nationwide.<sup>178</sup> Industry data indicate that there are currently 4,600 active cable systems in the United States.<sup>179</sup> Of this total, all but ten cable operators nationwide are small under the 400,000-subscriber size standard.<sup>180</sup> In addition, under the Commission's rate regulation rules, a "small system" is a cable system serving 15,000 or fewer subscribers.<sup>181</sup> Current Commission records show 4,600 cable systems nationwide.<sup>182</sup> Of this total, 3,900 cable systems have less than 15,000 subscribers, and 700 systems have 15,000 or more subscribers, based on the same records.<sup>183</sup> Thus, under this standard as well, we estimate that most cable systems are small entities.

13. Cable System Operators (Telecom Act Standard). The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is "a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual

<sup>175</sup> U.S. Census Bureau, 2007 NAICS Definitions, "517110 Wired Telecommunications Carriers" (partial definition), (Full definition stated in paragraph 6 of this IRFA) available at <http://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

<sup>176</sup> 13 CFR 121.201, NAICS code 517110.

<sup>177</sup> [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\\_2007\\_US\\_51SSSZ5&prodType=Table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5&prodType=Table).

<sup>178</sup> 47 CFR 76.901(e).

<sup>179</sup> August 15, 2015 Report from the Media Bureau based on data contained in the Commission's Cable Operations And Licensing System (COALS). See [www.fcc.gov/coals](http://www.fcc.gov/coals).

<sup>180</sup> See SNL KAGAN at [https://snl.cominteractiveX\\_top\\_cable\\_MSOs.aspx?period=2015Q1&sortcal=subscribersbasic&sortorder=desc](https://snl.cominteractiveX_top_cable_MSOs.aspx?period=2015Q1&sortcal=subscribersbasic&sortorder=desc).

<sup>181</sup> 47 CFR 76.901(c)

<sup>182</sup> See footnote 2, supra.

<sup>183</sup> August 5, 2015 report from the Media Bureau based on its research in COALS. See [www.fcc.gov/coals](http://www.fcc.gov/coals).

<sup>165</sup> *Trends in Telephone Service*, at Table 5.3.

<sup>166</sup> *Id.*

<sup>167</sup> 13 CFR 121.201, NAICS code 517110.

<sup>168</sup> [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\\_2007\\_US\\_51SSSZ5&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5&prodType=table).

<sup>169</sup> *Trends in Telephone Service*, at Table 5.3.

<sup>170</sup> *Id.*

<sup>171</sup> NAICS Code 517210. See <http://www.census.gov/cgi-bin/ssd/naics/naicsrch>.

revenues in the aggregate exceed \$250,000,000.”<sup>184</sup> There are approximately 52,403,705 cable video subscribers in the United States today.<sup>185</sup> Accordingly, an operator serving fewer than 524,037 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed \$250 million in the aggregate.<sup>186</sup> Based on available data, we find that all but nine incumbent cable operators are small entities under this size standard.<sup>187</sup> We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed \$250 million.<sup>188</sup> Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed \$250,000,000, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

14. All Other Telecommunications. “All Other Telecommunications” is defined as follows: This U.S. industry is comprised of establishments that are primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry.<sup>189</sup> The SBA has developed a small business size standard for “All Other Telecommunications,” which consists of all such firms with gross annual receipts of \$32.5 million or

less.<sup>190</sup> For this category, census data for 2007 show that there were 2,383 firms that operated for the entire year. Of these firms, a total of 2,346 had gross annual receipts of less than \$25 million.<sup>191</sup> Thus, a majority of “All Other Telecommunications” firms potentially affected by the rules adopted can be considered small.

#### D. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

15. This Report and Order does not adopt any new reporting, recordkeeping, or other compliance requirements.

#### E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

16. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its approach, which may include the following four alternatives, among others: (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.<sup>192</sup>

17. This Report and Order does not adopt any new reporting requirements. Therefore no adverse economic impact on small entities will be sustained based on reporting requirements. There will be a regulatory fee instituted on DBS providers due to the adoption of a new fee category, but we anticipate that the two primary DBS companies required to pay these fees are not small entities. Similarly, a new regulatory fee for Responsible Organizations (Resp. Org) has also been instituted in FY 2015 for the toll free number fee category that was previously adopted—the fee rate adopted is 12 cents per year. This is not a new reporting requirement, and should not have any adverse economic impact on small Resp. Org. entities because they are able to recover these assessed fees from their customers.

18. In keeping with the requirements of the Regulatory Flexibility Act, we have considered certain alternative means of mitigating the effects of fee increases to a particular industry segment. For example, beginning in FY

2015 the Commission has increased the *de minimis* threshold from under \$10 to \$500 (the total of all regulatory fees), which will impact many small entities that pay regulatory fees for ITSP, paging, cellular, cable, and Low Power Television/FM Translators. Historically, many of these small entities have been late in making their fee payments to the Commission by the due date. This increase in the *de minimis* threshold to \$500 will relieve regulatees both financially and administratively. Finally, regulatees may also seek waivers or other relief on the basis of financial hardship. See 47 CFR 1.1166.

#### F. Federal Rules That May Duplicate, Overlap, or Conflict

19. None.

### VIII. Ordering Clauses

20. Accordingly, *it is ordered* that, pursuant to sections 4(i) and (j), 9, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 159, and 303(r), this Report and Order and Further Notice of Proposed Rulemaking is hereby adopted.

21. *It is further ordered* that, as provided in paragraph 41, this Report and Order and Further Notice of Proposed Rulemaking shall be effective September 17, 2015.

22. *It is further ordered* that the Commission’s Consumer & Governmental Affairs Bureau, Reference Information Center, shall send a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the U.S. Small Business Administration.

Federal Communications Commission.

**Marlene H. Dortch.**

Secretary.

#### List of Subjects in 47 CFR Part 1

Administrative practice and procedure. Lawyers, Metric system, Penalties, Reporting and recordkeeping requirements, Telecommunications.

#### Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR, part 1 as follows:

### PART 1—PRACTICE AND PROCEDURE

■ 1. The authority citation for part 1 continues to read as follows:

**Authority:** 15 U.S.C. 79, *et seq.*; 47 U.S.C. 151, 154(i), 154(j), 155, 157, 160, 201, 225, 227, 303, 309, 332, 1403, 1404, 1451, 1452, and 1455.

■ 2. Section 1.1152 is revised to read as follows:

<sup>184</sup> 47 CFR 901 (f) and notes ff. 1, 2, and 3.

<sup>185</sup> See SNL KAGAN at <https://www.snl.com/interactivex/MultichannelIndustryBenchmarks.aspx>.

<sup>186</sup> 47.901(f) and notes ff. 1, 2, and 3.

<sup>187</sup> See SNL KAGAN at [www.snl.com/Interactivex/TopCableMSOs.aspx](http://www.snl.com/Interactivex/TopCableMSOs.aspx)

<sup>188</sup> The Commission does receive such information on a case-by-case basis if a cable operator appeals a local franchise authority’s finding that the operator does not qualify as a small cable operator pursuant to 76.901(f) of the Commission’s rules. See 47 CFR 76.901(f).

<sup>189</sup> <http://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

<sup>190</sup> 13 CFR 121.201; NAICS Code 517919.

<sup>191</sup> [http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN\\_2007\\_US\\_51SSSZ5&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5&prodType=table).

<sup>192</sup> 5 U.S.C. 603(c)(1) through (c)(4).

**§ 1.1152 Schedule of annual regulatory fees for wireless radio services.**

Exclusive use services (per license)	Fee amount <sup>1</sup>
1. Land Mobile (Above 470 MHz and 220 MHz Local, Base Station & SMRS) (47 CFR part 90):	
(a) New, Renew/Mod (FCC 601 & 159) .....	\$30.00
(b) New, Renew/Mod (Electronic Filing) (FCC 601 & 159) .....	30.00
(c) Renewal Only (FCC 601 & 159) .....	30.00
(d) Renewal Only (Electronic Filing) (FCC 601 & 159) .....	30.00
220 MHz Nationwide:	
(a) New, Renew/Mod (FCC 601 & 159) .....	30.00
(b) New, Renew/Mod (Electronic Filing) (FCC 601 & 159) .....	30.00
(c) Renewal Only (FCC 601 & 159) .....	30.00
(d) Renewal Only (Electronic Filing) (FCC 601 & 159) .....	30.00
2. Microwave (47 CFR part 101) (Private):	
(a) New, Renew/Mod (FCC 601 & 159) .....	20.00
(b) New, Renew/Mod (Electronic Filing) (FCC 601 & 159) .....	20.00
(c) Renewal Only (FCC 601 & 159) .....	20.00
(d) Renewal Only (Electronic Filing) (FCC 601 & 159) .....	20.00
3. Shared Use Services:	
Land Mobile (Frequencies Below 470 MHz—except 220 MHz):	
(a) New, Renew/Mod (FCC 601 & 159) .....	10.00
(b) New, Renew/Mod (Electronic Filing) (FCC 601 & 159) .....	10.00
(c) Renewal Only (FCC 601 & 159) .....	10.00
(d) Renewal Only (Electronic Filing) (FCC 601 & 159) .....	10.00
Rural Radio (Part 22):	
(a) New, Additional Facility, Major Renew/Mod (Electronic Filing) (FCC 601 & 159) .....	10.00
(b) Renewal, Minor Renew/Mod (Electronic Filing) (FCC 601 & 159) .....	10.00
Marine Coast:	
(a) New Renewal/Mod (FCC 601 & 159) .....	35.00
(b) New, Renewal/Mod (Electronic Filing) (FCC 601 & 159) .....	35.00
(c) Renewal Only (FCC 601 & 159) .....	35.00
(d) Renewal Only (Electronic Filing) (FCC 601 & 159) .....	35.00
Aviation Ground:	
(a) New, Renewal/Mod (FCC 601 & 159) .....	20.00
(b) New, Renewal/Mod (Electronic Filing) (FCC 601 & 159) .....	20.00
(c) Renewal Only (FCC 601 & 159) .....	20.00
(d) Renewal Only (Electronic Only) (FCC 601 & 159) .....	20.00
Marine Ship:	
(a) New, Renewal/Mod (FCC 605 & 159) .....	15.00
(b) New, Renewal/Mod (Electronic Filing) (FCC 605 & 159) .....	15.00
(c) Renewal Only (FCC 605 & 159) .....	15.00
(d) Renewal Only (Electronic Filing) (FCC 605 & 159) .....	15.00
Aviation Aircraft:	
(a) New, Renew/Mod (FCC 605 & 159) .....	10.00
(b) New, Renew/Mod (Electronic Filing) (FCC 605 & 159) .....	10.00
(c) Renewal Only (FCC 605 & 159) .....	10.00
(d) Renewal Only (Electronic Filing) (FCC 605 & 159) .....	10.00
4. CMRS Cellular/Mobile Services (per unit) (FCC 159) .....	<sup>2</sup> .17
5. CMRS Messaging Services (per unit) (FCC 159) .....	<sup>3</sup> .08
6. Broadband Radio Service (formerly MMDS and MDS) .....	635
7. Local Multipoint Distribution Service .....	635

■ 3. Section 1.1153 is revised to read as follows:

**§ 1.1153 Schedule of annual regulatory fees and filing locations for mass media services.**

	Fee amount
Radio [AM and FM] (47 CFR part 73):	
1. <i>AM Class A</i> :	
<=25,000 population .....	\$775
25,001–75,000 population .....	1,550
75,001–150,000 population .....	2,325
150,001–500,000 population .....	3,475

<sup>1</sup> Note that “small fees” are collected in advance for the entire license term. Therefore, the annual fee amount shown in this table that is a small fee (categories 1 through 5) must be multiplied by the

5- or 10-year license term, as appropriate, to arrive at the total amount of regulatory fees owed. Also, application fees may apply as detailed in § 1.1102 of this chapter.

<sup>2</sup> These are standard fees that are to be paid in accordance with § 1.1157(b) of this chapter.

<sup>3</sup> These are standard fees that are to be paid in accordance with 1.1157(b) of this chapter.

	Fee amount
500,001–1,200,000 population .....	5,025
1,200,001–3,000,000 population .....	7,750
>3,000,000 population .....	9,300
<b>2. AM Class B:</b>	
<=25,000 population .....	645
25,001–75,000 population .....	1,300
75,001–150,000 population .....	1,625
150,001–500,000 population .....	2,750
500,001–1,200,000 population .....	4,225
1,200,001–3,000,000 population .....	6,500
>3,000,000 population .....	7,800
<b>3. AM Class C:</b>	
<=25,000 population .....	590
25,001–75,000 population .....	900
75,001–150,000 population .....	1,200
150,001–500,000 population .....	1,800
500,001–1,200,000 population .....	3,000
1,200,001–3,000,000 population .....	4,500
>3,000,000 population .....	5,700
<b>4. AM Class D:</b>	
<=25,000 population .....	670
25,001–75,000 population .....	1,000
75,001–150,000 population .....	1,675
150,001–500,000 population .....	2,025
500,001–1,200,000 population .....	3,375
1,200,001–3,000,000 population .....	5,400
>3,000,000 population .....	6,750
<b>5. AM Construction Permit</b> .....	590
<b>6. FM Classes A, B1 and C3:</b>	
<=25,000 population .....	750
25,001–75,000 population .....	1,500
75,001–150,000 population .....	2,050
150,001–500,000 population .....	3,175
500,001–1,200,000 population .....	5,050
1,200,001–3,000,000 population .....	8,250
>3,000,000 population .....	10,500
<b>7. FM Classes B, C, C0, C1 and C2:</b>	
<=25,000 population .....	925
25,001–75,000 population .....	1,625
75,001–150,000 population .....	3,000
150,001–500,000 population .....	3,925
500,001–1,200,000 population .....	5,775
1,200,001–3,000,000 population .....	9,250
>3,000,000 population .....	12,025
<b>8. FM Construction Permits</b> .....	750
<b>TV (47 CFR part 73) Digital TV (UHF and VHF Commercial Stations):</b>	
1. Markets 1 thru 10 .....	46,825
2. Markets 11 thru 25 .....	43,200
3. Markets 26 thru 50 .....	27,625
4. Markets 51 thru 100 .....	16,275
5. Remaining Markets .....	4,850
6. Construction Permits .....	4,850
<b>Satellite UHF/VHF Commercial:</b>	
1. All Markets .....	1,575
<b>Low Power TV, Class A TV, TV/FM Translator, &amp; TV/FM Booster (47 CFR part 74)</b> .....	440

■ 4. Section 1.1154 is revised to read as follows:

**§ 1.1154 Schedule of annual regulatory charges for common carrier services.**

	Fee amount
<b>Radio Facilities:</b>	
1. Microwave (Domestic Public Fixed) (Electronic Filing) (FCC Form 601 & 159) .....	\$20.00.
<b>Carriers:</b>	
1. Interstate Telephone Service Providers (per interstate and international end-user revenues (see FCC Form 499–A) .....	\$.00331.
2. Toll Free Number Fee .....	.12 per Toll Free Number.

■ 5. Section 1.1155 is revised to read as follows:

**§ 1.1155 Schedule of regulatory fees for cable television services.**

	Fee amount
1. Cable Television Relay Service .....	\$660.
2. Cable TV System, Including IPTV (per subscriber) .....	0.96.
3. Direct Broadcast Satellite (DBS) .....	\$.12 per subscriber.

■ 6. Section 1.1156 is revised to read as follows:

**§ 1.1156 Schedule of regulatory fees for international services.**

(a) The following schedule applies for the listed services:

Fee category	Fee amount
Space Stations (Geostationary Orbit) .....	\$119,150
Space Stations (Non-Geostationary Orbit) .....	132,125
Earth Stations: Transmit/Receive & Transmit only (per authorization or registration) .....	310

(b) *International Terrestrial and Satellite*. Regulatory fees for International Bearer Circuits are to be paid by facilities-based common carriers that have active (used or leased) international bearer circuits as of December 31 of the prior year in any terrestrial or satellite transmission facility for the provision of service to an end user or resale carrier, which

includes active circuits to themselves or to their affiliates. In addition, non-common carrier satellite operators must pay a fee for each circuit sold or leased to any customer, including themselves or their affiliates, other than an international common carrier authorized by the Commission to provide U.S. international common carrier services. "Active circuits" for

these purposes include backup and redundant circuits. In addition, whether circuits are used specifically for voice or data is not relevant in determining that they are active circuits.

The fee amount, per active 64 KB circuit or equivalent will be determined for each fiscal year.

International terrestrial and satellite (capacity as of December 31, 2014)	Fee amount
Terrestrial Common Carrier Satellite Common Carrier Satellite Non-Common Carrier .....	\$0.03 per 64 KB Circuit.

(c) *Submarine cable*: Regulatory fees for submarine cable systems will be paid annually, per cable landing license,

for all submarine cable systems operating as of December 31 of the prior

year. The fee amount will be determined by the Commission for each fiscal year.

Submarine cable systems (capacity as of December 31, 2014)	Fee amount
<2.5 Gbps .....	\$7,175
2.5 Gbps or greater, but less than 5 Gbps .....	14,350
5 Gbps or greater, but less than 10 Gbps .....	28,675
10 Gbps or greater, but less than 20 Gbps .....	57,350
20 Gbps or greater .....	114,700

[FR Doc. 2015-23312 Filed 9-16-15; 8:45 am]  
BILLING CODE 6712-01-P

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Parts 27 and 74**

[GN Docket No. 12-268; FCC 14-50]

**Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions**

AGENCY: Federal Communications Commission.

**ACTION:** Final rule; announcement of effective date.

**SUMMARY:** In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, certain information collection requirements associated with the Commission's Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions Report and Order (*Incentive Auction Report and Order*), FCC 14-50. This document is consistent with the

*Incentive Auction Report and Order*, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the new information collection requirements.

**DATES:** The amendments to 47 CFR 27.14(k), 27.14(t)(6), 27.17(c), 27.19(b), 27.19(c), 74.602(h)(5)(ii), and 74.602(h)(5)(iii), published at 79 FR 48442, August 15, 2014, are effective on September 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** Cathy Williams by email at

Cathy.Williams@fcc.gov and telephone at (202) 418-2918.

**SUPPLEMENTARY INFORMATION:** This document announces that, on August 27, 2015, OMB approved certain information collection requirements contained in the Commission's *Incentive Auction Report and Order*, FCC 14-50, published at 79 FR 48442, August 15, 2014. The OMB Control Number is 3060-1180. The Commission publishes this document as an announcement of the effective date of these information collection requirements.

### Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on August 27, 2015, for the new information collection requirements contained in the Commission's rules at 47 CFR 27.14(k), 27.14(t)(6), 27.17(c), 27.19(b), 27.19(c), 74.602(h)(5)(ii), 74.602(h)(5)(iii). Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060-1180.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104-13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

*OMB Control Number:* 3060-1180.

*OMB Approval Date:* August 27, 2015.

*OMB Expiration Date:* August 31, 2018.

*Title:* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions.

*Form Number:* N/A.

*Respondents:* Business or other for-profit entities, state, local, or tribal government and not for profit institutions.

*Number of Respondents and Responses:* 378 respondents and 378 responses.

*Estimated Time per Response:* .5 hours-2 hours.

*Frequency of Response:* One-time and on occasion reporting requirements, twice within 12 years reporting requirement, 6, 10 and 12-years reporting requirements and third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for these collections are contained in 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 325(b), 332, 336(f), 338, 339, 340, 399b, 403, 534, 535, 1404, 1452, and 1454 of the Communications Act of 1934.

*Total Annual Burden:* 581 hours.

*Total Annual Cost:* No cost.

*Privacy Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Needs and Uses:* The FCC adopted the Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions Report and Order, FCC 14-50, on May 15, 2014, published at 79 FR 48442 (Aug. 15, 2014). The Commission sought approval from the Office of Management and Budget (OMB) for some of the information collection requirements contained in FCC 14-50. The Commission will use the information to ensure compliance with required filings of notifications, certifications, license renewals, license cancellations, and license modifications. Also, such information will be used to minimize interference and to determine compliance with Commission's rules.

The following is a description of the information collection requirements for which the Commission sought OMB approval:

Section 27.14(k) requires 600 MHz licensees to demonstrate compliance with performance requirements by filing a construction notification with the Commission, within 15 days of the applicable benchmark.

Section 27.14(t)(6) requires 600 MHz licensees to make a renewal showing as a condition of each renewal. The showing must include a detailed description of the applicant's provision of service during the entire license period and address: (i) The level and quality of service provided by the applicant (including the population served, the area served, the number of subscribers, the services offered); (ii) the date service commenced, whether service was ever interrupted, and the duration of any interruption or outage; (iii) the extent to which service is provided to rural areas; (iv) the extent to which service is provided to qualifying tribal land as defined in 47 CFR 1.2110(f)(3)(i); and (v) any other factors associated with the level of service to the public.

Section 27.17(c) requires 600 MHz licensees to notify the Commission

within 10 days of discontinuance if they permanently discontinue service by filing FCC Form 601 or 605 and requesting license cancellation.

Section 27.19(b) requires 600 MHz licensees with base and fixed stations in the 600 MHz downlink band within 25 kilometers of Very Long Baseline Array (VLBA) observatories to coordinate with the National Science Foundation (NSF) prior to commencing operations.

Section 27.19(c) requires 600 MHz licensees that intend to operate base and fixed stations in the 600 MHz downlink band in locations near the Radio Astronomy Observatory site located in Green Bank, Pocahontas County, West Virginia, or near the Arecibo Observatory in Puerto Rico, to comply with the provisions in 47 CFR 1.924.

Section 74.602(h)(5)(ii) requires 600 MHz licensees to notify the licensee of a studio-transmitter link (TV STL), TV relay station, or TV translator relay station of their intent to commence wireless operations and the likelihood of harmful interference from the TV STL, TV relay station, or TV translator relay station to those operations within the wireless licensee's licensed geographic service area. The notification is to be in the form of a letter, via certified mail, return receipt requested and must be sent not less than 30 days in advance of approximate date of commencement of operations.

Section 74.602(h)(5)(iii) requires all TV STL, TV relay station and TV translator relay station licensees to modify or cancel their authorizations and vacate the 600 MHz band no later than the end of the post-auction transition period as defined in 47 CFR 27.4.

These rules which contain information collection requirements are designed to provide for flexible use of this spectrum by allowing licensees to choose their type of service offerings, to encourage innovation and investment in mobile broadband use in this spectrum, and to provide a stable regulatory environment in which broadband deployment would be able to develop through the application of standard terrestrial wireless rules. Without this information, the Commission would not be able to carry out its statutory responsibilities.

Federal Communications Commission.

**Marlene H. Dortch,**  
*Secretary.*

[FR Doc. 2015-22595 Filed 9-16-15; 8:45 am]

**BILLING CODE 6712-01-P**



# Proposed Rules

Federal Register

Vol. 80, No. 180

Thursday, September 17, 2015

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF ENERGY

[Docket No. EERE-2015-BT-TP-0015]

RIN 1904-AD54

### Energy Conservation Program: Test Procedures for Small, Large, and Very Large Air-Cooled Commercial Package Air Conditioning and Heating Equipment

**AGENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Proposed rule; reopening of public comment period.

**SUMMARY:** On August 6, 2015, the U.S. Department of Energy (DOE) published a notice of proposed rulemaking (NPR) in the **Federal Register** regarding proposed amendments to the test procedures for small, large, and very large air-cooled commercial package air conditioning and heating equipment. DOE also held a related public meeting on September 4, 2015. The comment period for the NPR was scheduled to end September 8, 2015. After receiving a request for an additional two weeks to comment, DOE has decided to reopen the comment period for submitting comments and data in response to the NPR regarding test procedures for small, large, and very large air-cooled commercial package air conditioning and heating equipment. The comment period is extended.

**DATES:** The comment period for the NPR regarding test procedures for small, large, and very large air-cooled commercial package air conditioning and heating equipment published on August 6, 2015 (80 FR 46870) is reopened. DOE will accept comments, data, and information in response to the NPR received no later than October 2, 2015.

**ADDRESSES:** Any comments submitted must identify the NPR for Test Procedures for Small, Large, and Very Large Air-Cooled Commercial Package Air Conditioning and Heating Equipment, and provide docket number

EERE-2015-BT-TP-0015 and/or regulatory information number (RIN) number 1904-AD54. Interested persons may submit comments using any of the following methods:

1. *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.

2. *Email:* [CommPkgACHeat2015TP0015@ee.doe.gov](mailto:CommPkgACHeat2015TP0015@ee.doe.gov). Include the docket number EERE-2015-BT-TP-0015 and/or RIN 1904-AD54 in the subject line of the message.

3. *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586-2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see section V (Public Participation) of the August 6, 2015 NPR for test procedures for small, large, and very large air-cooled commercial package air conditioning and heating equipment.

**Docket:** The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at [www.regulations.gov](http://www.regulations.gov). All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. However, not all documents listed in the index may be publicly available, such as those containing information that is exempt from public disclosure.

A link to the docket Web page can be found at: [[www.regulations.gov/#!docketDetail;D=EERE-2015-BT-TP-0015](http://www.regulations.gov/#!docketDetail;D=EERE-2015-BT-TP-0015)]. This Web page contains a link to the docket for this NPR on the [www.regulations.gov](http://www.regulations.gov) site. The [www.regulations.gov](http://www.regulations.gov) Web page contains simple instructions on how to access all documents, including public comments, in the docket.

**FOR FURTHER INFORMATION CONTACT:** Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-6590. Email: [Ashley.Armstrong@ee.doe.gov](mailto:Ashley.Armstrong@ee.doe.gov).

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-8145. Email: [Michael.Kido@hq.doe.gov](mailto:Michael.Kido@hq.doe.gov).

For further information on how to submit a comment or review other public comments and the docket, contact Ms. Brenda Edwards at (202) 586-2945 or by email: [Brenda.Edwards@ee.doe.gov](mailto:Brenda.Edwards@ee.doe.gov).

**SUPPLEMENTARY INFORMATION:** The Energy Policy and Conservation Act of 1975 (EPCA), as amended, requires DOE to conduct an evaluation of its test procedures at least once every seven years for each class of covered equipment (including the equipment that is the subject of this rulemaking) to determine if an amended test procedure would more accurately or fully comply with the requirement to be reasonably designed to produce test results that reflect the energy efficiency, energy use, and operating costs during a representative average use cycle. DOE must either prescribe amended test procedures or publish a notice in the **Federal Register** regarding its determination not to amend test procedures. (42 U.S.C. 6314(a)(1)-(2))

On August 6, 2015, DOE published a notice of proposed rulemaking (NPR) in the **Federal Register** regarding potential amendments to the test procedures for small, large, and very large air-cooled commercial package air conditioning and heating equipment (80 FR 46870). The notice provided for the submission of written comments by September 8, 2015, and oral comments were also accepted at a public meeting held on September 4, 2015.

On September 4, 2015, DOE received a request from Goodman Manufacturing Co., seeking an additional two weeks to prepare and submit comments. On September 8, 2015, DOE received a request from Lennox International seeking an additional 30 days to review the technical aspects of the proposed test procedure. After careful

consideration of this request, DOE has determined that extending the public comment period by reopening to allow additional time for interested parties to submit comments is appropriate based on the foregoing reasons. Accordingly, DOE has decided to grant the request and reopen the public comment period on the NOPR for test procedures for small, large, and very large air-cooled commercial package air conditioning and heating equipment for 15 days to allow for additional data and comments to be submitted, especially in light of the public meeting discussion on specific topics. Consequently, DOE will consider any comments in response to the NOPR received by midnight of October 2, 2015, and deems any comments received by that time to be timely submitted.

Issued in Washington, DC, on September 11, 2015.

**Kathleen B. Hogan,**

*Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.*

[FR Doc. 2015-23416 Filed 9-16-15; 8:45 am]

**BILLING CODE 6450-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2015-3632; Directorate Identifier 2015-NM-023-AD]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to supersede Airworthiness Directive (AD) 2014-14-06 for all Airbus Model A318-111 and -112 airplanes; Model A319-111, -112, -113, -114, and -115 airplanes; Model A320-111, -211, -212, and -214 airplanes; and Model A321-111, -112, -211, -212, and -213 airplanes. AD 2014-14-06 currently requires inspecting the aft engine mount retainers for surface finish, cracks, and failure, and replacement if necessary. Since we issued AD 2014-14-06, inspection results have shown that the main cause of crack initiation remains the vibration dynamic effect that affects both retainers, either with “dull” or “bright” surface finishes. This proposed AD would require repetitive inspections for damage, cracks, broken, and missing

aft engine mount retainers, and replacement if necessary. We are proposing this AD to detect and correct failure of retainer brackets of the aft engine mount and consequent loss of the locking feature of the nuts of the inner and outer pins; loss of the pins will result in the aft mount engine link no longer being secured to the aft engine mount.

**DATES:** We must receive comments on this proposed AD by November 2, 2015.

**ADDRESSES:** You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For Airbus service information identified in this proposed AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>.

For Goodrich Aerostructures service information identified in this proposed AD, contact Goodrich Aerostructures, 850 Lagoon Drive, Chula Vista, CA 91910-2098; telephone 619-691-2719; email [jan.lewis@goodrich.com](mailto:jan.lewis@goodrich.com); Internet <http://www.goodrich.com/TechPubs>.

You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3632; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

#### FOR FURTHER INFORMATION CONTACT:

Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2015-3632; Directorate Identifier 2015-NM-023-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

##### Discussion

On July 3, 2014, we issued AD 2014-14-06, Amendment 39-17901 (79 FR 42655, July 23, 2014). AD 2014-14-06 requires actions intended to address an unsafe condition on all Model A318-111 and -112 airplanes; Model A319-111, -112, -113, -114, and -115 airplanes; Model A320-111, -211, -212, and -214 airplanes; and Model A321-111, -112, -211, -212, and -213 airplanes.

Since we issued AD 2014-14-06, Amendment 39-17901 (79 FR 42655, July 23, 2014), we have determined that additional inspections are necessary to address the identified unsafe condition. The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015-0021, dated February 13, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition. The MCAI states:

During in-service inspections, several aft engine mount retainers, fitted on aeroplanes equipped with CFM56-5A/5B engines, have been found broken. The results of the initial investigations highlighted that two different types of surface finish had been applied (respectively bright and dull material finishes), and that dull finish affects the strength of the retainer with regard to fatigue properties of the part. The pins which attach the engine link to the aft mount are secured

by two nuts, which do not have a self-locking feature; this function is provided by the retainer brackets. In case of failure of the retainer bracket, the locking feature of the nuts of the inner and outer pins is lost; as a result, these nuts could subsequently become loose.

In case of full loss of the nuts, there is the potential to also lose the pins, in which case the aft mount link will no longer be secured to the aft engine mount. The same locking feature is used for the three link assemblies of the aft mount.

This condition, if not detected and corrected, could lead to in-flight loss of an aft mount link, possibly resulting in damage to the aeroplane and injury to person on the ground.

To address this potential unsafe condition, EASA issued AD 2013-0050 ([http://ad.easa.europa.eu/blob/easa\\_ad\\_2013\\_0050\\_superseded.pdf](http://ad.easa.europa.eu/blob/easa_ad_2013_0050_superseded.pdf)) AD 2013-0050\_1 [which corresponds to FAA AD 2014-14-06, Amendment 39-17901 (79 FR 42655, July 23, 2014)] to require detailed inspections (DET) of the aft engine mount retainers and the replacement of all retainers with dull finish with retainers having a bright finish.

Since that [EASA] AD was issued, inspection results have shown that the main cause of crack initiation remains the vibration dynamic effect that affects both retainers, either with "dull" or "bright" surface finishes. The non-conforming "dull" surface's pitting is an aggravating factor.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2013-0050, which is superseded, and requires repetitive DET of all aft engine mount retainers and, depending on findings [damaged, cracked, broken, or missing retainers], their replacement.

This [EASA] AD is considered to be an interim action, pending development and availability of a final solution.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3632.

#### **Related Service Information Under 1 CFR Part 51**

Airbus has issued Service Bulletin A320-71-1060, dated October 9, 2014. This service information describes procedures for inspection of the aft engine mount retainers for surface finish (dull or bright), for damaged, cracked, broken, or missing retainers, and replacement.

Goodrich Aerostructures has issued Service Bulletin RA32071-160, dated September 18, 2014. This service information describes procedures for inspection of the aft engine mount inner retainers for cracks or failure, and replacement.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means

identified in the **ADDRESSES** section of this NPRM.

#### **FAA's Determination and Requirements of This Proposed AD**

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

#### **Explanation of "RC" Procedures and Tests in Service Information**

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which procedures and tests in the service information are required for compliance with an AD. Differentiating these procedures and tests from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The procedures and tests identified as Required for Compliance (RC) in any service information have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

As specified in a NOTE under the Accomplishment Instructions of the specified Airbus service information, procedures and tests that are identified as RC in any service information must be done to comply with the proposed AD. However, procedures and tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an alternative method of compliance (AMOC), provided the procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC will require approval of an AMOC.

#### **Costs of Compliance**

We estimate that this proposed AD affects 922 airplanes of U.S. registry.

The actions required by AD 2014-14-06, Amendment 39-17901 (79 FR 42655, July 23, 2014), and retained in this proposed AD take about 3 work-hours per product, at an average labor rate of \$85 per work-hour. Based on these figures, the estimated cost of the actions that are required by AD 2014-14-06 is \$255 per inspection cycle per product (for two engines).

We also estimate that it would take about 10 work-hours per product to comply with the basic requirements of this proposed AD, and 1 work-hour per product to report inspection findings. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$862,070, or \$935 per product.

In addition, we estimate that any necessary follow-on actions would take about 2 work-hours and require parts costing \$10,000, for a cost of \$10,170 per product. We have no way of determining the number of aircraft that might need these actions.

#### **Paperwork Reduction Act**

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120-0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES-200.

#### **Authority for this Rulemaking**

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with

promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

### Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), and adding the following new AD:

**Airbus:** Docket No. FAA–2015–3632; Directorate Identifier 2015–NM–023–AD.

#### (a) Comments Due Date

We must receive comments by November 2, 2015.

#### (b) Affected ADs

This AD replaces AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014).

#### (c) Applicability

This AD applies to the Airbus airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, all manufacturer serial numbers.

- (1) Airbus Model A318–111 and –112 airplanes.
- (2) Airbus Model A319–111, –112, –113, –114, and –115 airplanes.
- (3) Airbus Model A320–211, –212, and –214 airplanes.
- (4) Airbus Model A321–111, –112, –211, –212, and –213 airplanes.

#### (d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

#### (e) Reason

This AD was prompted by inspection results that have shown that the main cause of crack initiation in the aft engine mount retainers is the vibration dynamic effect that affects both retainers, either with “dull” or “bright” surface finishes. We are issuing this AD to detect and correct failure of retainer brackets of the aft engine mount and consequent loss of the locking feature of the nuts of the inner and outer pins; loss of the pins will result in the aft mount engine link no longer being secured to the aft engine mount.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Retained Inspection, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), with no changes. Within 3 months after August 27, 2014 (the effective date of AD 2014–14–06): Do a detailed inspection of the aft engine mount retainers for surface finish (dull or bright), and for cracks and failure, in accordance with Section 4.2.2, “Inspection Requirements,” of Airbus Alert Operators Transmission (AOT) A71N001–12, Rev. 2, dated February 27, 2013, except as specified in paragraph (h) of this AD.

#### (h) Retained Exception to Paragraph (g) of This AD, With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), with no changes. The actions required by paragraph (g) of this AD are not required to be done on airplanes with manufacturer serial numbers 4942 and higher, provided a review of maintenance records verifies that no aft engine mount retainers have been replaced since first flight of the airplane.

#### (i) Retained Repetitive Inspection and Retainer Replacement for Dull Finish Retainers, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), with

no changes. If, during the detailed inspection required by paragraph (g) of this AD, any installed dull finish aft engine mount retainer is found without cracks and not failed: Do the actions specified in paragraphs (i)(1) and (i)(2) of this AD.

(1) Within 25 flight cycles after doing the actions required by paragraph (g) of this AD: Repeat the detailed inspection specified in paragraph (g) of this AD.

(2) Within 50 flight cycles after doing the first detailed inspection specified in paragraph (g) of this AD: Replace all dull finish retainers with new retainers, in accordance with Section 4.2.3.1, “Replacement Procedure,” of Airbus AOT A71N001–12, Rev. 2, dated February 27, 2013.

#### (j) Retained Replacement of Cracked or Failed Retainers, With No Changes

This paragraph restates the requirements of paragraph (j) of AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), with no changes. If, during any detailed inspection specified in paragraph (g) of this AD, any installed aft engine mount retainer is found cracked or failed: Before further flight, replace all affected aft engine mount retainers with new retainers, in accordance with Section 4.2.3, “Replacement Procedure,” of Airbus AOT A71N001–12, Rev. 2, dated February 27, 2013.

#### (k) Retained Parts Prohibition, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), with no changes. As of August 27, 2014 (the effective date of AD 2014–14–06), no person may install any aft engine mount retainer with a dull finish on any airplane. The instructions of Airbus AOT A71N001–12, Rev. 2, dated February 27, 2013; or the Accomplishment Instructions of Goodrich Service Bulletin RA32071–146, Rev. 2, dated July 26, 2012; may be used to verify the correct finish of the part.

#### (l) Retained Credit for Previous Actions, With No Changes

This paragraph restates the provisions of paragraph (l) of AD 2014–14–06, Amendment 39–17901 (79 FR 42655, July 23, 2014), with no changes. This paragraph provides credit for actions required by paragraphs (g), (i), and (j) of this AD, if those actions were performed before August 27, 2014 (the effective date of AD 2014–14–06) using Airbus AOT A71N001–12, Rev. 1, dated August 9, 2012, which is not incorporated by reference in this AD.

#### (m) New Requirement of This AD: Repetitive Inspections

At the latest of the applicable times specified in paragraphs (m)(1), (m)(2), and (m)(3) of this AD: Do a detailed inspection for damaged, cracked, broken, or missing aft engine mount retainers, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–71–1060, dated October 9, 2014; or Goodrich Service Bulletin RA32071–160, dated September 18, 2014. Repeat the inspection of the aft engine mount

retainers thereafter at intervals not to exceed 12 months.

(1) Within 12 months since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness.

(2) Within 12 months after installation of new retainers.

(3) Within 9 months after the effective date of this AD.

**(n) New Requirement of This AD: Replacement of Retainers With Findings**

If, during any detailed inspection specified in paragraph (m) of this AD, any installed aft engine mount retainer is found damaged, cracked, broken, or missing: Before further flight, replace all affected aft engine mount retainers with new retainers, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-71-1060, dated October 9, 2014.

**(o) New Requirement of This AD: No Terminating Action**

Replacement of retainers on an airplane, as required by paragraph (n) of this AD, does not constitute terminating action for the repetitive inspections required by paragraph (m) of this AD for that airplane.

**(p) New Requirement of This AD: Required Reporting**

Submit a report of positive findings of any inspection required by paragraph (m) of this AD to Airbus at the applicable time specified in paragraph (p)(1) or (p)(2) of this AD. The report must include the inspection results, a description of any discrepancies found, the airplane serial number, and the number of landings and flight hours on the airplane.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

**(q) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149. Information may be emailed to: [9-0ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-0ANM-116-AMOC-REQUESTS@faa.gov). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer*: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements*: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(4) *Required for Compliance (RC)*: If any Airbus service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

**(r) Special Flight Permits**

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

**(s) Related Information**

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency Airworthiness Directive 2015-0021, dated February 13, 2015, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3632.

(2) For Airbus service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>.

(3) For Goodrich Aerostructures service information identified in this AD, contact Goodrich Aerostructures, 850 Lagoon Drive, Chula Vista, CA 91910-2098; telephone 619-691-2719; email [jan.lewis@goodrich.com](mailto:jan.lewis@goodrich.com); Internet <http://www.goodrich.com/TechPubs>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on September 9, 2015.

**Michael Kaszycki,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2015-23328 Filed 9-16-15; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**15 CFR Part 922**

**Initiation of Review of Management Plan and Regulations of the Monterey Bay National Marine Sanctuary; Intent To Conduct Scoping and Prepare Draft Environmental Impact Statement and Management Plan; Correction**

**AGENCY:** Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Correction.

**SUMMARY:** On August 27, 2015, NOAA published a notice of intent in the **Federal Register** (80 FR 51973) to initiate public scoping for the management plan review for Monterey Bay National Marine Sanctuary (MBNMS). This notice alerts the public of the addition of a public scoping meeting in Half Moon Bay on October 14, 2015. It also makes a correction to the docket number for submission of public comments on the online rulemaking portal at [www.regulations.gov](http://www.regulations.gov). The correct docket number is NOAA-NOS-2015-0099. The end of the scoping period remains October 30, 2015.

**DATES:** NOAA will accept public comments on the notice of intent published at 80 FR 51973 (August 27, 2015) through October 30, 2015. Locations and dates for public scoping meetings remain the same as described in the notice of intent, with the addition of a meeting on October 14, 2015 from 6 p.m. to 8 p.m. at the Half Moon Bay Yacht Club in Half Moon Bay, CA.

**ADDRESSES:** You may submit comments on this document, identified by NOAA-

NOS–2015–0099, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to [www.regulations.gov](http://www.regulations.gov)

#/docketDetail;D=NOAA-NOS-2015-0099, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- *Mail:* 99 Pacific Street, Bldg. 455A, Monterey, California 93940, Attn: Paul Michel, Superintendent.

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NOAA. All comments received are a part of the public record and will generally be posted for public viewing [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NOAA will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:**  
Dawn Hayes, 831.647.4256,  
[mbnmsmanagementplan@noaa.gov](mailto:mbnmsmanagementplan@noaa.gov).

**SUPPLEMENTARY INFORMATION:**

On August 27, 2015, NOAA published a notice of intent in the **Federal Register** (80 FR 51973) to initiate public scoping for the management plan review for Monterey Bay National Marine Sanctuary (MBNMS). In that notice, the docket number for submitting comments on the online rulemaking portal at [www.regulations.gov](http://www.regulations.gov) was incorrect. The correct docket number is NOAA–NOS–2015–0099. This notice makes a correction to the docket number for the online submission of public comments.

In addition, this notice alerts the public that NOAA will hold a fourth public scoping meeting in addition to the three meetings listed in the August 27, 2015 notice (80 FR 51973). The fourth meeting will be held at the Half Moon Bay Yacht Club in Half Moon Bay, CA on October 14, 2015 from 6 p.m. to 8 p.m.

**Authority:** 16 U.S.C. 1431 *et seq.*; 16 U.S.C. 470.

Dated: September 9, 2015.

**John Armor,**

*Acting Director, Office of National Marine Sanctuaries.*

[FR Doc. 2015–23417 Filed 9–16–15; 8:45 am]

**BILLING CODE 3510–NK–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 1**

[Docket No. FDA–2011–N–0146]

RIN 0910–AH23

**User Fee Program To Provide for Accreditation of Third-Party Auditors/ Certification Bodies To Conduct Food Safety Audits and To Issue Certifications; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA or we) is correcting a document that appeared in the **Federal Register** of July 24, 2015, entitled “User Fee Program for Accreditation of Third-Party Auditors/ Certification Bodies To Conduct Food Safety Audits and To Issue Certifications.” That document proposed amending the document, “Accreditation of Third-Party Auditors/ Certification Bodies to Conduct Food Safety Audits and to Issue Certifications,” and proposed establishing a reimbursement (user fee) program to assess fees and require reimbursement for the work performed to establish and administer the system for the Accreditation of Third-Party Auditors under the FDA Food Safety Modernization Act (FSMA). The document was published with an incorrect RIN. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Charlotte Christin, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–3708.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015–18141, in the **Federal Register** of July 24, 2015 (80 FR 43987), appearing on page 43987, in the second column, the RIN number heading is corrected to read “RIN 0910–AH23.”

Dated: September 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–23333 Filed 9–16–15; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[REG–138344–13]

RIN 1545–BL94

**Substantiation Requirement for Certain Contributions**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed regulations to implement the exception to the “contemporaneous written acknowledgement” requirement for substantiating charitable contribution deductions of \$250 or more. These proposed regulations provide rules concerning the time and manner for donee organizations to file information returns that report the required information about contributions (donee reporting).

**DATES:** Written or electronic comments must be received by December 16, 2015.

**ADDRESSES:** Send submissions to CC:PA:LPD:PR (REG–138344–13), Room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–138344–13), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG–138344–13).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Robert Basso at (202) 317–7011 (not a toll-free number); concerning comments or a request for a public hearing, Oluwafunmilayo Taylor at (202) 317–6901 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Paperwork Reduction Act**

The collection of information contained in this notice of proposed rulemaking will be submitted to the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer,

SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by November 16, 2015. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in § 1.170A–13(f)(18) of the Income Tax Regulations. The collection of information is necessary to properly substantiate charitable contribution deductions under the exception to the general requirements for substantiating charitable contribution deductions of \$250 or more. The collection of information is required to comply with the provisions of section 170(f)(8)(D) of the Internal Revenue Code (Code). The respondents are entities that receive charitable contributions and donors to such entities. The burden for the collection of information contained in proposed regulation § 1.170A–13(f)(18) will be reflected in the burden estimate for a form that the IRS intends to create to request the information specified in the proposed regulation. Once a draft form is available, comments will be invited via a notice in the **Federal Register** and on the IRS Web site.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

## Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under Code section 170(f)(8) governing the substantiation of charitable contributions of \$250 or more. Section 170(f)(8) was enacted by Section 13172(a) of the Omnibus Budget Reconciliation Act of 1993, Public Law 103–66 (107 Stat. 312, 455 (1993)), effective for contributions made on or after January 1, 1994. Section 1.170A–13(f) provides rules on substantiation of

charitable contributions of \$250 or more. See TD 8690 (1997–1 CB 68).

Section 170(f)(8)(A) requires a taxpayer who claims a charitable contribution deduction for any contribution of \$250 or more to obtain substantiation in the form of a contemporaneous written acknowledgment (CWA) from the donee organization. Under section 170(f)(8)(B), while the CWA need not be in any particular form, it must contain the following information: (1) The amount of cash and a description of any property other than cash contributed; (2) whether any goods and services were provided by the donee organization in consideration for the contribution; and (3) a description and good faith estimate of the value of any goods and services provided by the donee organization or a statement that such goods and services consist solely of intangible religious benefits.

The CWA must also be contemporaneous. Under sections 170(f)(8)(C) and 1.170A–13(f)(3), a CWA is contemporaneous if it is obtained by the taxpayer on or before the earlier of the date the taxpayer files an original return for the taxable year in which the contribution was made or the due date (including extensions) for filing the taxpayer's original return for that year. In the preamble to TD 8690, the Treasury Department and the IRS further emphasized this requirement, noting that “[a] written acknowledgment obtained after a taxpayer files the original return for the year of the contribution is not contemporaneous within the meaning of the statute.” TD 8690 (1997–1 CB 68).

Section 170(f)(8)(D) provides an exception to the CWA requirement. Under the exception, a CWA is not required if the donee organization files a return, on such form and in accordance with such regulations as the Secretary may prescribe, that includes the information described in section 170(f)(8)(B). When issuing TD 8690 in 1997, the Treasury Department and the IRS specifically declined to issue regulations under section 170(f)(8)(D) to effectuate donee reporting. The present CWA system works effectively, with minimal burden on donors and donees, and the Treasury Department and the IRS have received few requests since the issuance of TD 8690 to implement a donee reporting system.

In recent years, some taxpayers under examination for their claimed charitable contribution deductions have argued that a failure to comply with the CWA requirements of section 170(f)(8)(A) may be cured if the donee organization files an amended Form 990, “Return of

Organization Exempt From Income Tax,” that includes the information described in section 170(f)(8)(B) for the contribution at issue. These taxpayers argue that an amended Form 990 constitutes permissible donee reporting within the meaning of section 170(f)(8)(D), even if the amended Form 990 is submitted to the IRS many years after the purported charitable contribution was made. The IRS has consistently maintained that the section 170(f)(8)(D) exception is not available unless and until the Treasury Department and the IRS issue final regulations prescribing the method by which donee reporting may be accomplished. Moreover, the Treasury Department and the IRS have concluded that the Form 990 is unsuitable for donee reporting.

## Explanation of Provisions

The framework established by these proposed regulations for donee reporting under the section 170(f)(8)(D) exception is intended to provide for timely reporting, while also minimizing reporting burdens on donees and protecting donor privacy.

### *Manner of Donee Reporting*

The present CWA process requires that the acknowledgement provided to the donor contain information useful in preparing the donor's tax return for the year of the contribution. To effectively substitute for the CWA, any donee reporting process would require not only that an information return be filed with the IRS, but also that a copy be provided to the donor for use in preparing the donor's federal income tax return for the year of the contribution.

In order to better protect donor privacy, the Treasury Department and the IRS have concluded that the Form 990 series should not be used for donee reporting. Instead, before finalization of these proposed regulations, the IRS intends to develop a specific-use information return for donee reporting. Donees are not required to adopt donee reporting. Donees who opt to use donee reporting will be required to provide a copy of the information return to the donor at the address the donor provides for this purpose, and the information return will contain only the information related to that donor. The proposed regulations are reserved on the particular form that will be prescribed for this purpose.

Section 170(f)(8)(D) provides that a donee organization must include the information described in section 170(f)(8)(B) on its return for the donor to qualify for the donee reporting exception. Accordingly, the proposed

regulations require that donees who opt to use donee reporting must report that information as well as the donor's name, address, and taxpayer identification number. The donor's taxpayer identification number is necessary in order to properly associate the donation information with the correct donor. Unlike a CWA, which is not sent to the IRS, the donee reporting information return will be sent to the IRS, which must have a means to store, maintain, and readily retrieve the return information for a specific taxpayer if and when substantiation is required in the course of an examination. The Treasury Department and the IRS request comments on the scope of the information necessary to verify substantiation of charitable contribution deductions under donee reporting.

The Treasury Department and the IRS are concerned about the potential risk for identity theft involved with donee reporting given that donees will be collecting donors' taxpayer identification numbers and maintaining those numbers for some period of time. The Treasury Department and the IRS request comments on whether additional guidance is necessary regarding the procedures a donee should use in soliciting and maintaining a donor's taxpayer identification number and address to mitigate the risk.

In order to minimize the burden on donees, the proposed regulations provide that donee reporting is not required, but may be done at the option of a donee organization. If a contribution is not reported using donee reporting, then the donor must obtain a CWA. The Treasury Department and the IRS request comments on these provisions and whether additional guidance is necessary to clarify the requirements for donors and donees if the donee chooses to use donee reporting for some or all of the contributions it receives. Also, because of the potential burden on donee organizations, the Treasury Department and the IRS request comments on how the donee reporting process might be better designed to minimize donee burden, and how it may interact with the requirement under section 6115 to provide donors information regarding quid pro quo contributions.

#### *Time of Donee Reporting*

Section 170(f)(8) is premised on donors receiving timely substantiation of their donations of \$250 or more. The CWA assists a donor preparing a return (as well as the IRS examining the return) in determining whether, and in what amount, a donor may claim a charitable contribution deduction. H.R. Rept. No.

103–111, at 783, 785 (1993), 1993–3 CB 167, 359, 361; *Viralam v. Commissioner*, 136 T.C. 151, 171 (2011); *Addis v. Commissioner*, 118 T.C. 528, 536 (2002), *aff'd*, 374 F.3d 881 (9th Cir. 2004); *DiDonato v. Commissioner*, T.C. Memo. 2011–153. It would be inconsistent with the purpose of section 170(f)(8) to allow an exception to the CWA requirement of section 170(f)(8)(A) based on information that might be reported by a donee on a return that is filed many years after the purported charitable contribution was made. Rather, any alternative method to using a CWA for substantiating charitable contributions through donee reporting must provide timely information to both the IRS and the donor in order to satisfy the purpose of section 170(f)(8).

Accordingly, the proposed regulations provide that any information return under section 170(f)(8)(D) must be filed by the donee no later than February 28th of the year following the year in which the contribution is made, and the donee organization must provide a copy of the information return to the donor by the same date. An information return that is not filed timely with the IRS, with a copy provided to the donor, will not qualify under section 170(f)(8)(D).

February 28th is the date when numerous other information returns concerning transactions with other persons must be filed. See, for example, § 1.6041–6 (information at source), § 1.6045–1(j) (returns of brokers), and § 1.6049–4(g) (returns regarding payment of interest). The requirement that a donee organization provide a copy of the information return to the donor no later than February 28th of the year following the year in which the contribution is made is intended to provide donors with timely information needed to claim appropriate charitable contribution deductions on their returns, as well as to ensure sound tax administration—objectives that will not be met if donee reporting is allowed to occur long after the contribution was made. In addition, for donors to be relieved of the obligation to obtain a CWA, the donee must file the donee reporting information return, and communicate that it has done so to the donor, before the due date for the donor's return. The Treasury Department and the IRS request comments on the use of February 28th as the due date for filing a return and furnishing a copy to a donor.

#### **Proposed Effective Date**

The regulations are proposed to apply to contributions made on or after the date of publication of a Treasury

decision adopting these rules as final regulations in the **Federal Register**.

#### **Special Analyses**

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that, to the extent a donee reporting system is implemented under section 170(f)(8)(D), the statute itself specifies the bulk of the information that needs to be collected for purposes of these regulations. The proposed regulations require that, in order for a donor to be relieved of the current CWA requirement, a donee organization that uses donee reporting must file a return with the IRS reporting certain information and must furnish a copy of the return to the donor whose contribution is reported on such return. These regulations provide the content of the return under section 170(f)(8)(D), the time for filing the return, and the requirement to furnish a copy to the donor. Moreover, any burden associated with the collection of information under the proposed regulations is minimized by the fact that donee reporting under the proposed regulations is optional on the part of any donee, including small entities. Donees need not use this donee reporting process and donors can continue to use the current CWA process. Given the effectiveness and minimal burden of the CWA process, it is expected that donee reporting will be used in an extremely low percentage of cases.

Based on these facts, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

#### **Comments and Requests for a Public Hearing**

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments that are submitted timely to the IRS as prescribed in this preamble under the "Addresses"



heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at <http://www.regulations.gov> or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

#### Drafting Information

The principal authors of these regulations are Martin L. Osborne and Robert Basso of the Office of the Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the Treasury Department and the IRS participated in their development.

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

#### Proposed Amendment to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

#### PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

■ **Par. 2.** Section 170A–13 is amended by revising paragraph (f)(18) and adding paragraph (f)(19) to read as follows:

#### § 1.170A–13. Recordkeeping and return requirements for deductions for charitable contributions.

\* \* \* \* \*

(f) \* \* \*

(18) *Donee organization reporting*—(i) *Prescribed form.* [Reserved]

(ii) *Content of return.* A document will not qualify as a return for purposes of section 170(f)(8)(D) unless it contains all of the following information:

(A) The name and address of the donee;

(B) The name and address of the donor;

(C) The taxpayer identification number of the donor;

(D) The amount of cash and a description (but not necessarily the value) of any property other than cash contributed by the donor to the donee;

(E) Whether any goods and services were provided by the donee organization in consideration, in whole or in part, for the contribution by the donor; and

(F) A description and good faith estimate of the value of any goods and

services provided by the donee organization or a statement that such goods and services consist solely of intangible religious benefits.

(iii) *Time for filing return.* Every donee organization filing a return described in section 170(f)(8)(D) shall file such return on or before February 28 of the year following the calendar year in which the contribution was made. If the return is not filed timely, the return does not qualify under section 170(f)(8)(D), and section 170(f)(8)(A) through (C) applies to the contribution.

(iv) *Furnishing a copy to donor.* Every donee organization filing a return described in section 170(f)(8)(D) shall furnish a copy of the return to the donor whose contribution is reported on such return on or before February 28 of the year following the calendar year in which the contribution was made. The copy of the return shall be provided to the donor at the address the donor provides for this purpose.

(v) *Donee organization reporting at option of donee.* Donee organization reporting is not required. Donee reporting is available solely at the option of a donee organization, and, the requirements of section 170(f)(8)(A) through (C) apply to all contributions that are not reported using donee reporting.

(19) *Effective/applicability date.* Paragraphs (f)(1) through (17) of this section apply to contributions made on or after December 16, 1996. However, taxpayers may rely on the rules of paragraphs (f)(1) through (17) for contributions made on or after January 1, 1994. Paragraph (f)(18) of this section applies to contributions made on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

**John Dalrymple,**

*Deputy Commissioner for Services and Enforcement.*

[FR Doc. 2015–23291 Filed 9–16–15; 8:45 am]

**BILLING CODE 4830–01–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA–R09–OAR–2015–0316; FRL–9933–82–Region 9]

#### Approval and Promulgation of State Implementation Plans; Nevada; Regional Haze Progress Report

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The United States Environmental Protection Agency (EPA) proposes to approve a revision to the Nevada Regional Haze State Implementation Plan (SIP) submitted by the Nevada Division of Environmental Protection (NDEP) to document that the existing plan is adequate to achieve established goals for visibility improvement and emissions reductions by 2018. The Nevada Regional Haze SIP revision addresses the Regional Haze Rule (RHR) requirements under the Clean Air Act (CAA) to submit a report describing progress in achieving reasonable progress goals (RPGs) to improve visibility in federally designated Class I areas in Nevada and in nearby states that may be affected by emissions from sources in Nevada. EPA is proposing to approve Nevada's determination that the existing Nevada Regional Haze Implementation Plan is adequate to meet the visibility goals, and requires no substantive revision at this time.

**DATES:** Comments must be received by the designated contact at the address listed below on or before October 19, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R09–OAR–2015–0316, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit <http://www.epa.gov/dockets/comments.html> for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make.

For additional submission methods, the full EPA public comment policy, and general guidance on making effective comments, please visit <http://www.epa.gov/dockets/comments.html>.

The index to the docket (docket number EPA–R09–OAR–2015–0316) for this proposed rule is available electronically at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, such as CBI or other information that is restricted by statute. Certain other material, such as copyrighted material, is publicly

available only in hard copy form. Publicly available docket materials are available electronically at <http://www.regulations.gov> or in hard copy during normal business hours at the Planning Office of the Air Division, AIR-2, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. To view hard copies of documents listed in the docket index, EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Vijay Limaye, U.S. EPA, Region 9, Planning Office, Air Division, AIR-2, 75 Hawthorne Street, San Francisco, CA 94105. Vijay Limaye may be reached at telephone number (415) 972-3086 and via electronic mail at [Limaye.Vijay@epa.gov](mailto:Limaye.Vijay@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Throughout this document “we,” “us,” or “our” refer to EPA.

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**I. Overview of Proposed Action**

EPA is proposing to approve NDEP’s determination that the existing Nevada Regional Haze Implementation Plan<sup>1</sup> is adequate to achieve the established RPGs (*i.e.*, visibility goals) for Class I

<sup>1</sup> The Nevada Regional Haze Implementation Plan consists of the Nevada Regional Haze SIP, submitted to EPA in November 2009 and partially approved and partially disapproved by EPA in several related actions in 2012, and the partial Regional Haze Federal Implementation Plan (FIP) promulgated in 2012 and revised in 2013, as described further below.

areas by 2018, and therefore requires no substantive revision at this time. The State’s determination and EPA’s proposed approval are based on the Nevada Regional Haze 5-Year Progress Report (“Progress Report” or “Report”) submitted by NDEP to EPA on November 18, 2014, that addresses 40 CFR 51.308(g), (h), and (i) of the RHR.<sup>2</sup> Specifically, we propose to find that the Progress Report demonstrates that the emission control measures in the existing Nevada Regional Haze SIP are sufficient to enable Nevada, as well as other states with Class I areas affected by emissions from sources in Nevada, to meet all established RPGs for 2018 in accordance with § 51.308(g). As a result, we propose to approve NDEP’s determination that the existing Implementation Plan is adequate, and requires no further substantive revision at this time to achieve the established goals for visibility improvement in accordance with § 51.308(h). In addition, we are proposing to find that NDEP fulfilled the requirements in § 51.308(i)(2), (3), and (4) regarding State coordination with Federal Land Managers (FLMs). This coordination includes providing FLMs with an opportunity for consultation on the Progress Report, describing how NDEP addressed any comments from the FLMs, and providing procedures for continuing consultation with the FLMs. Finally, we propose to find that NDEP has fulfilled the requirements of CAA 110(a) and (l) and 40 CFR 51.102 regarding reasonable notice and public hearings with regard to the Progress Report.

**II. Background**

*A. Description of Regional Haze*

Regional haze is visibility impairment produced by many sources and activities located across a broad geographic area that emit fine particles that impair visibility by scattering and absorbing light, thereby reducing the clarity, color, and visible distance that one can see. These fine particles also can cause serious health effects and mortality in humans and contribute to environmental impacts, such as acid deposition and eutrophication of water bodies.

The RHR uses the deciview as the principle metric for measuring visibility and for the RPGs that serve as interim visibility goals toward meeting the national goal of achieving natural visibility conditions by 2064. A deciview expresses uniform changes in

<sup>2</sup> The Progress Report was deemed complete by operation of law on May 18, 2015.

haziness in terms of common increments across the entire range of visibility conditions, from pristine to extremely hazy conditions. Deciviews are determined by using air quality measurement to estimate light extinction, and then transforming the value of light extinction using a logarithmic function. A deciview is a more useful measure for tracking progress in improving visibility than light extinction because each deciview change is an equal incremental change in visibility perceived by the human eye. Most people can detect a change in visibility at one deciview.

*B. History of Regional Haze Rule*

In section 169A(a)(1) of the CAA Amendments of 1977, Congress created a program to protect visibility in designated national parks and wilderness areas, establishing as a national goal the “prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution.” In accordance with section 169A of the CAA and after consulting with the Department of Interior, EPA promulgated a list of 156 mandatory Class I Federal areas where visibility is identified as an important value.<sup>3</sup> In this notice, we refer to mandatory Class I Federal areas on this list as “Class I areas.” Nevada has one Class I area, Jarbidge Wilderness Area (“Jarbidge”), in the northeast corner of the State.

With the CAA Amendments of 1990, Congress added section 169B to address regional haze issues. EPA promulgated a rule to address regional haze on July 1, 1999, known as the Regional Haze Rule.<sup>4</sup> The RHR revised the existing visibility regulations in 40 CFR 51.308 to integrate provisions addressing regional haze impairment and to establish a comprehensive visibility protection program for Class I areas. As defined in the RHR, the RPGs must provide for an improvement in visibility for the most impaired days (“worst days”) over the period of the implementation plan and ensure no degradation in visibility for the least impaired days (“best days”) over the same period.<sup>5</sup>

*C. Nevada’s Regional Haze Plan*

NDEP submitted its Regional Haze SIP to EPA on November 18, 2009, as required by 40 CFR 51.308 for the first regional haze planning period ending in 2018. EPA approved most of the Nevada

<sup>3</sup> 44 FR 69122, November 30, 1979.

<sup>4</sup> See 64 FR 35713.

<sup>5</sup> 40 CFR 51.308(d)(1).

Regional Haze SIP on March 26, 2012,<sup>6</sup> with the exception of NDEP's determination of best available retrofit technology (BART) to control emissions of nitrogen oxides (NO<sub>x</sub>) at the Reid Gardner Generating Station (Reid Gardner). EPA published a new proposal on April 12, 2012, to approve in part and disapprove in part NDEP's BART determination for NO<sub>x</sub> at Reid Gardner.<sup>7</sup> EPA published a final rule on August 23, 2012, approving NDEP's BART determination for NO<sub>x</sub> on Units 1 and 2, but disapproving NDEP's determination for Unit 3 and the averaging time for the emission limits at all three units.<sup>8</sup> This final rule included a Federal Implementation Plan (FIP) for the disapproved elements. EPA subsequently agreed to reconsider the compliance date for Units 1, 2, and 3 at Reid Gardner in the FIP, which we extended by 18 months.<sup>9</sup>

### III. Requirements for Regional Haze Progress Reports

The RHR requires states to submit a report every five years in the form of a SIP revision to evaluate progress toward achieving the RPGs for each Class I area in the state and for those areas outside the state that may be affected by emissions from within the state.<sup>10</sup> The first progress reports are due five years from the submittal date of each state's initial Regional Haze SIP. Progress reports must be in the form of SIP revisions that comply with the procedural requirements of 40 CFR 51.102 and 51.103. These reports must contain an evaluation of seven elements, at a minimum, and include a determination of the adequacy of the state's existing Regional Haze SIP. In summary,<sup>11</sup> the seven elements are: (1) A description of the status of implementation of all measures included in the current Regional Haze SIP for achieving the RPGs in Class I areas within and outside the state; (2) a summary of the emission reductions achieved in the state through implementation of these measures; (3) an assessment of visibility conditions and changes on the most impaired and least impaired days for each Class I area in the state in terms of five-year averages of the annual values; (4) an analysis of changes in emissions over the past five years contributing to

visibility impairment from all sources and activities within the state based on the most recently updated emissions inventory; (5) an assessment of any significant changes in anthropogenic emissions within or outside the state over the past five years that have limited or impeded progress in reducing pollutant emissions and improving visibility; (6) an assessment of whether the elements and strategies in the current Regional Haze SIP are sufficient to enable the state, or other states affected by its emissions, to achieve the established RPGs; and (7) a review of the state's visibility monitoring strategy and any necessary modifications.

Based on an evaluation of the factors listed above as well as any other relevant information, a state is required to determine the adequacy of its existing Regional Haze SIP.<sup>12</sup> The state must take one of four possible actions based on the analysis in its progress report. In summary, these actions are to (1) provide a negative declaration to EPA that no further substantive revisions to the state's existing Regional Haze SIP is needed to achieve the RPGs; (2) provide notification to EPA and to other states in its region that its Regional Haze SIP is or may be inadequate to ensure reasonable progress due to emissions from sources in other states, and collaborate with other states to develop additional strategies to address the deficiencies; (3) provide notification and available information to EPA that the state's Regional Haze SIP is or may be inadequate to ensure reasonable progress due to emissions from sources in another country; or (4) revise its Regional Haze SIP within one year to address the deficiencies if the state determines that its existing plan is or may be inadequate to ensure reasonable progress in one or more Class I areas due to emissions from sources within the state.<sup>13</sup>

A state also must document that it provided FLMs with an opportunity for consultation prior to holding a public hearing on a Regional Haze SIP or plan revision.<sup>14</sup> A state must include a description of how it addressed any comments from the FLMs, and provide procedures for continuing consultation with the FLMs.<sup>15</sup>

### IV. Context for Understanding Nevada's Progress Report

To facilitate a better understanding of the Progress Report as well as EPA's evaluation of the Report, this section

provides background information on how the regional haze program applies to Nevada. This information describes the framework for measuring visibility progress, a profile of the relevant Class I areas, and the sources of data used in the Progress Report.

#### A. Framework for Measuring Progress

Visibility conditions at Class I areas are described by a "haze index" measured in deciviews and calculated using data collected from the Interagency Monitoring of Protected Visual Environments (IMPROVE) network monitors. Nevada has an IMPROVE monitor at Jarbidge that is designated "JARB1." To measure progress in deciviews, current visibility conditions (2008–2012) are compared to baseline conditions (2000–2004), and to projected conditions at the end of the planning period (2018). A state establishes two RPGs for each of its Class I areas: One for the 20 percent best days and one for the 20 percent worst days. The RPGs must provide for an improvement in visibility on the 20 percent worst days and ensure no degradation in visibility on the 20 percent best days, compared to average visibility conditions during the baseline period. In establishing the RPG, a state must consider the uniform rate of improvement in visibility (from the baseline to natural conditions in 2064) and the emission reductions measures needed to achieve it. Nevada set the RPGs for Jarbidge using atmospheric air quality modeling based on projected emission reductions from control strategies in the Nevada Regional Haze SIP as well as emission reductions expected to result from other Federal, state and local air quality programs, among other factors. The purpose of a progress report is to assess whether a state's plan is adequate to achieve the established RPGs and emissions reductions goals for 2018, and if not, whether additional emission reduction strategies are needed.

#### B. Relevant Class I Areas

Nevada's one Class I area, the Jarbidge Wilderness Area, is located within the Humboldt National Forest in the northeastern corner of the State within the populated Snake River Basin and less than 10 miles from the Idaho border. The baseline visibility conditions (2000–2004) at Jarbidge are 12.07 deciviews (dv) on the worst days and 2.56 dv on the best days. The RPG for the worst days in 2018 at Jarbidge is 11.05 dv, which is slightly under, and therefore better than, the uniform rate of progress (URP) in 2018, which is 11.09

<sup>6</sup> See 77 FR 17334.

<sup>7</sup> See 77 FR 21896.

<sup>8</sup> See 77 FR 50936.

<sup>9</sup> See proposed rule to grant extension, 78 FR 18280 (March 26, 2013), and final rule granting extension, 78 FR 53033 (August 28, 2013).

<sup>10</sup> 40 CFR 51.308(g).

<sup>11</sup> Please refer to 40 CFR 51.308(g) for the exact requirements.

<sup>12</sup> 40 CFR 51.308(h).

<sup>13</sup> *Id.*

<sup>14</sup> 40 CFR 51.308(i)(2).

<sup>15</sup> 40 CFR 51.308(i)(3) and (4).

dv.<sup>16</sup> While a subsequent correction for the worst days in 2018 resulted in projected visibility impairment of 11.8 dv on the worst days,<sup>17</sup> NDEP has retained the RPG of 11.05 dv for Jarbidge. The RPG for the best days in 2018 at Jarbidge is 2.50 dv, which represents a slight improvement from baseline conditions. The Progress Report addresses whether Nevada's RH SIP is making adequate progress from the baseline toward these RPGs.

The Nevada Regional Haze SIP identified 24 other Class I areas located in five neighboring states that are potentially affected by emissions of sulfates and nitrates from sources in Nevada.<sup>18</sup> Based on projections from air quality modeling for 2018, the highest contribution to sulfate extinction on the worst days from Nevada's emissions is 5.6 percent at Zion National Park in Utah, and on the best days is 7.2 percent at Sawtooth Wilderness Area in Idaho. For nitrate extinction in 2018, Nevada's highest contribution on the worst days is 20 percent at Desolation Wilderness in California, and on the best days is 12.4 percent at Joshua Tree National Park in California.<sup>19</sup> The remaining 20 Class I areas outside Nevada are projected to have smaller fractions of haze attributable to Nevada's emissions.

### C. Data Sources

Nevada's Progress Report is based on information available prior to March 2014. For the most part, NDEP relies on technical data and analysis in two reports from the Western Regional Air Partnership (WRAP), the regional planning organization that provides technical support to western states. The WRAP's reports are based on monitoring data from the IMPROVE network and emissions data from EPA's National

<sup>16</sup> The URP is a straight line from the baseline visibility condition (5-year annual average from 2000–2004) to the estimated natural background condition in 2064, as measured on the 20 percent best and worst days. The URP values for 2018 are the number of deciviews where the lines drawn to 2064 for best and worst days intersect 2018.

<sup>17</sup> See 76 FR 36464, June 22, 2011, footnote 18 ("In April 2011, the WRAP issued a draft report regarding an error in its visibility projections for about 15 Class I areas in the West, including Jarbidge. The draft report indicated that, as a result of the error, the projected visibility at Jarbidge in 2018 is 11.8 dv instead of 11.1 dv (rounded up from 11.05 dv).").

<sup>18</sup> Nevada Regional Haze State Implementation Plan, Chapter 4.3.3, October 2009. Light extinction is based on a model known as Particulate Matter Source Attribution Tracking (PSAT).

<sup>19</sup> 76 FR 36459, June 22, 2011.

Emissions Inventory (NEI). The first report is the "Western Regional Air Partnership Regional Haze Rule Reasonable Progress Summary Report," dated June 28, 2013, which includes Section 6.8 Nevada (Appendix A of the Progress Report). This report is based on the time period 2005–2009 and relies on the NEI from 2008. The WRAP updated the inventory before completing a second report titled "West-Wide Jump-Start Air Quality Modeling Study—Final Report" dated September 30, 2013. NDEP also uses NEI data from 2011, State emission inventory data for 2012, acid rain data from EPA's Air Market Program Database, and IMPROVE monitoring data from 2008 to 2012 to provide more current information and additional analysis. NDEP further relies on the WRAP's Technical Support System and the Visibility Information Exchange Web System as analytic tools.

### V. EPA's Evaluation of Nevada's Progress Report

This section describes Nevada's Progress Report and EPA's evaluation of the Report in relation to the seven elements listed in 40 CFR 51.308(g), the determination of adequacy in 40 CFR 51.308(h), the requirement for state and FLM coordination in 40 CFR 51.308(i) and the requirements for public participation in CAA section 110(a) and (l) and 40 CFR 51.102. While the Progress Report focuses on the elements of the Nevada Regional Haze SIP, the requirements in 40 CFR 51.308(g) and (h) apply to "implementation plans," which are defined to include approved SIPs and FIPs.<sup>20</sup> Accordingly, EPA has considered our regional haze BART FIP for Reid Gardner as well as the Nevada Regional Haze SIP in assessing the Progress Report. However, as described further below, all three of the BART-eligible units at Reid Gardner have been shut down. Therefore, the partial disapproval and partial FIP for Reid Gardner does not substantively influence our evaluation of the Progress Report.

#### A. Status of Implementation of All Measures

##### 1. NDEP's Analysis

The Progress Report describes the status of state and federal measures in

the Nevada Regional Haze SIP as well as new programs, rules, and legislation that will provide further emission reductions before the first phase of the regional haze program ends in 2018. Nevada's measures to control or otherwise reduce emissions that contribute to haze are organized into three broad categories: Review of BART Determinations, State Measures Other than BART, and Federal Programs.<sup>21</sup> The status of measures in each of these categories is summarized below.

*BART Implementation:* NDEP describes BART implementation in Nevada and in neighboring states that contribute to visibility impairment at Jarbidge. The four BART facilities in Nevada are Reid Gardner, Tracy Generating Station (Tracy), Fort Churchill Generating Station (Fort Churchill), and Mohave Generating Station (Mohave). Mohave closed in 2005.<sup>22</sup> The Nevada Regional Haze SIP requires the remaining three facilities to meet the emission limits associated with all BART control measures by January 1, 2015, with the exception of NO<sub>x</sub> at Reid Gardner, which has a compliance date of June 30, 2016, as shown in Table 1. As noted in the table, three units at Reid Gardner and two units at Tracy were scheduled to retire by the compliance date. Subsequent to NDEP's submittal of the Progress Report, all five of these units were shut down and are now in the process of being decommissioned and demolished.<sup>23</sup> The retirement of these five units, and the switching of three other units at Tracy and Fort Churchill to natural gas, is largely in response to the passage of Senate Bill (SB) 123 by the Nevada legislature in 2013, which is described in more detail in the next section regarding other State measures.

<sup>21</sup> Progress Report, Chapter Two, Status of Implementation of Control Measures, pages 2–1 thru 2–13.

<sup>22</sup> Even though Mohave's closure in 2005 predates the first phase of the RH program (2008–2018), NDEP addresses Mohave's emissions in its Progress Report because these emissions are included in the inventories and modeling that form the basis for the Nevada Regional Haze SIP. For example, the projected emission inventory for 2018 includes about 19,595 tpy of NO<sub>x</sub> and 8,701 tpy of SO<sub>2</sub> from Mohave.

<sup>23</sup> See Reid Gardner Generating Station Fact Sheet from Nevada Energy (May 2015), Frank A. Tracy Generating Station Fact Sheet from Nevada Energy (June 2015).

<sup>20</sup> 40 CFR 51.302.

TABLE 1—STATUS OF BART CONTROL MEASURES

Facility	Units	BART Control measures
Reid Gardner Generating Station .....	1, 2, 3 .....	NV Energy retired these three units as of December 31, 2014, as approved by the Public Utilities Commission of Nevada (PUCN)
Tracy Generating Station .....	1, 2 .....	NV Energy retired these two units as of December 31, 2014, as approved by the PUCN and in response to SB 123.
	3 .....	NV Energy is relying on alternative control technology and burning only natural gas to comply with the BART emissions limits as of the December 31, 2014, compliance date.
Fort Churchill Generating Station .....	1, 2 .....	NV Energy is relying on alternative control technology and burning only natural gas to comply with the BART emissions limits as of the December 31, 2014, compliance date.
Mohave Generating Station .....	All .....	This facility ceased operations in December 2005 and was subsequently fully decommissioned and demolished.

NDEP explains in the Progress Report that BART implementation in neighboring states is expected to contribute to visibility improvement at Jarbidge, which is located very near the Idaho border and downwind from sources in Oregon. Since source apportionment modeling identified substantial contributions of sulfur dioxide (SO<sub>2</sub>) from point sources in Idaho and Oregon,<sup>24</sup> NDEP provides updates on two facilities in Idaho (Amalgamated Sugar Company in Nampa and Monsanto/P4 Production in Soda Springs) and one facility in Oregon (Boardman Power Plant) that are subject to BART control measures. Each of these three facilities is reportedly in compliance with the required BART emission limits for SO<sub>2</sub> and NO<sub>x</sub>. However, since some of the compliance dates are not yet effective, more emission reductions are expected by 2018.

*Other State Measures:* Other State measures contributing to reasonable progress at Jarbidge and other Class I areas include cancellations of applications to build power plants, State legislation to reduce emissions from coal-fired power plants (*i.e.*, SB 123), an expanded renewable energy portfolio, and implementation of control measures to attain the National Ambient Air Quality Standards (NAAQS) as listed in Table 2. Regarding cancellations, NDEP explains that these measures represent additional emission reductions because the emissions from these unbuilt sources were included in the baseline and projected emission inventories in the Nevada Regional Haze SIP. Of the five proposed power plants that NDEP assumed would be producing emissions, three withdrew applications (White Pine, Toquop, and Copper Mountain), and two were built (Newmont TS Power Plant near Dunphy in northern Nevada

and Chuck Lenzie Generating Station near Las Vegas).<sup>25</sup> The Nevada Legislature in 2013 enacted SB 123 requiring the reduction of emissions from coal-fired power plants in Clark County, Nevada. SB 123 requires the retirement or elimination of not less than 800 megawatts of coal-fired electric generating capacity: 300 MW by December 2014, an additional 250 MW by December 2017, and an additional 250 MW by December 2019. This legislation also mandates the construction or acquisition of 350 MW from new renewable energy facilities. NV Energy must construct or acquire and own facilities with a total capacity of 550 MW to replace the coal-fired capacity eliminated between 2014 and 2019.<sup>26</sup> NV Energy's decision to retire BART units at Reid Gardner and Tracy, and to convert other BART units to natural gas at Tracy and Fort Churchill, was in response to this legislation.

NDEP also reports that Nevada is one of the first states to adopt a renewable portfolio standard that establishes a schedule requiring electric utilities to generate, acquire, or save a percentage of electricity from renewable energy systems or efficiency measures. Not less than 20 percent must come from renewable energy or efficiency measures from 2015 to 2019. The Nevada legislature also has enacted the "Solar Energy Systems Incentive Program," which requires the Public Utilities Commission of Nevada to set incentives and schedules to produce at least 250 MW of capacity from solar energy by 2021. At the time of the Progress Report, Nevada had installed 38 MW of capacity at a cost of \$160 million. Another example of renewable energy is the "Solar Thermal Demonstrations

Program" that promotes the installation of at least 3,000 solar thermal systems in homes, businesses, schools, and government buildings throughout the State. The Progress Report mentions several other programs to establish solar, wind, and waterpower energy systems along with a list of proposed generation plants that will rely on renewable energy.<sup>27</sup>

TABLE 2—STATUS OF OTHER STATE MEASURES

State measure	Effective date
Three Power Plants included in Inventory for 2018.	Never Built.
Legislation to Retire Coal-Fired Plants (800 mw).	2014–2019.
Legislation for New Renewable Energy (350 mw).	2014–2021.
Renewable Energy Portfolio NAAQS Attainment/Maintenance Regulations.	2015–2025. Ongoing.

*Federal Measures:* The Progress Report provides a summary of existing federal measures, those that were included in the Nevada Regional Haze SIP, as well as new federal measures as listed in Table 3. NDEP describes in the Report how each of these federal programs, rules, and standards contribute further reductions in visibility impairing pollutants.<sup>28</sup> All eight areas in Nevada that were designated non-attainment for one more NAAQS either have been redesignated to attainment and are operating under a maintenance plan or have a determination of attainment indicating that the area is attaining the NAAQS. The control measures for attainment that remain in place include fugitive dust regulations, oxygenated fuel programs, gasoline vapor recovery, transportation control measures,

<sup>24</sup> Nevada Regional Haze SIP, Section 4.3, November 2009.

<sup>25</sup> Newmont TS is a 220-megawatt power plant using coal-fired boilers with modern control technologies operating since 2008. Chuck Lenzie is 1,102-megawatt generating station using gas-fired steam engines operating since 2006.

<sup>26</sup> Public Utilities Commission of Nevada, Docket No. 14–05003, May 1, 2014, (Appendix C).

<sup>27</sup> Progress Report, Chapter 2, pages 2–8 thru 2–9.

<sup>28</sup> Progress Report, Chapter 2, pages 2–3 thru 2–6.

residential wood burning regulations, woodstove replacement programs, and alternative fuel vehicle program.

woodstove replacement programs, and alternative fuel vehicle program.

TABLE 3—STATUS OF FEDERAL MEASURES

Existing Federal Measures	
Heavy Duty Highway Rule (PM, NO <sub>x</sub> , SO <sub>x</sub> )	Phased in 2006–2010.
Tier 2 Vehicle and Gasoline Program (NO <sub>x</sub> , VOC)	Effective in 2005.
Non-Road Mobile Diesel Emissions Program (NO <sub>x</sub> , CO)	Phased in 2004–2012.
Maximum Achievable Control Technology Program	Ongoing Applicability.
New Federal Measures	
Mercury and Air Toxics Rule (Toxic Gases, SO <sub>2</sub> )	Final Rule in 2011.
Revised NAAQS for Sulfur Dioxide	Final Rule in 2010.
Revised NAAQS for Nitrogen Dioxide	Final Rule in 2010.
Revised NAAQS for Fine Particulate Matter	Final Rule in 2012.
North American Emission Control Areas (NO <sub>x</sub> , PM <sub>2.5</sub> , SO <sub>2</sub> )	Effective in 2012; 2015.
Tier 3 Vehicle Emission and Fuel Standards Program (SO <sub>x</sub> )	Effective in 2017.

PM = Particulate Matter.  
 VOC = Volatile Organic Compounds.

2. EPA’s Evaluation

EPA proposes to find that NDEP adequately addresses the requirement in 40 CFR 51.308(g)(1) to describe the status of all measures included in the Nevada Regional Haze SIP. NDEP provides a detailed and comprehensive update of state and federal measures, including new measures that are expected to contribute further to visibility improvement. The Progress Report’s description of BART implementation, legislation, programs, and rules provides a thorough summary of the regulatory requirements that underpin Nevada’s regional haze program.

B. Summary of Emission Reductions Achieved

1. NDEP’s Analysis

The Progress Report focuses on SO<sub>2</sub> and NO<sub>x</sub> emissions, which are the primary pollutants of concern from anthropogenic sources. NDEP reports that SO<sub>2</sub> and NO<sub>x</sub> emissions have decreased substantially in Nevada due to the implementation of control measures as well as other changes in State energy policy and source activity as described above in the status of measures. According to EPA’s acid rain data,<sup>29</sup> annual SO<sub>2</sub> emissions from Electricity Generating Units (EGUs) in Nevada decreased by 44,107 tpy (82 percent) from 53,346 tpy in 2005 to 9,239 tpy in 2006. Similarly, NO<sub>x</sub> emissions from power plants decreased by 23,257 tpy (54 percent) from 43,242 tpy in 2005 to 19,985 tpy in 2006. NDEP points out that while these large decreases from 2005 to 2006 are mostly

due to the closure of Mohave Generating Station, emissions continued to decrease steadily thereafter. From 2006 to 2013, power plant emissions of SO<sub>2</sub> decreased by about 20 percent (9,239 to 7,427 tpy) and NO<sub>x</sub> emissions decreased by about 61 percent (19,985 to 7,796 tpy).<sup>30</sup> The closure of units at Reid Gardner and Tracy, and the implementation of control measures on other units at Tracy and Fort Churchill, should contribute further emission reductions not reflected in the acid rain data for 2013.

The Progress Report also quantifies emission reductions resulting from the cancellation of plans to construct three power plants and lower actual emissions from the two plants that were built. NDEP includes this analysis because projected emissions from these five sources are included in the emission inventory for 2018 that provides the basis for the RPG at Jarbidge. The reductions due to permit cancellations are 5,814 tpy of SO<sub>2</sub>, 6,136 tpy of NO<sub>x</sub>, and 5,814 tpy of particulate matter (PM<sub>10</sub>). Moreover, the two new plants that were built (Newmont and Chuck Lenzie) have combined actual emissions in 2012 that are less than projected for the emission inventory in 2018.<sup>31</sup> NDEP states that these unrealized emissions, in effect, would result in lower modeled visibility impairment in 2018, particularly at Class I areas near southern and eastern Nevada where the two built sources are located and the three cancelled sources had planned to locate.

<sup>30</sup> Progress Report, Chapter 3, Table 3–2, page 3–5.

<sup>31</sup> Progress Report, Chapter 3, Table 3–1, page 3–4.

2. EPA’s Evaluation

EPA proposes to find that NDEP adequately addresses the requirement in 40 CFR 51.308(g)(2) to provide a summary of the emission reductions from implementing the measures in the Nevada Regional Haze SIP. NDEP documents that SO<sub>2</sub> and NO<sub>x</sub> emissions from Nevada’s power plants have decreased substantially, especially due to the closure of Mohave. NDEP makes the case that emissions from the power sector should continue to decline as BART controls and SB 123 are implemented, further reducing emissions from Reid Gardner, Tracy, and Fort Churchill. While it is difficult to quantify emission reductions from other state and federal programs, we agree that other state and federal measures should contribute to declining emissions, particularly from mobile and stationary sources. While the cancellation of proposed facilities does not constitute emission reductions per se, we recognize that the inclusion of these projected emissions in the 2018 inventory likely inflated the projected emissions used as the basis of the RPGs for Jarbidge and Class I areas affected by Nevada’s emissions. We also note that NDEP’s summary of emission reductions is complemented by its analysis of recent changes in emissions from all sources in Section D of this proposal.

C. Assessment of Visibility Conditions and Changes at Jarbidge

1. NDEP’s Analysis

*Current Visibility Conditions:* NDEP reports on current visibility conditions for the 20 percent worst days and 20 percent best days at Jarbidge for the five-

<sup>29</sup> USEPA Clean Air Markets Division, Air Markets Program Data, Acid Rain Program.

years from 2008 to 2012 as displayed in Table 4.<sup>32</sup> The five-year annual average haze index at Jarbidge for this current time period is 12.0 dv on worst days and 1.9 dv on best days. On worst days, the annual averages for visibility impairment are strongly influenced by

light extinction due to particulate organic matter (POM), followed by coarse mass and sulfate. On the best days, visibility impairment is dominated by light extinction due to sulfate, followed by POM and coarse mass. The Progress Report notes that

sources of POM are predominantly natural, while sources of fine soil and coarse mass are about equally split between natural and anthropogenic. The dominant source of sulfate is SO<sub>2</sub> from anthropogenic sources.

TABLE 4—CURRENT ANNUAL AND FIVE-YEAR ANNUAL AVERAGE VISIBILITY CONDITIONS FOR WORST AND BEST DAYS AT JARBIDGE<sup>33</sup>

Year	Haze index (dv)	Sulfate (Mm <sup>-1</sup> )	Nitrate (Mm <sup>-1</sup> )	POM (Mm <sup>-1</sup> )	EC (Mm <sup>-1</sup> )	Soil (Mm <sup>-1</sup> )	Coarse mass (Mm <sup>-1</sup> )	Sea salt (Mm <sup>-1</sup> )
<b>Worst Days</b>								
2008 .....	12.5	3.72	1.12	12.06	1.48	2.61	4.84	0.04
2009 .....	11.1	4.43	0.53	7.32	1.12	2.31	5.66	0.30
2010 .....	10.0	3.30	1.04	4.33	0.77	2.49	5.66	0.06
2011 .....	11.7	4.16	0.67	7.71	1.21	2.49	6.85	0.40
2012 .....	14.9	3.87	1.18	23.97	3.11	2.63	5.17	0.21
Average .....	12.0	3.9	0.9	11.1	1.5	2.5	5.6	0.2
<b>Best Days</b>								
2008 .....	1.9	1.14	0.22	0.23	0.09	0.12	0.27	0.05
2009 .....	1.8	0.95	0.16	0.31	0.11	0.12	0.28	0.03
2010 .....	1.8	1.09	0.15	0.30	0.12	0.06	0.24	0.03
2011 .....	2.1	1.21	0.19	0.39	0.13	0.10	0.26	0.07
2012 .....	2.0	0.95	0.18	0.37	0.18	0.10	0.37	0.04
Average .....	1.9	1.1	0.2	0.3	0.1	0.1	0.3	0.0

EC = Elemental Carbon.

*Difference between Current and Baseline Visibility Conditions:* NDEP presents the difference between the current five-year annual average (2008–2012) and the baseline five-year annual average (2000–2004) for Jarbidge, as displayed in Table 5, which also includes successive five-year annual averages for the intervening time periods (2005–2009, 2006–2010, and 2007–2011).<sup>34</sup> The differences calculated in the table are between the baseline and the current visibility condition represented by the time period 2008–2012. A negative difference indicates a reduction in haze (*i.e.*, improved visibility). Comparing baseline to current visibility conditions on worst days, the haze index declined slightly (12.1 to 12.0 dv) with corresponding decreases in light extinction for sulfate, nitrate, and elemental carbon, but a noticeable increase in POM. On the best days, the haze index decreases from the baseline

to current visibility conditions (2.6 to 1.9 dv) with corresponding decreases in light extinction for sulfate, nitrate, POM, and elemental carbon, with the three other pollutants remaining the same.

NDEP also analyzes the relative percentage contribution and rank of each pollutant to visibility impairment on the worst and best days for the five-year annual average baseline and successive five-year time periods, as displayed in Table 5.<sup>35</sup> This analysis reveals that POM (ranging from 35.5 to 43.0 percent), coarse mass (21.9 to 26.1 percent), and sulfate (15.1 to 17.0 percent) rank first, second, and third, respectively, as the largest contributors to light extinction on worst days in each of the five-year periods from the baseline to current time period. On the worst days, POM dominates the contributions to visibility impairment for the baseline as well as all subsequent time periods. The data for sulfate and nitrate show small but continued

improvement on worst days based on these five-year annual averages.

On the best days for each five-year period of annual averages, sulfate (ranging from 4.10 to 50.5 percent), POM (15.1 to 26.1 percent), and coarse mass (12.4 to 13.2 percent) rank first, second, and third except for the baseline period in which nitrate is third, contributing 9.8 percent. On average across all five-year periods, nitrate and elemental carbon each contribute about 10 percent to visibility impairment on best days. NDEP explains that the sulfate contribution is most likely high because best days represent times when there are fewer emissions from natural sources, resulting in relatively higher contribution to impairment from anthropogenic emissions. Although the ranking changes from worst days to best days, POM, coarse mass, and sulfate are the three largest contributors to visibility impairment at Jarbidge.

<sup>32</sup> Progress Report, Chapter 4, Table 4–1, page 4–3.

<sup>33</sup> The data on visibility conditions is from the IMPROVE monitor at Jarbidge (JARB1) that measures light extinction in terms of inverse megameters (Mm<sup>-1</sup>) that are directly related to

gaseous and aerosol concentrations. The haze index is measured in deciviews, which is a metric of haze proportional to the logarithm of the light extinction.

<sup>34</sup> See Progress Report, Chapter 4, Table 4–2, page 4–4.

<sup>35</sup> Progress Report, Table 4–4, Percent Contribution to Aerosol Extinction by Species, page 4–10. These results excluded Rayleigh and are expressed as a percentage of Mm<sup>-1</sup>.

TABLE 5—BASELINE AND FIVE-YEAR ANNUAL AVERAGE VISIBILITY CONDITIONS FOR THE WORST AND BEST DAYS AT JARBIDGE

Time period	Haze index (dv)	Sulfate (Mm <sup>-1</sup> )	Nitrate (Mm <sup>-1</sup> )	POM (Mm <sup>-1</sup> )	EC (Mm <sup>-1</sup> )	Soil (Mm <sup>-1</sup> )	Coarse mass (Mm <sup>-1</sup> )	Sea salt (Mm <sup>-1</sup> )
<b>Worst Days</b>								
Baseline .....	12.1	4.0	1.1	10.0	1.6	2.4	5.5	0.1
2005–2009 .....	12.4	4.4	1.4	10.0	1.7	2.6	5.9	0.2
2006–2010 .....	12.2	4.0	1.1	9.6	1.6	2.7	6.1	0.1
2007–2011 .....	11.7	3.9	1.0	8.4	1.2	2.7	6.2	0.2
2008–2012 .....	12.0	3.9	0.9	11.1	1.5	2.5	5.6	0.2
Difference .....	–0.1	–0.1	–0.2	1.1	–0.1	0.1	0.1	0.1
<b>Best Days</b>								
Baseline .....	2.6	1.2	0.3	0.8	0.3	0.1	0.3	0.0
2005–2009 .....	2.2	1.1	0.2	0.5	0.2	0.	0.3	0.0
2006–2010 .....	2.0	1.1	0.2	0.4	0.1	0.1	0.3	0.0
2007–2011 .....	2.0	1.1	0.2	0.3	0.1	0.1	0.3	0.0
2008–2012 .....	1.9	1.1	0.2	0.3	0.1	0.1	0.3	0.0
Difference .....	–0.7	–0.1	–0.1	–0.5	–0.2	0.0	0.0	0.0

To support its analysis of current conditions, NDEP presents a set of rolling five-year averages of the annual averages, and includes the current estimate of natural conditions, as shown in Table 6.<sup>36</sup> The rolling five-year average of the annual averages reveals more clearly the trend in visibility conditions over time.

TABLE 6—FIVE-YEAR ANNUAL AVERAGE HAZE INDEX FOR BASELINE AND SUCCESSIVE TIME PERIODS MEASURED AT JARB1  
[In deciviews]

Days measured (20 Percent)	Baseline conditions	Interim five-year time periods			Current conditions	Natural conditions
	2000–2004	2005–2009	2007–2011	2007–2012	2008–2012	
Worst .....	12.1	12.4	12.2	11.7	12.0	7.9
Best .....	2.6	2.2	2.0	2.0	1.9	1.1

NDEP also presents the change in visibility conditions between the baseline and current period for best and worst days in comparison to the RPG in 2018 using the 2008 to 2012 average as displayed in Table 7.<sup>37</sup> While visibility on the best days shows improvement, only modest progress is shown for the worst days due to significant contribution of POM to light extinction at Jarbidge, particularly in 2012 as shown in Table 4.

TABLE 7—REASONABLE PROGRESS GOAL SUMMARY FOR JARBIDGE  
[In deciviews]

Best days			Worst days				
Baseline (2000–2004)	Current (2008–2012)	Visibility improvement	Baseline (2000–2004)	Current (2008–2012)	Visibility improvement	2018 RPG	Progress in 2012 to 2018 RPG
2.6 .....	1.9	0.7	12.1	12.0	0.1	11.05	9.5%

*Changes in Visibility Impairment over Past Five Years:* The distinguishing feature of annual visibility impairment on the worst days from 2008 to 2012 is the variability of light extinction due to POM and its corresponding effect on the haze index as shown in Table 4. While light extinction for other pollutants is relatively flat during this current five-year period, POM varies by almost 20 Mm<sup>-1</sup>, from a low of 4.33 Mm<sup>-1</sup> in 2010 to a high of 23.97 Mm<sup>-1</sup> in 2012. Levels of POM spiked in 2012, which NDEP attributes to emissions from wildfires. As the table shows, on the worst days POM has a strong influence

on the year-to-year variability in visibility conditions, and can cause a corresponding increase in the 2008–2012 five-year annual average. Visibility impairment on worst days generally has not changed much over the five years except for the variations due to light extinction from POM. Visibility on best

<sup>36</sup> Progress Report Table 4–3, page 4–6.

<sup>37</sup> Progress Report Table 4–6, page 4–14. This table omits the RPG for the best days, which is 2.56 dv.



days, by contrast, generally is improving over the current time period with little variability from year to year. For the best days, there is a noticeable reduction in visibility impairment due to sulfate, nitrate, POM, and elemental carbon.

NDEP presents a trend analysis for the period from 2000 to 2012, focusing on sulfates and nitrates, as an annual average and as a rolling five-year average during this 13-year time period based on IMPROVE data.<sup>38</sup> Analyzing this longer time period demonstrates that on the worst and best days visibility impairment resulting from light extinction due to sulfate and nitrate is improving over time, both on an annual basis as well as five-year annual averages. NDEP also includes an analysis showing the effect of a large spike in nitrates in December 2005 (41 Mm<sup>-1</sup>) that increases the annual average as well as all the five-year averages that include data from 2005.

2. EPA's Evaluation

EPA proposes to find that NDEP adequately addresses the requirement in 40 CFR 51.308(g)(3) to assess the visibility conditions and changes in each of the State's Class I areas for the least and most impaired days in terms of the current conditions, difference between current and baseline conditions, and over the past five years. The analysis indicates that visibility on the best days at Jarbidge is getting better, but that visibility on the worst days is flat or only minimally improving. However, NDEP offers compelling evidence that light extinction due to POM has dominated visibility conditions on the worst days, particularly in 2012 as shown in Table 4.

D. Analysis of Changes in Emissions

1. NDEP's Analysis

NDEP relies on the WRAP's analysis<sup>39</sup> to describe the changes in emissions from the baseline<sup>40</sup> in 2002 to the emissions inventory in 2008, the

beginning of Nevada's current five-year time period. NDEP also uses NEI data from 2008 to 2011 to augment its analysis.<sup>41</sup> As shown in Table 8, emissions of all visibility-impairing pollutants decreased from the baseline inventory to 2008, except for fine soil and coarse mass. Notably, actual emissions in 2008 are lower than the projected 2018 emissions for all pollutants, with the exception of fine soil and coarse mass. For example, point source emissions of SO<sub>2</sub> decreased by 78 percent, while point source emissions of NO<sub>x</sub> decreased by over 50 percent from the baseline to 2008. These large reductions in the anthropogenic emissions of SO<sub>2</sub> and NO<sub>x</sub> represent a successful strategy of reducing anthropogenic emissions within the State. NDEP notes that the increase in fine soil and coarse mass are likely due to updates in inventory development methods rather than actual increases, which is plausible given the small changes in soil and coarse mass observed at the Jarbridge monitor.

TABLE 8—COMPARISON OF EMISSION INVENTORIES IN 2002, 2008, AND 2018 FOR NEVADA OF ALL VISIBILITY IMPAIRING POLLUTANTS<sup>42</sup>

Pollutants	2002 Baseline (tpy)	2008 Inventory (tpy)	2018 Projection (tpy)	2008 Actuals as a percent of 2018 projections
Sulfur Dioxide .....	67,743	17,058	46,224	37
Nitrogen Oxides .....	162,397	119,513	135,496	88
Ammonia .....	12,092	9,382	14,503	65
Volatile Organic Compounds .....	897,102	351,142	897,707	39
Primary Organic Aerosol .....	24,734	11,816	24,822	48
Elemental Carbon .....	6,409	4,425	5,638	78
Fine Soil .....	21,208	40,301	24,134	167
Coarse Mass .....	161,142	321,257	188,287	171

NDEP analyzes the differences between the baseline and current emissions based on WRAP's WestJump2008 inventory for eight categories of emissions as summarized below. This analysis focuses on the percentage change in the emissions of each pollutant by source category in 2002 and 2008, and adds an analysis of changes in emissions from 2008 to 2011 where NEI data is available.

*Sulfur Dioxide:* Total anthropogenic emissions of SO<sub>2</sub> decreased by 75 percent from 65,543 tons in 2002 to 16,552 tons in 2008, representing a

significant reduction in particular from point and area sources as shown in Table 9. Point source emissions alone decreased by 78 percent (50,720 to 11,067 tpy) during this period, and area source emissions decreased by 63 percent (12,953 to 4,863 tpy). As a percentage of total statewide emissions, anthropogenic and natural, point source emissions decreased from 75 percent of the total in the 2002 (50,720 of 67,743 tons) to 65 percent of the total in the 2008 (11,067 tons of a total 16,552 tons). Moreover, the NEI inventories show a further decrease in SO<sub>2</sub> emissions from

point sources of 44 percent from 10,409 tpy in 2008 to 5,863 tpy in 2011, primarily due to reductions in coal-fired emissions from power plants. On-road and off-road mobile emissions decreased by 34 percent (454 to 298 tpy) and 77 percent (1,403 to 322 tpy), respectively, from 2002 to 2008. Data from the NEI indicate further reductions in emissions from mobile sources from 2008 to 2011, a 47 percent decrease in on-road emissions (511 to 270 tpy) and a 87 percent decrease in off-road emissions (316 to 41 tpy).

<sup>38</sup> Nevada RH Progress Report, Chapter 4, Figures 4–12 through 4–15, pages 4–15 thru 4–19.

<sup>39</sup> WRAP Regional Haze Rule Reasonable Progress Summary Report, June 28, 2013. *West-Wide Jump-Start Air Quality Modeling Study—Final Report*, September 30, 2013.

<sup>40</sup> WRAP refers to the baseline as 2002, the midyear of the baseline inventory period from 2000 to 2004.

<sup>41</sup> Data from the NEI are slightly different from the WestJump2008 inventory, which leverages more recent inventory development performed by the WRAP.

<sup>42</sup> The WRAP compared data between the baseline (2002) and emission inventory (2008) for nine source categories: Point sources, area sources, oil and gas, on-road mobile, off-road mobile, fugitive dust and road dust, windblown dust, biogenic, and fires.

TABLE 9—CHANGES IN SULFUR DIOXIDE EMISSIONS BY CATEGORY (TPY)

Source category	2002 (Baseline)	2008 (WestJump2008)	Difference (percent change)
<b>Anthropogenic Sources</b>			
Point .....	50,720	11,067	-39,653 (-78%)
Area .....	12,953	4,863	-8,090 (-62%)
On-Road Mobile .....	454	298	-156 (-34%)
Off-Road Mobile .....	1,403	322	-1,081 (-77%)
Area Oil and Gas .....	0	0	0
Fugitive and Road Dust .....	0	0	0
Anthropogenic Fire .....	12	2	-10 (-83%)
<b>Total Anthropogenic .....</b>	<b>65,543</b>	<b>16,552</b>	<b>-48,991 (-75%)</b>
<b>Natural Sources</b>			
Natural Fire .....	2,200	506	-1,694 (-77%)
Biogenic .....	0	0	0
Windblown Dust .....	0	0	0
<b>Total Natural .....</b>	<b>2,200</b>	<b>506</b>	<b>-1,694 (-77%)</b>
<b>All Sources</b>			
<b>Total Emissions .....</b>	<b>67,743</b>	<b>17,058</b>	<b>-50,685 (-75%)</b>

*Nitrogen Oxides:* The total statewide inventory of NO<sub>x</sub> emissions from all sources decreased by 26 percent from 162,397 tpy in 2002 to 118,766 tpy in 2008 as shown in Table 10. Over this time period, NO<sub>x</sub> emissions from anthropogenic sources decreased by 23 percent (139,353 tpy to 107,827 tpy), and natural emissions decreased by 53 percent (23,044 tpy to 10,939 tpy). Anthropogenic emissions of NO<sub>x</sub> in Nevada are primarily from point and on-road mobile sources, followed by off-road and area sources. From the 2002 to 2008 inventories, NO<sub>x</sub> emissions from point sources decreased by about 50 percent (59,864 to 29,344 tpy), on-road mobile increased by about 22 percent (41,089 to 50,068 tpy), off-road mobile

decreased by about 48 percent (32,565 to 17,081 tpy), and area sources increased by 98 percent (5,725 to 11,321 tpy). Increases in on-road mobile and area source emission inventories were offset by larger decreases in emissions from point and off-road mobile sources. The NEI point source inventory shows a decrease of 57 percent in NO<sub>x</sub> emissions from 2008 to 2011. NDEP attributes the 22 percent increase in on-road mobile emissions to the use of different air quality models to estimate emissions in 2002 (MOBILE6) and in 2008 (MOVES2010), a growth in the number of vehicles, and the fact that federal vehicle emissions standards were not fully implemented. NEI data from 2008 and 2011 show a 36 percent

increase in on-road mobile NO<sub>x</sub> emissions, possibly related to population growth. The NEI shows a continuing decrease in off-road mobile emissions of 12 percent from 2008 to 2012. NDEP states that the increase in emissions from area sources may be a result of a reclassification of some off-road mobile sources into area source category, which may have contributed to the decrease in emissions from off-road mobile sources. This is consistent with the reclassification of in-flight aircraft emissions and locomotive emissions outside of rail yards from the off-road mobile category to the area source category in the 2008 NEI.<sup>43</sup>

TABLE 10—CHANGES IN NITROGEN OXIDE EMISSIONS BY CATEGORY (TPY)

Source category	2002 (Baseline)	2008 (WestJump2008)	Difference (percent change)
<b>Anthropogenic Sources</b>			
Point .....	59,864	29,344	-30,520
Area .....	5,725	11,321	5,597
On-Road Mobile .....	41,089	50,068	8,979
Off-Road Mobile .....	32,565	17,081	-15,484
Area Oil and Gas .....	63	0	-63
Fugitive and Road Dust .....	0	0	0
Anthropogenic Fire .....	48	13	-35
<b>Total Anthropogenic .....</b>	<b>139,353</b>	<b>107,827</b>	<b>-31,526 (-23%)</b>
<b>Natural Sources</b>			
Natural Fire .....	8,026	3,575	-4,451

<sup>43</sup> See <http://www.epa.gov/ttnchie1/net/2008inventory.html> ("Description of NEI Data Categories").

TABLE 10—CHANGES IN NITROGEN OXIDE EMISSIONS BY CATEGORY (TPY)—Continued

Source category	2002 (Baseline)	2008 (WestJump2008)	Difference (percent change)
Biogenic .....	15,018	7,364	-7,654
Windblown Dust .....	0	0	0
Total Natural .....	23,044	10,939	-12,105 (-53%)
<b>All Sources</b>			
Total Emissions .....	162,397	118,766	-43,631 (-26%)

*Ammonia:* Total statewide emissions of ammonia decreased by 22 percent (12,092 to 9,382 tpy) from 2002 to 2008. Of this total, anthropogenic emissions decreased by 34 percent (10,408 to 6,893 tpy) while natural emissions increased by 48 percent (1,684 to 2,490 tpy). The primary source of anthropogenic emissions of ammonia is area sources, and to a lesser extent on-road mobile sources, while fire is the dominant natural source.<sup>44</sup> Area sources of ammonia emissions decreased by about 29 percent (8,009 to 5,717 tpy) from 2002 to 2008. On-road mobile sources, the next largest category of anthropogenic emissions, decreased by about 58 percent (2,030 to 849 tpy). Despite an increase of 48 percent in natural fire (1,684 to 2,490 tpy), there was a net decrease in statewide emissions. Ammonia is not a criteria pollutant and is not included in the NEI, so no data for 2011 were provided.

*Volatile Organic Compounds:* Data from the 2002 and 2008 inventories as well as from the NEI for the 2008 to 2011 time period show large reductions in volatile organic compounds (VOC) emissions from natural sources with lesser reductions from anthropogenic sources. Biogenic emissions from natural sources dominate the Nevada VOC emissions inventory. Total statewide VOC emissions decreased by 61 percent from 897,102 tpy in 2002 to 351,142 tpy in 2008. This large reduction is mostly due to a decrease in biogenic emissions over this time period by 67 percent from 794,139 tpy to 262,912 tpy. NDEP notes that these changes may reflect enhancements to the inventory method, use of different meteorological years, and improved emission factors and data sources. There were also decreases in on-road mobile (36,257 to 21,302 tpy) and natural fire

(17,606 to 4,204 tpy), and an increase in area sources (28,592 to 40,973 tpy), all of which are a very small part of the total inventory. VOC emissions in the NEI show a decrease in point source (17 percent), on-road mobile (20 percent), and off road mobile (18 percent) from 2008 to 2011.

*Primary Organic Aerosol:* Wildfires are the dominant source of primary organic aerosol (POA) emissions, 90 percent of the total in 2002 (22,501 of a total 24,734 tpy) and 58 percent in 2008 (6,831 of a total 11,816 tpy). Anthropogenic sources, namely area and mobile, also are important contributors. Overall, total emissions of POA decreased by 52 percent from 2002 to 2008. Natural fire emissions of POA decreased 70 percent (22,501 to 6,831 tpy), reflecting the high variability of wildfires from year to year. Except for anthropogenic fire, all other categories of anthropogenic sources of POA (primarily area, mobile, and fugitive) increased during this time period with the total anthropogenic emissions increasing by 123 percent from 2,233 to 4,985 tpy.

*Elemental Carbon:* Natural fire (*i.e.*, wildfires) also dominate EC emissions at 73 percent of the 2002 inventory (4,674 of 6,409 tpy), but only 23 percent of the 2008 inventory (1,130 to 4,425 tpy), a reduction of 76 percent (4,674 to 1,130 tpy). Consequently, total emissions decreased by 31 percent (6,409 to 4,425 tpy) mostly due to the decrease in natural fire. Total anthropogenic emissions increased by 90 percent (1,735 to 3,295 tpy) due mostly to an increase in on-road mobile sources from 235 to 1,891 tpy over this time period. On-road mobile is the largest source of elemental carbon in the 2008 inventory at 43 percent, while the next largest category is natural fire emissions contributing 26 percent. Area and point sources, by contrast, contribute less than one percent each to the 2008 inventory.

*Fine Soil:* Total emissions of fine soils increased by 90 percent (21,208 to 40,301 tpy) from the 2002 to the 2008 inventory. The largest increases were in

fugitive dust (6,128 to 19,216 tpy) and windblown dust (10,438 to 17,051 tpy). NDEP reports that increases in these source categories were likely due to updates to inventory development methods rather than actual increases.

*Coarse Mass:* Total emissions of coarse mass increased by about 99 percent (161,142 to 321,257 tpy), mostly due to large increases in anthropogenic fugitive and road dust (56,799 to 161,532 tpy) and in natural windblown dust (93,946 to 153,459 tpy). Fugitive dust includes sources such as agricultural operations, construction, and mining operations. Windblown dust is largely from vacant lands. NDEP attributes these increases in part to updates in the inventory development methods rather than actual increases. Nonetheless, increases in fugitive dust may be due to increases in population, while increases in road dust may be due to increases in vehicle miles traveled. Point source and natural fire emissions decreased.

## 2. EPA's Evaluation

We propose to find that NDEP adequately addresses the requirement in 40 CFR 51.308(g)(4) to analyze the change in emissions over the past five years of pollutants contributing to visibility impairment from all sources and activities within the state, using the most recently updated emission inventories. NDEP's analysis of emission data makes a strong case that the State is reducing emissions of SO<sub>2</sub> and NO<sub>x</sub> from anthropogenic sources, especially point sources.

### E. Assessment of Anthropogenic Emissions Impeding Progress

#### 1. NDEP's Analysis

NDEP reports that progress toward achieving its visibility goal of 11.05 dv at Jarbidge by 2018 has not been impeded by any significant anthropogenic emission changes within or outside the State. NDEP reaches this conclusion by evaluating significant emission changes within Nevada, the effect of emissions from sources outside

<sup>44</sup> The WRAP has created an operational policy level definition of fire activity as discretely natural or anthropogenic. See the *WRAP Regional Haze Rule Reasonable Progress Summary Report*, section 3.2.1 and the WRAP's *Policy for Categorizing Fire Emissions* (November 15, 2001), available at <http://www.wrapair.org/forums/fejff/documents/nbtt/FirePolicy.pdf>.

of Nevada on Jarbidge, and the effect of Nevada's emissions on nearby Class I areas.

*Emission Changes within Nevada and Visibility Conditions at Jarbidge:* NDEP analyzes the baseline and rolling five-year annual averages of light extinction data from the JARB1 monitor for the best and worst days from 2005 through 2012. For the worst days, the data show a reduction in sulfate and nitrate extinction for the three most recent five-year periods (2006–2010, 2007–2011, and 2008–2012), but an increase in POM

extinction, due to a spike in 2012 that NDEP attributes to wildfires.<sup>45</sup> On the best days, visibility impairment is reduced from the baseline to the current period due to decreases in extinction from sulfate, nitrate, POM, and elemental carbon. Light extinction for soil, coarse mass, and sea salt remain fairly constant on best days.

Actual emissions of SO<sub>2</sub>, NO<sub>x</sub>, PM<sub>10</sub>, and VOC from point sources in Nevada<sup>46</sup> have decreased significantly over a 10-year period (2002–2012) and over the last five years (2008–2012) as

presented in Table 11.<sup>47</sup> The years 2002, 2005, 2008, and 2011 are the most complete inventory years submitted to EPA for the NEI. The data for 2012 are actual emission values for major and minor point sources from Nevada's permitting database. As shown in the table, SO<sub>2</sub> emissions from point sources dropped dramatically after the closure of Mohave in 2005, and decreased by another 50 percent from 2008 to 2012. Likewise, NO<sub>x</sub> emissions decreased by 30,000 tpy after 2005, and decreased another 62 percent from 2008 to 2012.

TABLE 11—ACTUAL EMISSIONS OF NEVADA POINT SOURCES (TPY)

Year	SO <sub>2</sub>	NO <sub>x</sub>	PM <sub>10</sub>	VOC
2002	50,619	55,876	6,868	2,132
2005	54,243	52,087	4,643	1,646
2008	10,497	21,680	3,465	1,600
2011	5,959	10,548	3,331	971
2012	5,278	8,324	2,629	986

PM<sub>10</sub> = particulate matter less than 10 microns.

*Emissions from Outside Sources Effecting Jarbidge:* NDEP's analysis focuses on three BART sources in Idaho and Oregon to determine whether these previously identified point sources are impeding progress on the worst days at Jarbidge. Comparing baseline emissions to the NEI in 2011, total SO<sub>2</sub> emissions from these three sources decrease by about 40 percent (26,243 to 15,782 tpy) from 2002 to 2011. Total NO<sub>x</sub> emissions decrease by about 31 percent (11,010 to 7,611 tpy) over the same time period. Moreover, emissions from these sources will continue to decline over time given staggered compliance dates through 2018. With visibility impairment resulting from sulfate and nitrate trending downward at Jarbidge and the implementation of BART controls in Idaho and Oregon, NDEP concludes that there are no significant changes in anthropogenic emissions from outside the State that are impeding progress at Jarbidge.

In assessing point source emissions from Idaho and Oregon, NDEP references source apportionment modeling of particulate sulfate and nitrate extinction for 2018 that was performed by the WRAP for the Nevada Regional Haze SIP.<sup>48</sup> The purpose of the modeling is to determine source areas that contribute to visibility impairment

on the worst days at Jarbidge. The area of greatest sulfate contribution is Outside Domain<sup>49</sup> (43.8 percent), followed by Idaho (10.3 percent), Oregon (7.2 percent), and Pacific Offshore (6.9 percent). The area of greatest nitrate contribution is Idaho (30.3 percent), followed by Outside Domain (27.5 percent), Nevada (13.1 percent), and Utah (10.6 percent). Based on these results, Idaho is the second largest contributor of modeled sulfate and the largest contributor of modeled nitrate concentrations. Oregon is the third largest contributor of modeled sulfate concentrations. While this analysis supports the focus on emissions from Idaho and Oregon, the fact that Outside Domain contributes 43.8 percent of the modeled sulfate and 27.5 percent of the modeled nitrate is another indication that Nevada has limited control over a large subset of the emissions impairing visibility at Jarbidge.

*Nevada's Emissions Effect on Nearby Class I Areas:* NDEP also addresses the potential effect of Nevada's emissions on nearby Class I areas in other states using particulate source apportionment modeling conducted by the WRAP for the first round of regional haze SIPs. This modeling estimated Nevada's projected contributions to light

extinction from sulfates and nitrates at Class I areas in adjacent states in 2018.<sup>50</sup> In light of the 75 percent reduction in Nevada's SO<sub>2</sub> emissions (see Table 9) and 26 percent reduction in NO<sub>x</sub> emissions (see Table 10) between 2002 and 2008, NDEP concludes that Nevada's emission reductions are not impeding progress in reducing visibility impairment at Class I areas in adjacent states.

2. EPA's Evaluation

EPA proposes to find that NDEP adequately addresses the requirement in 40 CFR 51.308(g)(5) to assess any significant changes in anthropogenic emissions within or outside the state over the past five years that have limited or impeded progress in reducing emissions and improving visibility. NDEP provides a comprehensive analysis of emission changes within and outside the State, and examines the potential effect of these changes at Jarbidge and at other Class I areas. All indications are that the total statewide emissions of SO<sub>2</sub> and NO<sub>x</sub> are decreasing (see Tables 9, 10, and 11), and most of the pollutants are already at levels below those in the projected emission inventory for 2018 (see Table 8). Based on NDEP's analysis, EPA proposes to concur with NDEP that

<sup>45</sup> Progress Report, Chapter 6, pages 6–2 thru 6–3.

<sup>46</sup> SO<sub>2</sub> emissions from point sources were 68 percent of the total anthropogenic emissions in Nevada in 2008 (WestJump2008). Area source emissions of SO<sub>2</sub> were 29 percent of total anthropogenic emissions in 2008.

<sup>47</sup> Progress Report, Table 6–1, page 6–4.

<sup>48</sup> Nevada Regional Haze SIP, Chapter 4, Table 4–5: Summary of 2018 Model Results for Jarbidge Wilderness Area, based on Particulate Matter Source Attribution Tracking, page 31.

<sup>49</sup> Outside Domain as a source category represents the background concentrations of pollutants from international sources that enter the modeling

domain, in this case the western United States and portions of Canada and Mexico.

<sup>50</sup> Nevada Regional Haze SIP, Chapter 4, Tables 4–3: Nevada's Sulfate Extinction Contribution to Class I Areas Outside of Nevada and Table 4–4: Nevada's Nitrate Extinction Contribution to Class I Areas Outside of Nevada, pages 14–17.

there is no evidence that any recent changes in emissions from any specific sources or source categories are impeding progress.

*F. Assessment of Plan Elements and Strategy*

1. NDEP's Analysis

The Progress Report concludes that the existing elements and strategies in the Nevada Regional Haze Implementation Plan are sufficient to enable Nevada and other neighboring states to meet the RPGs by 2018 in terms of reducing emissions from anthropogenic sources. Nevada has already achieved significant emission reductions in the first phase of the regional haze program, with additional reductions expected by 2018. Actual emissions of visibility impairing pollutants in 2008, with the exception of fine soil and coarse mass, are already less than the projected emissions in 2018 (see Table 8). Notably actual SO<sub>2</sub> emissions in 2008 are about 40 percent and actual NO<sub>x</sub> emissions are about 90 percent of the respective totals in the projected emission inventory for 2018. The NEI data for 2008 and 2011 also demonstrate further reductions in SO<sub>2</sub> and NO<sub>x</sub> emissions from point sources in Nevada (see Table 11). Moreover, further reductions in anthropogenic emissions are expected from the power sector as a result of BART implementation, shutdowns, and conversions to natural gas or lower sulfur fuels. In the case of Jarbidge, NDEP notes that emissions from natural sources can dominate visibility impairment on the worst days, and

much of the anthropogenic emissions are from out-of-state. NDEP states that given the current and expected SO<sub>2</sub> and NO<sub>x</sub> emission reductions from power plants, further reductions from any other non-utility or industrial point sources are unnecessary at this time.

Regarding visibility conditions, trend analysis of monitoring data at Jarbidge from 2000 to 2012 demonstrates improvement in visibility impairment from sulfate and nitrate on the worst and best days, both on an annual average basis as well as five-year annual averages.<sup>51</sup> NDEP notes that, although the visibility benefit from anthropogenic emission reductions is overshadowed by contributions from natural sources, visibility is slowly improving at Jarbidge on the worst days and shows considerable improvement on the best days (see Tables 5, 6, and 7). Where it appears that visibility improvement on worst days is not keeping pace with emission reductions (e.g., the 14.9 dv annual average for 2012 in Table 4), NDEP asserts that this is due to large contributions from natural sources (e.g., light extinction from POM of 23.97 Mm<sup>-1</sup> in 2012). In terms of anthropogenic sources, NDEP notes that sulfate contributes the most to visibility impairment on worst days at Jarbidge, but most of the sulfate is from out-of-state sources. Nitrate has only a small contribution to visibility impairment on the worst days.

2. EPA's Evaluation

EPA proposes to find that the Progress Report adequately addresses the requirement in 40 CFR 51.308(g)(6) to

assess whether the current elements and strategies in the Regional Haze Implementation Plan are sufficient to enable Nevada, and other states affected by Nevada's emissions, to meet all established RPGs.

In particular, the Report analyzes trends in statewide emissions and visibility conditions at Jarbidge, as well as the additional emission reductions expected through 2018. The Report indicates that anthropogenic emissions of SO<sub>2</sub>, NO<sub>x</sub>, ammonia and VOC are decreasing. In particular, the emission reductions reflect substantial decreases in total anthropogenic emissions of SO<sub>2</sub> and NO<sub>x</sub>. However, anthropogenic emissions of POA, fine soil, elemental carbon and coarse mass are increasing. While these increases may be partially attributable to changes in inventory development methodologies, they highlight the need for greater attention to these pollutants in future planning periods.

With regard to visibility trends, the Progress Report explains that Jarbidge is not on track to meet the 2018 RPG for the worst days due to the large contribution from POM, which NDEP attributes mostly to wildfires and windblown dust. EPA concurs that POM has a large impact on the worst days and that much of the POM is attributable to natural sources, particularly wildfires. Furthermore, we note that the trend of high POM extinction (with significant interannual variability) dominating the worst days at Jarbidge has continued during 2013 and 2014, for which the IMPROVE data are now available, as shown in Tables 12 and 13.

TABLE 12—2013 AND 2014 AVERAGE VISIBILITY CONDITIONS FOR WORST AND BEST DAYS AT JARBIDGE

Year	Haze index (dv)	Sulfate (Mm <sup>-1</sup> )	Nitrate (Mm <sup>-1</sup> )	POM (Mm <sup>-1</sup> )	EC (Mm <sup>-1</sup> )	Soil (Mm <sup>-1</sup> )	Coarse mass (Mm <sup>-1</sup> )	Sea salt (Mm <sup>-1</sup> )
<b>Worst Days</b>								
2013 .....	11.7	3.5	1.0	8.4	1.3	2.7	5.9	0.1
2014 .....	12.2	3.1	0.6	14.5	2.3	2.2	4.5	0.2
<b>Best Days</b>								
2013 .....	1.5	0.9	0.1	0.2	0.0	0.1	0.2	0.0
2014 .....	1.8	1.0	0.2	0.3	0.1	0.1	0.2	0.1

<sup>51</sup> Progress Report, Chapter 4, Section 4.6: Visibility Trends, pages 4–15 thru 4–19.

TABLE 13—FIVE-YEAR ANNUAL AVERAGE VISIBILITY CONDITIONS FOR WORST AND BEST DAYS AT JARBIDGE

Year	Haze index (dv)	Sulfate (Mm <sup>-1</sup> )	Nitrate (Mm <sup>-1</sup> )	POM (Mm <sup>-1</sup> )	EC (Mm <sup>-1</sup> )	Soil (Mm <sup>-1</sup> )	Coarse mass (Mm <sup>-1</sup> )	Sea salt (Mm <sup>-1</sup> )
<b>Worst Days</b>								
2009–2013 .....	12.0	3.8	0.9	10.7	1.5	2.5	5.9	0.2
2010–2014 .....	12.2	3.6	0.9	12.1	1.8	2.5	5.6	0.2
<b>Best Days</b>								
2009–2013 .....	1.9	1.0	0.2	0.4	0.1	0.1	0.3	0.0
2010–2014 .....	1.9	1.0	0.2	0.4	0.1	0.1	0.3	0.0

However, we also note that not all POM is from natural sources. POA and VOC, the precursors to POM, are also emitted by anthropogenic sources, particularly area and mobile sources. Moreover, other pollutants, particularly coarse mass and sulfates, both of which have a significant anthropogenic component, also contribute to impairment on the worst days at Jarbidge. Accordingly, in developing its Regional Haze SIP for the next planning period, NDEP should consider implementing additional control measures to address anthropogenic emissions of POA, VOC, SO<sub>2</sub>, and coarse mass.

Nonetheless, given the substantial reductions in anthropogenic emissions of SO<sub>2</sub> and NO<sub>x</sub>, improvement in visibility conditions on the best days, and evidence that the worst days are slowly improving, we propose to find that the current plan is sufficient for meeting the RPGs.

*G. Review of Visibility Monitoring Strategy*

1. NDEP’s Analysis

The primary monitoring network, nationally and in Nevada, for the measurement and characterization of pollutants contributing to regional haze is the IMPROVE network. NDEP intends to rely on the continued availability of quality assured data collected through the IMPROVE network to comply with the regional haze monitoring requirements in the RHR. NDEP finds that the IMPROVE site at Jarbidge, Nevada’s only Class I area, is sufficiently representative to support a determination of reasonable progress. NDEP concludes that no modification to the State’s visibility monitoring strategy is necessary at this time.

2. EPA’s Evaluation

EPA proposes to find that NDEP adequately addresses the requirement in 40 CFR 51.308(g)(7) to review its visibility monitoring strategy and make

any modifications as necessary. We are not aware of any evidence of a need to modify Nevada’s monitoring strategy for measuring visibility at this time.

*H. Determination of Adequacy*

1. NDEP’s Determination

NDEP has determined that no substantive revision of the Nevada Regional Haze Implementation Plan is warranted at this time in order to achieve the RPGs in 2018 for visibility improvement at Jarbidge and at other Class I areas affected by emissions from Nevada. NDEP concludes that no additional controls are necessary based on the evidence presented in the Progress Report regarding the first half of the first phase of the program. The Report documents a substantial reduction in anthropogenic emissions in Nevada as well as an improvement in visibility at Jarbidge even though BART controls and other state and federal measures are not yet fully implemented. Further changes in source activity that were not included in the State’s plan further support the conclusion that progress is adequate.

2. EPA’s Evaluation

EPA proposes to find that NDEP adequately addresses the requirements in 40 CFR 51.308(h) by determining that the existing Nevada Regional Haze Implementation Plan requires no substantive revisions at this time to achieve the established RPGs at Jarbidge and at other Class I areas affected by emissions from Nevada. We propose to concur with the State’s negative declaration based on the analysis and documentation presented in the Progress Report.

NDEP demonstrates that emissions from anthropogenic sources within the State are decreasing as are emissions from point sources in Idaho and Oregon that contribute to visibility impairment at Jarbidge. While the monitoring data indicates that best days at Jarbidge are getting better, we are concerned that

visibility conditions on the worst days are relatively flat or only slightly improving. However, this lack of progress on the worst days is largely attributable to the impact of POM, which results primarily from natural sources. Therefore, we propose to approve NDEP’s determination that the Nevada Regional Haze Implementation Plan requires no substantive revisions at this time.

*I. Consultation With Federal Land Managers*

1. NDEP’s Consultation

NDEP provided FLMs with a draft Progress Report on June 14, 2014, for a 60-day review prior to the public comment period, received comments from the U.S. Department of Interior National Parks Service (NPS) and the U.S. Department of Agriculture Forest Service (USFS), and responded to those comments as documented in Appendix C of the Progress Report. The letter from NPS dated August 15, 2014, supported the Report’s findings, and provided four short comments on how to improve specific aspects of the analyses. The letter from USFS dated August 29, 2014, acknowledged the opportunity to work with NDEP, but provided no specific comments. In the Progress Report, NDEP reaffirmed its commitment to continue participating in the WRAP and consulting with other states, FLMs, and tribes regarding SIP revisions and implementation of other programs that may contribute to visibility impairment.

2. EPA’s Evaluation

EPA proposes to find that NDEP has addressed the requirements in 40 CFR 51.308(i)(2), (3), and (4) to provide FLMs with an opportunity for consultation in person and at least 60 days prior to a public hearing on the revised plan; include a description in the revised plan of how it addressed any comments from the FLMs; and provide procedures for continuing consultation between the State and FLMs. These

procedural requirements for the Progress Report, a revision to the Regional Haze SIP in this case, are documented in Appendices C and D attached to the Report.

#### J. Public Participation

##### 1. NDEP's Public Process

NDEP provided a 30-day public comment period on the draft Progress Report as well as an opportunity for a public hearing. The public hearing, scheduled for October 15, 2014, was cancelled because no request for a hearing was received. During the public comment period, NDEP received one set of comments from the Sierra Club and National Parks Conservation Association in a letter dated October 16, 2014.<sup>52</sup> These organizations questioned whether NDEP's analysis supports its determination that progress in implementing the Nevada Regional Haze Implementation Plan is adequate to achieve the 2018 RPGs for Jarbidge and other Class I areas affected by Nevada's emissions. NDEP provided detailed responses to these comments in Appendix D of the Progress Report.

##### 2. EPA's Evaluation

EPA proposes to find that NDEP has fulfilled the requirements of CAA 110(a) and (l) and 40 CFR 51.102 regarding reasonable notice and public hearings.

#### VI. EPA's Proposed Action

EPA is proposing to approve the Nevada Regional Haze Progress Report submitted to EPA on November 18, 2014, as meeting the applicable requirements of the CAA and RHR.

#### VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations.<sup>53</sup> Thus, in reviewing SIP submissions, EPA's role is to approve state decisions, provided that they meet the criteria of the CAA. Accordingly, this proposed action is to approve state law as meeting Federal requirements, and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under

Executive Order 12866 (58 FR 51735, October 4, 1993);

- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because it does not involve technical standards; and

- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Organic carbon, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Visibility, Volatile organic compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: September 1, 2015.

**Jared Blumenfeld,**

*Regional Administrator, Region IX.*

[FR Doc. 2015-23272 Filed 9-16-15; 8:45 am]

**BILLING CODE 6560-50-P**

#### DEPARTMENT OF COMMERCE

#### National Oceanic and Atmospheric Administration

#### 50 CFR Part 622

RIN 0648-BD76

#### Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Dolphin and Wahoo Fishery Off the Atlantic States and Snapper-Grouper Fishery of the South Atlantic Region; Amendments 7/33

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The South Atlantic Fishery Management Council (Council) has submitted Amendment 7 to the Fishery Management Plan (FMP) for the Dolphin and Wahoo Fishery off the Atlantic States (Dolphin and Wahoo FMP) and Amendment 33 to the FMP for the Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP) (Amendments 7/33) for review, approval, and implementation by NMFS. Amendments 7/33 propose actions to revise the landing fish intact provisions for vessels that lawfully harvest dolphin, wahoo, or snapper-grouper in or from Bahamian waters and return to the U.S. exclusive economic zone (EEZ). The U.S. EEZ as described in this document refers to the Atlantic EEZ for dolphin and wahoo and the South Atlantic EEZ for snapper-grouper. The purpose of Amendments 7/33 is to improve the consistency and enforceability of Federal regulations with regards to landing fish intact and to increase the social and economic benefits related to the recreational harvest of these species.

**DATES:** Written comments must be received on or before November 16, 2015.

**ADDRESSES:** You may submit comments on Amendments 7/33 identified by "NOAA-NMFS-2015-0047" by any of the following methods:

- *Electronic submissions:* Submit electronic comments via the Federal e-Rulemaking Portal: <http://www.regulations.gov>. Go to [www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2015-0047](http://www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2015-0047), click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Nikhil Mehta, Southeast Regional

<sup>52</sup> The letter to Adele Malone, NDEP, is signed by David VonSeggern, Chair, Sierra Club Toiyabe Chapter; Gloria Smith, Managing Attorney, Sierra Club; and Lynn Davis, Senior Program Manager, Nevada Field Office, National Parks Conservation Association.

<sup>53</sup> 42 U.S.C. 7410(k); 40 CFR 52.02(a).

Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

**Instructions:** Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of Amendments 7/33, which includes an environmental assessment, a Regulatory Flexibility Act analysis, and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at [http://sero.nmfs.noaa.gov/sustainable\\_fisheries/s\\_atl/generic/2015/dw7\\_sg33/index.html](http://sero.nmfs.noaa.gov/sustainable_fisheries/s_atl/generic/2015/dw7_sg33/index.html).

**FOR FURTHER INFORMATION CONTACT:**

Nikhil Mehta, Southeast Regional Office, telephone: 727-824-5305, or email: [nikhil.mehta@noaa.gov](mailto:nikhil.mehta@noaa.gov).

**SUPPLEMENTARY INFORMATION:**

The dolphin and wahoo fishery is managed under the Dolphin and Wahoo FMP and the snapper-grouper fishery is managed under the Snapper-Grouper FMP. The FMPs were prepared by the Council and are implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Magnuson-Stevens Act also requires that NMFS, upon receiving a plan or amendment, publish an announcement in the **Federal Register** notifying the public that the plan or amendment is available for review and comment.

**Background**

Current Federal regulations require that dolphin or wahoo or snapper-grouper species harvested in or from the U.S. EEZ must be maintained with the heads and fins intact and not be in fillet form. However, as implemented through Amendment 8 to the Snapper-Grouper FMP, an exception applies to snapper-grouper species that are lawfully harvested in Bahamian waters and are onboard a vessel returning to the U.S. through the EEZ (63 FR 38298, July 16, 1998). Amendment 8 to the Snapper-Grouper FMP allows that in the South Atlantic EEZ, snapper-grouper lawfully harvested in Bahamian waters are exempt from the requirement that they

be maintained with head and fins intact, provided valid Bahamian fishing and cruising permits are on board the vessel and the vessel is in transit through the South Atlantic EEZ. A vessel is in transit through the South Atlantic EEZ when it is on a direct and continuous course through the South Atlantic EEZ and no one aboard the vessel fishes in the EEZ.

The Bahamas does not allow for the commercial harvest of dolphin, wahoo, or snapper-grouper species by U.S. vessels in Bahamian waters. Therefore, the measures proposed in Amendments 7/33 only apply to the recreational harvest of these species in The Bahamas and on a vessel returning from Bahamian water to the U.S. EEZ.

**Actions Contained in Amendments 7/33**

Amendments 7/33 would revise the landing fish intact provisions for vessels that lawfully harvest dolphin, wahoo, and snapper-grouper in Bahamian waters and return to the U.S. EEZ. Amendments 7/33 would allow for dolphin and wahoo fillets to enter the U.S. EEZ after lawful harvest in Bahamian waters; specify the condition of any dolphin, wahoo, and snapper-grouper fillets; describe how the recreational bag limit would be determined for any fillets; explicitly prohibit the sale or purchase of any dolphin, wahoo, or snapper-grouper recreationally harvested in Bahamian waters; specify the required documentation to be onboard any vessels that have these fillets, and specify transit and stowage provisions for any vessels with these fillets.

*Landing Fish Intact*

Currently, all dolphin and wahoo in or from the Atlantic EEZ are required to be maintained with head and fins intact. These fish may be eviscerated, gilled, and scaled, but must otherwise be maintained in a whole condition. Amendments 7/33 would allow for dolphin and wahoo lawfully harvested in Bahamian waters to be exempt from this provision when returning to the Atlantic EEZ. Dolphin or wahoo lawfully harvested in or from Bahamian waters would be able to be stored on ice more effectively for transit through the U.S. EEZ in fillet form, given the coolers generally used on recreational vessels. Allowing fishers on these vessels to be exempt from the landing fish intact regulations would increase the social and economic benefits for recreational fishers returning to the U.S. EEZ from Bahamian waters. This proposed exemption would also allow for increased consistency between the dolphin and wahoo and snapper-

grouper regulations. This proposed action would not be expected to substantially increase recreational fishing pressure or otherwise change recreational fishing behavior, because these species would not be exempt from U.S. recreational bag limits, fishing seasons, size limits, or other management measures in place in the U.S. EEZ, including prohibited species (e.g., goliath grouper and Nassau grouper). Therefore, the Council and NMFS anticipate that there are likely to be neither positive nor negative additional biological effects to these species.

Snapper-grouper possessed in the South Atlantic EEZ are currently exempt from the landing fish intact requirement if the vessel lawfully harvests snapper-grouper in The Bahamas. This action would retain this exemption for snapper-grouper species and revise it to include additional requirements.

*Condition of Fillets*

To better allow for identification of the species of any fillets in the U.S. EEZ, Amendments 7/33 would require that the skin be left intact on the entire fillet of any dolphin, wahoo, or snapper-grouper carcass (fillet) transported from Bahamian waters through the U.S. EEZ. This requirement will assist law enforcement in identifying fillets to determine whether they are only of the species to be exempted by Amendments 7/33.

*Recreational Bag Limits*

Currently, all dolphin, wahoo, and snapper-grouper harvested or possessed in or from the EEZ must adhere to the U.S. bag and possession limits. Amendments 7/33 would not revise those bag and possession limits, but would specify how fillets are counted with respect to determining the number of fish onboard a vessel in transit from Bahamian waters through the U.S. EEZ and ensuring compliance with U.S. bag and possession limits. Amendments 7/33 would specify that for any dolphin, wahoo, or snapper-grouper species lawfully harvested in Bahamian waters and onboard a vessel in the U.S. EEZ in fillet form, two fillets of the respective species of fish, regardless of the length of each fillet, is equivalent to one fish. This measure is intended to assist law enforcement by helping ensure compliance with the relevant U.S. bag and possession limits.



*Sale and Purchase Restrictions of Recreationally Harvested Dolphin, Wahoo or Snapper-Grouper*

Amendments 7/33 would explicitly prohibit the sale or purchase of any dolphin, wahoo, and snapper-grouper recreationally harvested in The Bahamas and transported through the U.S. EEZ. The Council determined that establishing a specific prohibition to the sale or purchase of any of these species from The Bahamas was necessary to ensure consistency with the current Federal regulations that prohibit recreational bag limit sales of these species. The Council wanted to ensure that Amendments 7/33 and the accompanying rulemaking do not create an opportunity for these fish to be sold or purchased.

*Required Documentation*

Amendments 7/33 would revise the documentation requirements for snapper-grouper species and implement documentation requirements for dolphin and wahoo lawfully harvested in Bahamian waters and in transit through the U.S. EEZ. For snapper-grouper lawfully harvested under the exemption, the current requirement is that valid Bahamian fishing and cruising permits are on the vessel. Amendments 7/33 would retain the current requirement that valid Bahamian fishing and cruising permits are onboard and additionally require that all vessel passengers have stamped and dated government passports. These documentation requirements would apply to individuals onboard a vessel in transit through the U.S. EEZ from Bahamian waters with dolphin, wahoo, or snapper-grouper fillets. Requiring vessel passengers to have a valid government passport with current stamps and dates from The Bahamas will increase the likelihood that the vessel was lawfully fishing in The Bahamas and that any dolphin, wahoo, or snapper-grouper fillets on the vessel were harvested in Bahamian waters and not in the U.S. EEZ.

*Transit and Stowage Provisions*

Snapper-grouper vessels operating under the current exemption have specific transit requirements when in the South Atlantic EEZ as described in § 622.186(b). These vessels are required to be in transit when they enter the South Atlantic EEZ with Bahamian snapper-grouper onboard. A vessel is in transit through the South Atlantic EEZ when it is on “a direct and continuous course through the South Atlantic EEZ and no one aboard the vessel fishes in the EEZ.” Amendments 7/33 would

revise the snapper-grouper transit provisions, also apply the transit provisions to vessels operating under the proposed exemption for dolphin and wahoo, and require fishing gear to be appropriately stowed on vessels transiting through the U.S. EEZ with fillets of these species. The proposed definition for “fishing gear appropriately stowed” would mean that “terminal gear (*i.e.*, hook, leader, sinker, flasher, or bait) used with an automatic reel, bandit gear, buoy gear, handline, or rod and reel must be disconnected and stowed separately from such fishing gear. Sinkers must be disconnected from the down rigger and stowed separately.” The Council determined that specifying criteria for transit and fishing gear stowage for vessels returning from The Bahamas under the exemption would assist in the enforceability of the proposed regulations and increase consistency with the state of Florida’s gear stowage regulations.

A proposed rule that would implement measures outlined in Amendments 7/33 has been drafted. In accordance with the Magnuson-Stevens Act, NMFS is evaluating Amendment 7/33 and the proposed rule to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law. If the determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

**Consideration of Public Comments**

The Council submitted Amendments 7/33 for Secretarial review, approval, and implementation on May 1, 2015.

Comments received on or before November 16, 2015, will be considered by NMFS in the approval, partial approval, or disapproval decision regarding Amendments 7/33. Comments received after that date will not be considered by NMFS in this decision. All relevant comments received by NMFS on the amendment or the proposed rule during their respective comment periods will be addressed in the final rule.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: September 14, 2015.

**Alan D. Risenhoover,**

*Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 622**

[Docket No. 150817720-5720-01]

**RIN 0648-BF21**

**Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Greater Amberjack Management Measures**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes to implement management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). If implemented, this action would revise the commercial and recreational annual catch limits (ACLs) and annual catch targets (ACTs), the commercial trip limit, and the recreational minimum size limit for greater amberjack in the Gulf of Mexico (Gulf) exclusive economic zone. Additionally, this rule would correct an error in the Gulf gray triggerfish recreational accountability measures (AMs). The purpose of this rule is to modify Gulf greater amberjack management measures to end overfishing and achieve optimal yield for the greater amberjack resource.

**DATES:** Written comments must be received on or before October 19, 2015.

**ADDRESSES:** You may submit comments on the proposed rule, identified by “NOAA-NMFS-2015-0094” by any of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to [www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2015-0094](http://www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2015-0094), click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- **Mail:** Submit written comments to Richard Malinowski, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

**Instructions:** Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public

viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office Web site at [http://sero.nmfs.noaa.gov/sustainable\\_fisheries/gulf\\_fisheries/reef\\_fish/2015/greater\\_amberjack\\_framework/index.html](http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2015/greater_amberjack_framework/index.html).

**FOR FURTHER INFORMATION CONTACT:** Richard Malinowski, Southeast Regional Office, NMFS, telephone: 727-824-5305, email: [rich.malinowski@noaa.gov](mailto:rich.malinowski@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The Gulf reef fish fishery is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

### Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to achieve on a continuing basis the optimum yield from federally managed fish stocks. This mandate is intended to ensure that fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, while also protecting marine ecosystems.

The greater amberjack resource in the Gulf was declared overfished by NMFS on February 9, 2001. Secretarial Amendment 2 established a greater amberjack rebuilding plan that started in 2003 and was scheduled to rebuild the stock in 2012 (68 FR 39898, July 3, 2003). In 2006, a Southeast Data, Assessment and Review (SEDAR) benchmark stock assessment (SEDAR 9) occurred and was subsequently updated in 2010 (SEDAR 9 Update). In response to new scientific information from SEDAR 9 and the SEDAR 9 Update, the rebuilding plan was revised in both Amendments 30A and 35 to the FMP (73 FR 38139, July 3, 2008, and 77 FR 67574, December 13, 2012). However, the rebuilding time period ended in 2012, without the stock being rebuilt.

A 2014 stock assessment indicates the Gulf greater amberjack stock remains overfished and is undergoing overfishing. The Council's Scientific and Statistical Committee (SSC) reviewed this assessment at their June 2014 meeting and used the acceptable biological catch (ABC) control rule to recommend an ABC equivalent to 75 percent of the maximum fishing mortality threshold to end overfishing and rebuild the stock. The ABCs recommended by the Council's SSC in this framework action are: 1,720,000 lb (780,179 kg) for 2015; 2,230,000 lb (1,011,511 kg) for 2016; 2,490,000 lb (1,129,445 kg) for 2017; and 2,620,000 lb (1,188,412 kg) for 2018.

In August 2014, pursuant to section 304(e)(2) of the Magnuson-Stevens Act, NMFS notified the Council of the 2014 stock assessment results that indicated that the greater amberjack stock continued to be overfished and undergoing overfishing. Following that notification, the Council was required under section 304(e)(3) of the Magnuson-Stevens Act to prepare a plan amendment or regulations within 2 years to end overfishing immediately and rebuild the greater amberjack stock.

For this framework action, the Council chose to reduce the current stock ACL of 1,780,000 lb (807,394 kg) to the SSC's ABC recommendation for 2015 of 1,720,000 lb (780,179 kg). Furthermore, the Council decided to maintain the 2015 catch levels through 2018, which results in an ABC and stock ACL that will be 49 percent of the 2018 overfishing limit (OFL), and is expected to rebuild the stock by 2019. The Council also considered an alternative in the framework action that would have set the stock ACL at zero. However, this alternative, which is projected to rebuild the stock by 2017, would have the greatest negative socio-economic impacts on fishing communities for relatively little biological benefit.

Although the Council did not explicitly discuss its obligations under section 304(e)(3) of the Magnuson-Stevens Act, the framework action and this proposed rule fulfill the Council's responsibility to "prepare and implement a fishery management plan, plan amendment, or proposed regulations for the fishery" under that provision. Consistent with the requirements of sections 304(e)(3) and (4), the framework action and proposed rule are projected to end overfishing immediately and rebuild the stock in as short as time possible, taking into account the needs of fishing communities. The specified time for rebuilding is 4 years, well below the

maximum time of 10 years specified in section 304(4)(A)(ii) of the Magnuson-Stevens Act, and the harvest restrictions are fairly and equitably allocated between the commercial and recreational sectors by virtue of the established ACL allocation, the increased recreational size limit, and the decreased commercial trip limit.

### Management Measures Contained in This Proposed Rule

This rule would revise the commercial and recreational ACLs and ACTs (which are expressed as quotas in the regulatory text), the commercial trip limit, and the recreational minimum size limit for greater amberjack in the Gulf.

#### *Commercial and Recreational ACLs and ACTs*

This rule would revise the commercial and recreational ACLs and ACTs for Gulf greater amberjack. All ACL and ACT weights are described in round weight. The final rule for Amendment 35 to the FMP set the current commercial ACL at 481,000 lb (218,178 kg) and the current commercial ACT at 409,000 lb (185,519 kg). That final rule also set the current recreational ACL at 1,299,000 lb (589,216 kg) and the current recreational ACT at 1,130,000 lb (512,559 kg).

This proposed rule would reduce the commercial and recreational ACLs and ACTs. The current sector allocation of 27 percent for the commercial sector and 73 percent for the recreational sector would not change through this framework action. The commercial ACL would be set at 464,400 lb (210,648 kg) and the commercial ACT would be set at 394,740 lb (179,051 kg). The recreational ACL would be set at 1,255,600 lb (569,531 kg) and the recreational ACT would be set at 1,092,372 lb (495,492 kg).

#### *Commercial Trip Limit*

The current greater amberjack commercial trip limit was established in Amendment 35 to the FMP at 2,000 lb (907 kg), round weight, in an effort to reduce harvest rates, prevent commercial ACL overages, and provide a longer fishing season for the commercial sector (77 FR 67574, November 13, 2012). However, in 2013, the commercial ACL and ACT were still exceeded by approximately 12 percent, triggering the commercial AMs and closing the commercial sector in season. This rule would reduce the commercial trip limit to 1,500 lb (680 kg), gutted weight; 1,560 lb (708 kg), round weight. The Council determined that the proposed trip limit would further

reduce the likelihood of exceeding the commercial ACL and ACT and could extend the length of the commercial fishing season.

#### *Recreational Size Limit*

This rule would revise the greater amberjack recreational minimum size limit. In 2008, Amendment 30A to the FMP set the greater amberjack recreational minimum size limit at 30 inches (76 cm), fork length (FL), (73 FR 38139, July 3, 2008).

A greater amberjack with a 30-inch (76-cm), FL, is approximately 2 years old and the majority of the fish at that size have likely not yet reached sexual maturity. At the proposed recreational minimum size limit of 34 inches (86.4 cm), FL, it is estimated that 85 percent of females are reproductively mature. Additionally, based upon a review of greater amberjack recreational landings from 2012 through 2013, 34 inches (86.4 cm), FL, was the most frequently landed size of greater amberjack. The Council determined that increasing the recreational minimum size limit from 30 inches (76 cm), FL, to 34 inches (86.4 cm), FL, would provide an opportunity for a greater number of sexually mature greater amberjack to spawn, which could assist in Council efforts to end overfishing and rebuild the stock.

#### **Other Actions Contained in the Framework Action**

In addition to the measures being proposed in this rule, the framework action would revise the greater amberjack ABC and OFL based upon the results of SEDAR 33 and the Council's SSC recommendation. All ABC and OFL weights are described in round weight. The current greater amberjack ABC is 1,780,000 lb (807,394 kg) and the current OFL is 2,380,000 lb (1,079,550 kg), which were established in Amendment 35 to the FMP (77 FR 67574, November 13, 2012). This framework action would revise the ABC and OFL for 4 years, beginning in 2015. The ABC, which is equal to the stock ACL would be set at 1,720,000 lb (780,179 kg). The OFL would be set at 2,660,000 lb (1,206,556 kg) for 2015; 3,210,000 lb (1,456,032 kg) for 2016; 3,420,000 lb (1,551,286 kg) for 2017; and 3,510,000 lb (1,592,109 kg) for 2018, and subsequent years.

The framework action also contained an action to modify the greater amberjack recreational closed season. However, the Council decided not to revise the recreational season at this time. Therefore, the current recreational closed season of June 1 through July 31 remains in effect.

#### **Additional Proposed Changes to Codified Text**

Amendment 30A to the FMP implemented ACLs and AMs for Gulf gray triggerfish (73 FR 38139, July 3, 2008). The recreational AM was a post-season AM that reduced the length of the following recreational fishing season by the amount necessary to ensure recreational landings did not exceed the recreational ACT the following fishing year. To determine a reduced season, recreational landings were evaluated relative to the recreational ACL based on a moving multi-year average of landings. In Amendment 37 to the FMP, this post-season AM was replaced with an in-season AM (which is based on a single season of landings data), so the recreational sector closes when the recreational ACT is reached or projected to be reached (78 FR 27084, May 9, 2013). However, during the implementation of Amendment 37, the last sentence in § 622.41(b)(2)(iii), which states that "Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP," was not removed. NMFS has only recently noticed this error. This rule corrects this error by removing this sentence. The recreational ACL and ACT for gray triggerfish implemented in Amendment 37 to the FMP remain unchanged.

#### **Classification**

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with the framework action, the FMP, the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

NMFS prepared an IRFA for this rule, as required by section 603 of the RFA, 5 U.S.C. 603. The IRFA describes the economic impact that this proposed rule, if implemented, would have on small entities. A description of the proposed rule, why it is being considered, and the objectives of, and legal basis for this proposed rule are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A copy of the full analysis is available from the NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-

keeping, or other compliance requirements are introduced by this proposed rule. Accordingly, this rule does not implicate the Paperwork Reduction Act.

This proposed rule, if implemented, would be expected to directly affect all commercial vessels that harvest Gulf greater amberjack under the FMP. Changes to recreational ACLs, ACTs, and/or minimum size limits in this proposed rule would not directly apply to or regulate charter vessel and headboat (for-hire) businesses. Any impact to the profitability or competitiveness of for-hire fishing businesses would be the result of changes in for-hire angler demand and would therefore be indirect in nature. The RFA does not consider recreational anglers, who would be directly affected by this proposed rule, to be small entities, so they are outside the scope of this analysis and only the effects on commercial vessels were analyzed.

As of March 25, 2015, there were 863 vessels with valid or renewable Gulf reef fish commercial vessel permits. On average (2009 through 2013), 211 vessels commercially landed greater amberjack each year from Gulf Federal waters. Their average annual vessel-level revenue for 2009 through 2013 was approximately \$130,000 (2013 dollars), of which \$2,400 was from greater amberjack.

No other small entities that would be directly affected by this proposed rule have been identified.

The Small Business Administration (SBA) has established size criteria for all major industry sectors in the U.S., including commercial finfish harvesters (NAICS code 114111). A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of \$20.5 million for all its affiliated operations worldwide. All of the vessels directly regulated by this rule are believed to be small entities based on the SBA size criteria.

Because all entities expected to be affected by this proposed rule are small entities, NMFS has determined that this proposed rule would affect a substantial number of small entities. Moreover, the issue of disproportionate effects on small versus large entities does not arise in the present case.

This proposed rule would reduce the current greater amberjack commercial ACT by 14,260 lb (6,468 kg), round weight, from 409,000 lb (185,519 kg) to 394,740 lb (179,051 kg), round weight, or 3.5 percent. Additionally, this

proposed rule would reduce the greater amberjack commercial trip limit from 2,000 lb (907 kg), round weight, to 1,560 lb (708 kg), round weight; 1,500 lb (680 kg), gutted weight. On its own, the reduction in the commercial ACT would be expected to result in a shorter fishing season and fewer commercial trips that harvest greater amberjack. Conversely, the reduced commercial trip limit would be expected to increase the commercial fishing season length and the overall number of trips necessary to harvest the full commercial ACT. When the actions to reduce the commercial ACT and the trip limit are analyzed together, the expected recurring annual reduction in total ex-vessel revenue from this proposed rule is estimated to be \$20,703 (2013 dollars), assuming there is no substitution of other species and no change in effort, harvest rates, or prices. In addition, the season is predicted to be 5 days longer under the preferred commercial ACT and trip limit alternatives than under the no action alternatives for these actions. Assuming the reduction in greater amberjack revenues is distributed evenly across the average number of vessels that commercially harvest greater amberjack per year (211 vessels), the annual per-vessel loss would be \$98 (2013 dollars), or less than 1 percent of the average annual revenue earned by these vessels for all species harvested. Because this estimate is based on average performance, some vessels may be affected more or less than others, depending on their overall catch composition, landing capacity, and fishing behavior.

Thirty vessels, on average per year (2009 through 2013), were identified that commercially landed greater amberjack in excess of 1,500 lb (680 kg), gutted weight, on a single trip (14 percent of the average number of vessels that harvested greater amberjack each year). In 2013, the total weight of greater amberjack harvested in excess of 1,500 lb (680 kg), gutted weight, per trip accounted for approximately 10 percent of total greater amberjack landings. Thus, for the 211 vessels that commercially harvest greater amberjack, the proposed reduction in the commercial trip limit, assuming effort remains constant, would be expected to reduce total commercial greater amberjack harvests by approximately 39,000 lb (17,690 kg), round weight, and \$46,800 (2013 dollars) in total ex-vessel revenue annually. Averaged across the 30 vessels per year with trip harvests above 1,500 lb (680 kg), gutted weight, this reduction would equal approximately \$1,560 (2013 dollars) per

vessel, or approximately 1 percent of their average annual revenue. These losses would be reduced if increased landings of other species can be substituted for greater amberjack landings or if new trips harvesting greater amberjack were to occur. It is assumed that the full commercial ACT would be harvested under the preferred trip limit alternative. Therefore, if the trip limit change implemented by this proposed rule results in a decrease in greater amberjack landings and revenues for some vessels, it would result in an increase in greater amberjack landings and revenues for other vessels.

The following discussion analyzes the alternatives that were not selected as preferred by the Council. Only the actions which contain alternatives that would have direct economic effects on small entities merit inclusion in the following discussion.

Four alternatives were considered for the action to modify the commercial and recreational ACLs and ACTs for Gulf greater amberjack. The first alternative, the no action alternative, would not be expected to have any direct economic effects. This alternative was not selected because the stock ACL would exceed the ABC calculated by the most recent greater amberjack assessment and recommended by the SSC and would, therefore, be inconsistent with the NS 1 guidelines. The second alternative would set the stock ACL from 2015 through 2018 equal to the ABC values recommended by the SSC. This alternative included two sub-options. The first sub-option would use the Council's ACL/ACT control rule as established in the Generic ACL/AM Amendment (76 FR 82044, December 29, 2011), which would set the commercial ACT at a level reduced by 15 percent from the commercial ACL for greater amberjack and set the recreational ACT at a level reduced by 13 percent from the recreational ACL. The second sub-option would not use the ACL/ACT control rule and instead would apply a 20-percent buffer that would reduce both the recreational and commercial ACLs by 20 percent to establish the recreational and commercial ACTs. This alternative would increase the stock ACL each year from 2015 through 2018, which would be expected to result in greater economic benefits than the preferred alternative in the framework action. However, this alternative was not selected as preferred by the Council as a result of the following factors: the stock remains overfished and is undergoing overfishing, the 10-year rebuilding plan time period ended and the stock has not been rebuilt, and the

stock biomass has been relatively stable (at overfished levels) since 2000, while experiencing harvest levels below what is currently projected to rebuild the stock in upcoming years. The third alternative is the preferred alternative, which would set a constant stock ACL equal to the 2015 ABC value recommended by the SSC. The same two sub-options for setting the ACT that were considered for the second alternative were also considered for the third alternative. The first sub-option, selected as preferred by the Council, would apply a 15-percent buffer to the commercial ACL to set the commercial ACT and apply a 13-percent buffer to the recreational ACL to set the recreational ACT. The second sub-option would not use the ACL/ACT control rule and instead would apply a 20-percent buffer that would reduce both the recreational and commercial ACLs by 20 percent to establish the recreational and commercial ACTs. The fourth alternative would set the stock ACL and stock ACT at zero. The fourth alternative would stop all directed harvest of greater amberjack and would be expected to result in greater economic losses than the preferred ACL/ACT alternative.

Five alternatives were considered for the action to modify the greater amberjack commercial trip limit. The first alternative, the no action alternative, would maintain the current 2,000 lb (907 kg), round weight, trip limit and would not be expected to have any direct economic effects. The second alternative is the preferred alternative, which would establish a 1,500 lb (680 kg), gutted weight, trip limit for greater amberjack. The third, fourth, and fifth alternatives would have established 1,000 lb (454 kg), 750 lb (340 kg), and 500 lb (227 lb), gutted weight trip limits, respectively. Although these three alternatives would be expected to extend the season, they would increase the likelihood that trips are no longer profitable and decrease the likelihood that the full commercial ACT would be harvested during the fishing year. As such, these three alternatives would be expected to result in greater economic losses to affected small entities than the preferred trip limit alternative.

An item contained in this proposed rule that is not part of the framework action is the removal of the last sentence in § 622.41(b)(2)(iii), "Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP." This sentence, which pertains to the evaluation of recreational landings of gray triggerfish relative to the ACL, was inadvertently not removed in the

final rule implementing Amendment 37 to the FMP (78 FR 27084, May 9, 2013). The removal of this sentence will clarify the criteria used to trigger recreational AMs as written in the Federal regulations; however, it is not expected to have any effect on current management practices. This is because NMFS has managed gray triggerfish in accordance with the preferred alternatives specified in Amendment 37 since its implementation. Therefore, this is an administrative change only and is not expected to have any direct economic effects on small entities. As such, this component of the proposed rule is outside the scope of the RFA.

**List of Subjects in 50 CFR Part 622**

Commercial, Fisheries, Fishing, Greater amberjack, Gulf, Recreational, Reef fish.

Dated: September 11, 2015.

**Samuel D. Rauch III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

**PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC**

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.37, revise paragraph (c)(4) to read as follows:

**§ 622.37 Size Limits.**

\* \* \* \* \*

(c) \* \* \*

(4) *Greater amberjack*—34 inches (86.4 cm), fork length, for a fish taken by a person subject to the bag limit specified in § 622.38(b)(1) and 36 inches (91.4 cm), fork length, for a fish taken by a person not subject to the bag limit.

\* \* \* \* \*

■ 3. In § 622.39, revise paragraphs (a)(1)(v) and (a)(2)(ii) to read as follows:

**§ 622.39 Quotas.**

\* \* \* \* \*

(a) \* \* \*

(1) \* \* \*

(v) *Greater amberjack*—394,740 lb (179,051 kg), round weight.

\* \* \* \* \*

(2) \* \* \*

(ii) *Recreational quota for greater amberjack*. The recreational quota for greater amberjack is 1,092,372 lb (495,492 kg), round weight.

\* \* \* \* \*

■ 4. In § 622.41, revise paragraphs (a)(1)(iii), (a)(2)(iii), and (b)(2)(iii) to read as follows:

**§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).**

(a) \* \* \*

(1) \* \* \*

(iii) The commercial ACL for greater amberjack is 464,400 lb (210,648 kg), round weight.

(2) \* \* \*

(iii) The recreational ACL for greater amberjack is 1,255,600 lb (569,531 kg), round weight.

(b) \* \* \*

(2) \* \* \*

(iii) The recreational ACL for gray triggerfish is 241,200 lb (109,406 kg), round weight. The recreational ACT for gray triggerfish is 217,100 lb (98,475 kg), round weight.

\* \* \* \* \*

■ 5. In § 622.43, revise paragraph (a) to read as follows:

**§ 622.43 Commercial trip limits.**

\* \* \* \* \*

(a) *Gulf greater amberjack*. Until the quota specified in § 622.39(a)(1)(v) is reached, 1,500 lb (680 kg), gutted weight; 1,560 lb (708 kg), round weight. See § 622.39(b) for the limitations regarding greater amberjack after the quota is reached.

\* \* \* \* \*

[FR Doc. 2015-23347 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-22-P**

# Notices

Federal Register

Vol. 80, No. 180

Thursday, September 17, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## AGENCY FOR INTERNATIONAL DEVELOPMENT

### Meeting: Board for International Food and Agricultural Development

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 8:30 a.m. to 4 p.m. EDT on Wednesday, October 21, 2015 in the South Ballroom of the Memorial Union at Purdue University, 101 N Grant St, West Lafayette, Indiana. The meeting will be streamed live on the Internet. The link to the global live stream is on BIFAD's home page: <http://www.usaid.gov/bifad>.

The central theme of this public meeting will be *Crossroads: Science, Innovation, Markets, and Policy for Feeding the World*. Dr. Brady Deaton, BIFAD Chair, will preside over the public business meeting, which will begin promptly at 8:30 a.m. EDT with opening remarks. At this meeting, the Board will address old and new business and hear updates from USAID, the university community, and other experts on climate-smart agriculture, plant sciences and the role of various constituents in feeding the world's population.

Starting at 9 a.m., Dr. Waded Cruzado, BIFAD Board Member will present the BIFAD Award for Scientific Excellence which recognizes individual researchers and/or a team of researchers for significant achievements in work performed through USAID's Feed the Future Innovation Labs.

Starting at 9:30 a.m., BIFAD will hear from the first panel hosted by Dr. Jeffrey Dukes, Director of the Purdue Climate Change Research Center and Professor of Forestry & Natural Resources and Biological Sciences. Dr. Thomas Hertel, Distinguished Professor of Agriculture will moderate the panel titled *Climate-Smart Agriculture—Closing the Yield*

*Gap in a Changing Climate*. Presenters for this panel are Dr. Mitch Tuinstra, Professor of Plant Breeding and Genetics and Wickersham Chair; Dr. Linda Prokopy, Associate Professor, Natural Resource Science; and an additional panelist to be determined. The panel will conclude with a 15 minute comment period.

Starting at 11:15 a.m., Dr. Karen Plaut, Senior Associate Dean for Research and Faculty Affairs, will moderate a panel on *Plant Sciences Research and Education Pipeline*. Presenters for this panel are Dr. Melba Crawford, Associate Dean of Engineering for Research; Dr. Katy Rainey, Assistant Professor of Agronomy; and Dr. Jian Kang Zhu, Distinguished Professor of Plant Biology. This panel will conclude with a 15 minute comment period.

Starting at 2:15 p.m., Dr. Jay Akridge, Glen W. Sample Dean of Agriculture, will moderate a panel on *US Ag Industry's Role in Feeding the World*. Presenters for this panel are Ted McKinney, Director of the Indiana State Department of Agriculture; and Jim Moseley, a local farmer.

At 3:30 p.m., Chairman Deaton will moderate a half-hour public comment period. At 4 p.m. EDT Dr. Deaton, will make closing remarks and adjourn the public meeting. At 4 p.m., after the meeting has been adjourned, BIFAD and members of the public are invited to view the Purdue University poster display.

Those wishing to attend the meeting or obtain additional information about BIFAD should contact Susan Owens, Executive Director and Designated Federal Officer for BIFAD in the Bureau for Food Security at USAID. Interested persons may write to her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue NW., Room 2.09-067, Washington, DC, 20523-2110 or telephone her at (202) 712-0218.

#### Susan Owens,

*Executive Director and USAID Designated Federal Officer for BIFAD, Bureau for Food Security, U.S. Agency for International Development.*

[FR Doc. 2015-23418 Filed 9-16-15; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0047]

#### Oral Rabies Vaccine Trial; Availability of a Supplement to an Environmental Assessment and Finding of No Significant Impact

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has prepared a supplement to an environmental assessment and finding of no significant impact relative to an oral rabies vaccination field trial in New Hampshire, New York, Ohio, Vermont, and West Virginia. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard Chipman, Rabies Program Coordinator, Wildlife Services, APHIS, 59 Chennell Drive, Suite 7, Concord, NH 03301; (603) 223-9623. To obtain copies of the supplement to the environmental assessment and the finding of no significant impact, contact Ms. Beth Kabert, Environmental Coordinator, Wildlife Services, 140-C Locust Grove Road, Pittstown, NJ 08867; (908) 735-5654, fax (908) 735-0821, email: [beth.e.kabert@aphis.usda.gov](mailto:beth.e.kabert@aphis.usda.gov).

**SUPPLEMENTARY INFORMATION:** The Wildlife Services (WS) program in the Animal and Plant Health Inspection Service (APHIS) cooperates with Federal agencies, State and local governments, and private individuals to research and implement the best methods of managing conflicts between wildlife and human health and safety, agriculture, property, and natural resources. Wildlife-borne diseases that can affect domestic animals and humans are among the types of conflicts that APHIS-WS addresses. Wildlife is the dominant reservoir of rabies in the United States.

On July 17, 2015, we published in the **Federal Register** (80 FR 42467-42469, Docket No. APHIS-2015-0047) a

notice<sup>1</sup> in which we announced the availability, for public review and comment, of a supplement to an environmental assessment (EA) that examined the potential environmental impacts associated with the proposed field trial to test the safety and efficacy of an experimental oral rabies vaccine for wildlife in New Hampshire, New York, Ohio, Vermont, and West Virginia. In addition, the supplement analyzed the geographic shift of the field trial zone in Ohio and an increase in bait distribution density in portions of West Virginia.

We solicited comments on the EA for 30 days ending August 17, 2015. We received one comment by that date, which supported the oral rabies vaccination program.

In this document, we are advising the public of our finding of no significant impact (FONSI) regarding the implementation of a field trial to test the safety and efficacy of the ONRAB wildlife rabies vaccine in New Hampshire, New York, Ohio, Vermont, and West Virginia, including portions of U.S. Department of Agriculture Forest Service National Forest System lands, but excluding Wilderness Areas. The finding, which is based on the EA, the 2013 supplement to the EA, and the 2015 supplement to the EA, reflects our determination that the distribution of this experimental wildlife rabies vaccine will not have a significant impact on the quality of the human environment.

The 2015 supplement to the EA and the FONSI may be viewed on the APHIS Web site at <http://www.aphis.usda.gov/wildlifedamage/nepa> and on the Regulations.gov Web site (see footnote 1). Copies of the 2015 supplement to the EA and the FONSI are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained as described under **FOR FURTHER INFORMATION CONTACT**.

The 2015 supplement to the EA and the FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*); (2) regulations of the Council on Environmental Quality for

implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 14th day of September 2015.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015-23381 Filed 9-16-15; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### National Advisory Committee for Implementation of the National Forest System Land Management Planning Rule

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meetings.

**SUMMARY:** The National Advisory Committee for Implementation of the National Forest System Land Management Planning Rule Committee (Committee) will meet in Tempe, Arizona. Attendees may also participate via webinar and conference call. The Committee operates in compliance with the Federal Advisory Committee Act (FACA) (Pub. L. 92-463). Additional information relating to the Committee, including the meeting summary/minutes, can be found by visiting the Committee's Web site at: <http://www.fs.usda.gov/main/planningrule/committee>.

**DATES:** The meetings will be held in-person and via webinar/conference call on the following dates and times:

- Monday, October 5, 2015 from 9:00 a.m. to 5:00 p.m. MST
- Tuesday, October 6, 2015 from 9:00 a.m. to 5:00 p.m. MST
- Wednesday, October 7, 2015 from 9:00 a.m. to 5:00 p.m. MST
- Thursday, October 8, 2015 from 9:00 a.m. to 2:00 p.m. MST.

All meetings are subject to cancellation. For updated status of meetings prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** The meeting will be held at the Sheraton Phoenix Airport Hotel Tempe, 1600 S. 52nd Street, Tempe, Arizona. For anyone who would like to attend via webinar and/or conference call, please visit the Web site listed above or contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. Written comments may be submitted as described under

**SUPPLEMENTARY INFORMATION.** All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the USDA Forest Service Washington Office—Yates Building, 201 14th Street SW., Mail Stop 1104, Washington, DC, 20250-1104. Please call ahead to facilitate entry into the building.

#### **FOR FURTHER INFORMATION CONTACT:**

Chalonda Jasper, Committee Coordinator, by phone at 202-260-9400, or by email at [cjasper@fs.fed.us](mailto:cjasper@fs.fed.us).

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The purpose of this meeting is to provide:

1. Continued deliberations on formulating advice for the Secretary,
2. Discussion of Committee work group findings,
3. Dialogue with key Forest Service personnel and stakeholders from Region 3, the Southwestern Region, regarding the land management plan revision processes currently underway in the region,
4. Hearing public comments, and
5. Administrative tasks.

This meeting is open to the public. The agenda will include time for people to make oral comments of three minutes or less. Individuals wishing to make an oral comment should submit a request in writing by September 30, 2015, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Committee may file written statements with the Committee's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Chalonda Jasper, USDA Forest Service, Ecosystem Management Coordination, 201 14th Street SW., Mail Stop 1104, Washington, DC, 20250-1104, or by email at [cjasper@fs.fed.us](mailto:cjasper@fs.fed.us). The agenda and summary of the meeting will be posted on the Committee's Web site within 21 days of the meeting.

**Meeting Accommodations:** If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

<sup>1</sup> To view the notice, the EA, and the FONSI, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0047>.

Dated: September 10, 2015.

**Glenn Casamassa,**

*Associate Deputy Chief, National Forest System.*

[FR Doc. 2015-23327 Filed 9-16-15; 8:45 am]

**BILLING CODE 3411-15-P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Pacific Northwest National Scenic Trail Advisory Council

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Pacific Northwest National Scenic Trail Advisory Council (Council) will meet in Sandpoint, Idaho. The Council is authorized under Section 5(d) of the National Trails System Act of 1968 (Act) and operates in compliance with the Federal Advisory Committee Act (FACA). Additional information concerning the Council, including the meeting summary/minutes, can be found by visiting the Council's Web site at: <http://www.fs.usda.gov/main/pnt/working-together/advisory-committees>.

**DATES:** The meeting will be held on the following dates and times:

- Wednesday, October 14, 2015 from 8 a.m. to 5 p.m. PDT
- Thursday, October 15, 2015 from 8 a.m. to 5 p.m. PDT

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** The meeting will be held at the Best Western Edgewater Resort, 56 Bridge Street, Sandpoint, Idaho. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Pacific Northwest Regional Office of the United States Forest Service: 1220 SW 3rd Avenue, Portland, OR 97204. Please call ahead at 503-808-2468 to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Matt McGrath, Pacific Northwest National Scenic Trail Program Manager, by phone at 425-583-9304, or by email at [mtmcgrath@fs.fed.us](mailto:mtmcgrath@fs.fed.us).

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to provide:

1. Overview of legislation, policy, and interagency planning requirements for National Scenic Trails;
2. Discussion of planning approach, process, and schedule for the Pacific Northwest National Scenic Trail comprehensive plan; and
3. Recommendations regarding the work, priorities, and schedule for the Advisory Council.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by October 2, 2015, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Council may file written statements with the Council's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Matt McGrath, Pacific Northwest National Scenic Trail Program Manager, 2930 Wetmore Avenue, Suite 3A, Everett, Washington 98201, or by email to [mtmcgrath@fs.fed.us](mailto:mtmcgrath@fs.fed.us).

**Meeting Accommodations:** If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: September 10, 2015.

**Dianne C. Guidry,**

*Deputy Regional Forester.*

[FR Doc. 2015-23410 Filed 9-16-15; 8:45 am]

**BILLING CODE 3411-15-P**

## DEPARTMENT OF AGRICULTURE

### Rural Utilities Service

#### Energy Answers Arecibo, LLC: Extension of Comment Period for a Draft Environmental Impact Statement

**AGENCY:** Rural Utilities Service, USDA.

**ACTION:** Extension of comment period for a Draft Environmental Impact Statement.

**SUMMARY:** The Rural Utilities Service (RUS), an agency within the U.S. Department of Agriculture (USDA), has issued a Draft Environmental Impact Statement (EIS) for Energy Answers Arecibo, LLC's (Energy Answers) proposed Waste to Energy Project

(Project) in Arecibo, Puerto Rico. RUS published a notice of availability and public hearing on August 7, 2015, that provided a comment period ending on the date announced in the U.S. Environmental Protection Agency's (USEPA) EIS receipt notice of September 28, 2015. RUS is extending the public comment period for the Draft EIS by an additional 45 days to November 12, 2015.

**DATES:** With this notice, RUS extends the public comment period to November 12, 2015. Comments submitted to RUS regarding the Draft EIS prior to this announcement do not need to be resubmitted as a result of this extension to the comment period.

**ADDRESSES:** Written comments on the Draft EIS and questions about the proposed project may be submitted to: Ms. Lauren McGee Rayburn at the contact information provided in this notice. The Draft EIS is available in both Spanish and English at the following Web site: <http://www.rd.usda.gov/publications/environmental-studies/impact-statements/arecibo-waste-energy-generation-and-resource>. Requests for CD or hardcopies may be directed to Ms. McGee Rayburn, Environmental Scientist, Rural Utilities Service, 84 Coxe Ave., Suite 1E, Ashville, North Carolina 28801, *telephone:* (202) 695-2540, *fax:* (202) 690-0649, or *email:* [Lauren.McGee@wdc.usda.gov](mailto:Lauren.McGee@wdc.usda.gov).

**FOR FURTHER INFORMATION CONTACT:** Ms. Lauren McGee Rayburn, Environmental Scientist, Rural Utilities Service, 84 Coxe Ave., Suite 1E, Ashville, North Carolina 28801, *telephone:* (202) 695-2540, *fax:* (202) 690-0649, or *email:* [Lauren.McGee@wdc.usda.gov](mailto:Lauren.McGee@wdc.usda.gov).

**SUPPLEMENTARY INFORMATION:** RUS has issued a Draft EIS for Energy Answers' proposed Waste to Energy Project (Project) in Arecibo, Puerto Rico. RUS issued the Draft EIS to inform interested parties and the general public about the proposed Project and to invite the public to comment on the scope, proposed action, and other issues addressed in the Draft EIS. The Draft EIS addresses the construction, operation, and maintenance of Energy Answers' proposed Project, a waste-to-energy generation and resource recovery facility in the Cambalache Ward of Arecibo, Puerto Rico. RUS prepared the EIS in accordance with the National Environmental Policy Act (NEPA), as amended, the Council on Environmental Quality's Regulation for Implementing the Procedural Provisions of the NEPA (40 CFR parts 1500-1508), and RUS's Environmental Policies and Procedures (7 CFR part 1794). RUS published a



notice of availability and public hearing in the **Federal Register** at 80 FR 47452 on August 7, 2015, that provided a comment period ending on the date announced in the U.S. Environmental Protection Agency's (USEPA) EIS receipt notice or September 28, 2015. RUS is extending the public comment period for the Draft EIS to November 12, 2015.

The Draft EIS is available in both Spanish and English for review at the following Web site: <http://www.rd.usda.gov/publications/environmental-studies/impact-statements/arecibo-waste-energy-generation-and-resource>. The Draft EIS will be available for review and comment until November 12, 2015. Following this review period, RUS may prepare a Final EIS. After a 30-day review period of the Final EIS, RUS may publish a Record of Decision (ROD). Notices announcing the availability of the Final EIS and ROD will be published in the **Federal Register** and in local newspapers.

Any final action by RUS related to the proposed Project will be subject to, and contingent upon, compliance with all relevant presidential executive orders and federal, state, and local environmental laws and regulations in addition to the completion of the environmental review requirements as prescribed in RUS's Environmental Policies and Procedures, 7 CFR part 1794, as amended.

Dated: September 10, 2015.

**Christopher A. McLean,**

*Assistant Administrator—Electric Programs, Rural Utilities Service.*

[FR Doc. 2015-23377 Filed 9-16-15; 8:45 am]

**BILLING CODE 3410-15-P**

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request; Correction

*Agency:* U.S. Census Bureau.

*Title:* Current Population Survey, Annual Social and Economic Survey.

*OMB Control Number:* 0607-0354.

In the **Federal Register** of September 11, 2015, Vol. 80, No. 176, Page 54766, the Legal Authority contained incorrect information. The correct information is:

**Legal Authority:** Title 13, United States Code, Sections 8(b), 141, 182; and Title 29, United States Code, Sections 1-9.

Dated: September 11, 2015.

**Glenna Mickelson,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 2015-23300 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-07-P**

## DEPARTMENT OF COMMERCE

[Docket No. 150817729-5729-01]

### Privacy Act of 1974; Amended System of Records

**AGENCY:** National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

**ACTION:** Notice of Proposed Amendment to Privacy Act System of Records: COMMERCE/NOAA-14, Dr. Nancy Foster Scholarship Program.

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4) and (11), the Department of Commerce proposes to amend the system of records entitled "COMMERCE/NOAA-14, Dr. Nancy Foster Scholarship Program" to update the routine uses to include (1) disclosure for breach notifications, (2) disclosure to the appropriate agency (whether Federal, state, local, or foreign) for law enforcement purposes, (3) disclosure to the medical advisor if disclosure to the individual could have an adverse effect upon the individual, (4) disclosure pursuant to an Office of Management and Budget (OMB) request in connection to private relief legislation as set forth in OMB Circular No. A-19, and (5) disclosure to a contractor of the Department having need for the information in performance of the contract; and to change the system name to "Dr. Nancy Foster Scholarship Program; Office of Education, Educational Partnership Program (EPP); Ernest F. Hollings Undergraduate Scholarship Program and National Marine Fisheries Service Recruitment, Training, and Research Program." We invite public comment on the amended information collection announced in this publication.

**DATES:** To be considered, written comments must be submitted on or before October 19, 2015. Unless comments are received, the new system of records will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

**ADDRESSES:** Comments may be mailed to:

Program Administrator, Dr. Nancy Foster Scholarship Program, National Ocean Service, Office of the Assistant Administrator, 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910-3281.

Deputy Director of NOAA Education, Educational Partnership Program and Ernest F. Hollings Undergraduate Scholarship Program, Office of Education, 1315 East-West Highway,

10th Floor, Silver Spring, MD 20910-3281.

Administrative Assistant, Mendy Willis, National Marine Fisheries Service Recruitment, Training, Research Program at the University of Florida, P.O. Box 110240, Gainesville, FL 32611.

**FOR FURTHER INFORMATION CONTACT:** Program Administrator, Dr. Nancy Foster Scholarship Program, National Ocean Service, Office of the Assistant Administrator, 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910-3281.

Deputy Director of NOAA Education, Educational Partnership Program and Ernest F. Hollings Undergraduate Scholarship Program, Office of Education, 1315 East-West Highway, 10th Floor, Silver Spring, MD 20910-3281.

Administrative Assistant, Mendy Willis, National Marine Fisheries Service Recruitment, Training, Research Program at the University of Florida, P.O. Box 110240, Gainesville, FL 32611.

**SUPPLEMENTARY INFORMATION:** The purpose of this amendment is to add information on the Ernest F. Hollings Undergraduate Scholarship Program; Educational Partnership Program's (EPP)—Undergraduate Scholarship Program, Graduate Sciences Program, Cooperative Science Centers, and Environmental Entrepreneurship Program and the (NMFS)—Recruiting, Training, and Research Program alumni form to this information collection. Recently, the Dr. Nancy Foster Scholarship Program's alumni form, and this NMFS alumni form became part of the EPP's information collection under the Paperwork Reduction Act (PRA) approved under OMB Control No. 0648-0568. Because these information collections are associated under the PRA, to the information collected should be maintained in the same system of records.

Additionally, the purpose of this amendment is to update the routine uses for this system of records as follows: (a) Add routine uses that were not included in the original notice, published in the **Federal Register** on the October 17, 2002 (67 FR 64085-64086); and (b) add the breach notification routine use, published in the **Federal Register** on August 10, 2007 (72 FR 45009-45010), for all Department systems of records.

**Authority:** National Marine Sanctuaries Amendments Act of 2000 (Pub. L. 106-513 sec. 318); Section 4002 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (Public Law 110-69). Under Appendix I to OMB Circular No. A-130, para. 3a(8), we are

required to conduct biennial reviews of SORNs and update them as needed.

#### COMMERCE/NOAA-14

##### SYSTEM NAME:

COMMERCE/NOAA-14, Dr. Nancy Foster Scholarship Program; Office of Education, Educational Partnership Program (EPP); Ernest F. Hollings Undergraduate Scholarship Program and National Marine Fisheries Service Recruitment, Training, and Research Program.

##### SECURITY CLASSIFICATION:

Moderate.

##### SYSTEM LOCATION:

a. The National Ocean Service, Office of the Assistant Administrator, 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910-3281.

b. NOAA Office of the Chief Information Officer, 1315 East-West Highway, 9th Floor, Silver Spring, MD 20910-3281.

c. The National Marine Fisheries Service Recruitment, Training, and Research Program at the University of Florida, P.O. Box 110240, Gainesville, FL 32611 (database only, not associated with a system).

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Scholarship applicants; recipients of scholarship awards; and alumni, who are scholarship recipients that have completed their studies under the Dr. Nancy Foster or EPP scholarship programs.

##### CATEGORIES OF RECORDS IN THE SYSTEM:

Application packages, including: General Information Sheet (name, citizenship, current school, grade point average, major field of study, year of study, current and permanent address, telephone number, and email address, extracurricular activities, school honors and awards, non-academic work and volunteer activities, essay on college education plan and career goals), Statement of Intent, Institute Certification, Transcripts, and Letters of Recommendation; Annual Progress Reports; Tuition Statements and Receipts.

Student tracking information: Name, citizenship, funding, area of study, performance, activities, publications.

Alumni information: Scholarship program name; general information (last name, first name, email address, program completion dates, last name if different from last name while in program, graduation date, optional—gender, race/ethnicity); post educational information (institution name,

institution state, degree field of study and area of discipline); current employment information (occupation, field of work, area of work and industry sector).

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Marine Sanctuaries Amendments Act of 2000 (Pub. L. 106-513 sec. 318). The Administrator of the National Oceanic and Atmospheric Administration (NOAA) is authorized by Section 4002 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act, Public Law 110-69, to establish and administer education programs such as the Educational Partnership Program (EPP) Graduate Sciences Program and EPP Undergraduate Scholarship Program to enhance the understanding of ocean, coastal, Great Lakes, and atmospheric science and stewardship to the general public and other coastal stakeholders, including groups underrepresented in the ocean and atmospheric sciences and in policy careers.

##### PURPOSES:

Records will be used to track scholarship recipients' academic progress, to make annual financial awards, and to track scholarship recipients' graduate studies and career progress.

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. In the event that a system or records maintained by the Department to carry out its functions indicates a violation or potential violation of law or contract, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute or contract, or rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, state, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or contract, or rule, regulation or order issued pursuant thereto, or protecting the interest of the Department.

2. A record from this system of records may be disclosed to a Federal, state or local agency maintaining civil, criminal or other relevant enforcement information, or other pertinent information, such as current licenses, if necessary to obtain information relevant

to a Department decision concerning the assignment, hiring or retention of an individual, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

3. A record from this system of records may be disclosed to a Federal, state, local, or international agency, in response to its request, in connection with the assignment, hiring, or retention of an individual, the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. A record from this system of records may be disclosed in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

5. A record in this system of records may be disclosed to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

6. A record in this system of records which contains medical information may be disclosed, as a routine use, to the medical advisor of any individual submitting a request for access to the record under the Act and 15 CFR part 4b if, in the sole judgment of the Department, disclosure to the individual could have an adverse effect upon the individual, under the provision of 5 U.S.C. 552a(f)(3) and implementing regulations at 15 CFR 4b.6.

7. A record in this system of records may be disclosed to the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552).

8. A record in this system may be transferred to the Office of Personnel Management or to the National Science Foundation, National Center for Science and Engineering Statistics (NCSES) or to an evaluation contractor for personnel research purposes, as a data source for management information; for the production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained; or for related manpower studies.

9. A record from this system of records may be disclosed to the Administrator, General Services Administration (GSA), or his designee,

during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose and any other relevant (*i.e.* GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

10. A record in this system of records may be disclosed, as a routine use, to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

11. A record in this system of records may be disclosed, as a routine use, to a contractor of the Department having need for the information in the performance of the contract, but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

12. A record in this system of records may be disclosed to appropriate agencies, entities and persons when (1) it is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or whether systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Not applicable.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Electronic databases, with restricted access, and hard copy files, kept in a locked cabinet.

**RETRIEVABILITY:**

Scholarship recipient files will be alphabetized by recipient's last name, and the student databases can be searched by last name.

**SAFEGUARDS:**

Buildings employ security systems. Records are maintained in areas accessible only to authorized personnel who are properly screened and cleared.

**RETENTION AND DISPOSAL:**

Records retention and disposal is in accordance with the agency's records disposition schedule, the NOAA Records Schedule Chapter: [http://www.corporateservices.noaa.gov/audit/records\\_management/schedules/chapter\\_400\\_finance.pdf](http://www.corporateservices.noaa.gov/audit/records_management/schedules/chapter_400_finance.pdf)

**SYSTEM MANAGER(S) AND ADDRESS:**

For records at location a.: Program Administrator, Dr. Nancy Foster Scholarship Program, National Ocean Service, Office of the Assistant Administrator, 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910-3281.

For records at location b.: Deputy Director of NOAA Education, Educational Partnership Program and Ernest F. Hollings Undergraduate Scholarship Program, Office of Education, 1315 East-West Highway, 10th Floor, Silver Spring, MD, 20910-3281.

For records at location c.: Administrative Assistant, Mendy Willis, National Marine Fisheries Service Recruitment, Training, Research Program at the University of Florida, P.O. Box 110240, Gainesville, FL 32611.

**NOTIFICATION PROCEDURE:**

Information may be obtained from: For records at location a.: Program Administrator, Dr. Nancy Foster Scholarship Program, National Ocean Service, Office of the Assistant Administrator, 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910-3281.

For records at location b.: Deputy Director of NOAA Education, Educational Partnership Program and Ernest F. Hollings Undergraduate Scholarship Program, Office of Education, 1315 East-West Highway, 10th Floor, Silver Spring, MD 20910-3281.

For records at location c.: Administrative Assistant, Mendy Willis, National Marine Fisheries Service Recruitment, Training, Research Program at the University of Florida, P.O. Box 110240, Gainesville, FL 32611.

**RECORD ACCESS PROCEDURES:**

Requests from individuals should be addressed to:

For records at location a.: Program Administrator, Dr. Nancy Foster Scholarship Program, National Ocean Service, Office of the Assistant

Administrator, 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910-3281.

For records at location b.: Deputy Director of NOAA Education, Educational Partnership Program and Ernest F. Hollings Undergraduate Scholarship Program, Office of Education, 1315 East-West Highway, 10th Floor, Silver Spring, MD 20910-3281.

For records at location c.: Administrative Assistant, Mendy Willis, National Marine Fisheries Service Recruitment, Training, Research Program at the University of Florida, P.O. Box 110240, Gainesville, FL 32611.

**CONTESTING RECORD PROCEDURES:**

The Department's rules for access, for contesting contents, and for appealing initial determination by the individual concerned appear in 15 CFR part 4. Use addresses in the RECORDS ACCESS PROCEDURES section above for desired locations.

**RECORD SOURCE CATEGORIES:**

Scholarship and grant applicants and recipients.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

Dated: September 9, 2015.

**Michael J. Toland,**

*Department of Commerce, Acting Freedom of Information and Privacy Act Officer.*

[FR Doc. 2015-23133 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-22-P**

**DEPARTMENT OF COMMERCE**

[Docket No. 150806684-5684-01]

**Privacy Act of 1974, Altered System of Records**

**AGENCY:** U.S. Census Bureau, U.S. Department of Commerce.

**ACTION:** Notice of amendment, Privacy Act System of Records, COMMERCE/CENSUS-9, Longitudinal Employer-Household Dynamics System.

**SUMMARY:** In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552A(e)(4) and (11); and Office of Management and Budget (OMB) Circular A-130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," the Department of Commerce is issuing this notice to amend the system of records under, COMMERCE/CENSUS-9, Longitudinal Employer-Household Dynamics System, to update the categories of records, the authorities for maintenance of the system, the routine uses, the system manager(s) and

address, and the policies and practices for storing, retaining, disposing, and safeguarding of the records, and to add three new sections to the system addressing the notification procedure, record access procedures, and contesting procedures. The purpose of Longitudinal Employer-Household Dynamics system of records is to enable the Census Bureau to undertake studies intended to improve the quality of its core demographic and economic censuses and surveys and to conduct policy-relevant research. By using administrative record data from other agencies, the Census Bureau will be able to improve the quality and usefulness of its data, while reducing costs and respondent burden. We invite public comment on the system amendment announced in this publication.

**DATES:** To be considered, written comments on the proposed amendments must be submitted on or before October 19, 2015. Unless comments are received, the amended system of records will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

**ADDRESSES:** Please address comments to: Byron Crenshaw, Privacy Compliance Branch, Room—8H021, U.S. Census Bureau, Washington, DC 20233–3700.

**FOR FURTHER INFORMATION CONTACT:** Chief, Privacy Compliance Branch, Room—8H021, U.S. Census Bureau, Washington, DC 20233–3700.

**SUPPLEMENTARY INFORMATION:** The Department of Commerce proposes to amend the system of records under, COMMERCE/CENSUS–9, Longitudinal Employer-Household Dynamics System. The purpose of Longitudinal Employer-Household Dynamics system of records is to enable the Census Bureau to undertake studies intended to improve the quality of its core demographic and economic censuses and surveys and to conduct policy-relevant research. By using administrative record data from other agencies, the Census Bureau will be able to improve the quality and usefulness of its data, while reducing costs and respondent burden.

This amendment makes the following seven changes to the information provided under the system. The first change updates the categories of records in the system to provide additional information and details surrounding the records including the use of administrative records. The second change updates the authorities for maintenance of the system by specifying which sections of Title 13 of the United States Code (U.S.C.) applies to this system of records. The third change

updates the routine uses of records maintained by the system of records to indicate that the records in this system of records are solely for statistically purposes. The fourth change clarifies the storage of records including those obtained from source datasets. The fifth change updates the system manager and address to reflect that the system of records is being maintained in another program area. The sixth change updates the policies and practices for storing, retaining, disposing, and safeguarding of the records. The last change adds three new sections that address the notification procedure, record access procedures, and contesting procedures, to this system; these section were not included in the last publication of this notice in the **Federal Register** on May 10, 2002 (67 FR 31766). The entire resulting system of records, as amended, appears below.

**COMMERCE/CENSUS–9  
SYSTEM NAME:**

COMMERCE/CENSUS–9,  
Longitudinal Employer-Household  
Dynamics System.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Bowie Computer Center, U.S. Census  
Bureau, 17101 Melford Boulevard,  
Bowie, MD 20715.

**CATEGORIES OF INDIVIDUALS COVERED BY THE  
SYSTEM:**

The population of the United States. In order to approximate coverage of the entire U.S. population, the U.S. Census Bureau (Census Bureau) will combine administrative record files from the Internal Revenue Service, the Social Security Administration, selected Census Bureau economic and demographic censuses and surveys, and comparable data from selected state agencies.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Records in this system of records consist of working statistical files (*i.e.*, those files being analyzed to produce survey results), survey data files (*i.e.*, those files containing answers directly from the respondent), and/or data contact files (*i.e.*, those files used for contacting respondents). Some records in this system of records may be obtained from datasets maintained by the COMMERCE/CENSUS–8, Statistical Administrative Records System where direct identifiers have been replaced with a unique nonidentifying code (called the Protected Identification Key (PIK)) prior to delivery to this system of records, and, therefore are not on the

working statistical files. These categories of records are maintained on unique data sets that are extracted or combined on an as needed basis using the unique non-identifying codes but with the original identifiers removed. Additionally, some records from this system of records may be obtained from the Internal Revenue Service, the Social Security Administration, selected Census Bureau economic and demographic censuses and surveys, and comparable data from selected state agencies. Records in this system of records may contain information such as: Demographic Information—*e.g.*, gender, race, ethnicity, education, marital status, tribal affiliation, veterans status; Geographic Information—*e.g.*, address; Economic Information—*e.g.*, income, job information, total assets; Business information—*e.g.*, business name, revenues, number of employees, and industry codes in support of economic statistical products; Respondent contact information—*e.g.*, name, address, telephone number, age, and sex in support of survey and census data collection efforts; and Processing Information—*e.g.*, processing codes and quality indicators. See the COMMERCE/CENSUS–8, Statistical Administrative Records System SORN for more information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

13 U.S.C. 6 and 9.

**PURPOSES:**

The purpose of Longitudinal Employer-Household Dynamics system of records is to enable the Census Bureau to undertake studies intended to improve the quality of its core demographic and economic censuses and surveys and to conduct policy-relevant research. By using administrative record data from other agencies, the Census Bureau will be able to improve the quality and usefulness of its data, while reducing costs and respondent burden.

**ROUTINE USES OF RECORDS MAINTAINED IN THE  
SYSTEM, INCLUDING CATEGORIES OF USERS AND  
PURPOSES OF SUCH USES:**

A record in this system of records may be disclosed to appropriate agencies, entities and persons when: (1) It is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or whether

systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records will be stored in a secure computerized system and on magnetic tape; output data will be either electronic or paper copy. Paper copies or magnetic media will be stored in a secure area within a locked drawer or cabinet. Source data sets containing personal identifiers will be maintained in a secure restricted-access environment.

**RETRIEVABILITY:**

Records are maintained within a secure, restricted access environment where direct identifiers have been deleted and replaced by unique serial identification numbers (PIK). The records can be retrieved by the PIK by only a limited number of persons sworn to uphold the confidentiality of Census Bureau data and who have a need to know. The purpose of these identifiers is not to facilitate retrieval of information concerning specific individuals, but only to develop matched data sets for subsequent statistical extracts.

**SAFEGUARDS:**

The Census Bureau is committed to respecting respondent privacy and protecting confidentiality. Through the Data Stewardship Program, we have implemented management, operational, and technical controls and practices to ensure high-level data protection to respondents of our census and surveys. (1) The Census Bureau unauthorized browsing policy protects respondent information from casual or inappropriate use by any person with access to data protected by Title 13 of the United States Code (U.S.C.). (2) All employees permitted to access the system are subject to the restrictions, penalties, and prohibitions of 13 U.S.C. 9 and 214 as modified by 18 U.S.C. 3551, *et seq.*, the Privacy Act of 1974 (5 U.S.C. 552a(b)(4)); 26 U.S.C. 7213,

7213A, and 7431; and 42 U.S.C. 1306, as well as any additional restrictions imposed by statutory authority of a sponsor. (3) All Census Bureau employees and persons with special sworn status will be regularly advised of regulations issued pursuant to Title 13 U.S.C. governing the confidentiality of the data, and will be required to complete an annual Title 13 awareness program; and those who have access to Federal Tax Information data will be regularly advised of regulations issued pursuant to Title 26 U.S.C. governing the confidentiality of the data, and will be required to complete an annual Title 26 awareness program. (4) All computer systems that maintain sensitive information are in compliance with the Federal Information Security Management Act, which includes auditing and controls over access to restricted data. (5) The use of unsecured telecommunications to transmit individually identifiable information is prohibited. (6) Paper copies that contain sensitive information are stored in secure facilities in a locked drawer or file cabinet behind a locked door. (7) Additional data files containing direct identifiers will be maintained solely for the purpose of data collection activities, such as respondent contact and preloading an instrument for a continued interview, and will not be transferred to, or maintained on, working statistical files. (8) While the original data are housed at the Census Bureau they are afforded the same protections as data held confidential under 13 U.S.C. 9.

**RETENTION AND DISPOSAL:**

Records are retained in accordance with the General Records Schedule and Census Bureau's records control schedules that are approved by the National Archives and Records Administration. Records are retained in accordance with agreements developed with sponsoring agencies or source entity. Federal tax information administrative record data will be retained and disposed of in accordance with Publication 1075, *Tax Information Security Guidelines for Federal, State, and Local Agencies and Entities*. The Census Bureau issues an Annual Safeguard Activity Report that includes information on the retention and disposal of federal administrative record source data. Due to IRS regulation, Title 26 data cannot be transferred to the National Archive and Records Administration (NARA). Permanent data will be archived at the Census Bureau. Generally, records are retained for less than 10 years, unless a longer period required by the survey sponsor is

necessary for statistical purposes or for permanent archival retention.

**SYSTEM MANGER(S) AND ADDRESS:**

Associate Director for Research and Methodology, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233.

**Custodian:**

Director, Longitudinal Employer-Household Dynamics Program, Center for Economic Studies, Research and Methodology Directorate, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233.

**NOTIFICATION PROCEDURE:**

None.

**RECORD ACCESS PROCEDURES:**

None.

**CONTESTING RECORD PROCEDURES:**

None.

**RECORD SOURCE CATEGORIES:**

The Internal Revenue Service, the Social Security Administration, selected Census Bureau economic and demographic censuses and surveys, and comparable data from selected State Employment Security Agencies.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

Pursuant to 5 U.S.C. 552 a(k)(4), this system of records is exempted from the notification, access, and contest requirements of the agency procedures (under 5 U.S.C. Section 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f)). This exemption is applicable as the data are maintained by the Census Bureau and required by Title 13 to be used solely as statistical records and are not used in whole or in part in making any determination about an identifiable individual or establishment. This exemption is made in accordance with the Department's rules, which appear in 15 CFR part 4 Subpart B, and in accordance with agency rules published in this **Federal Register** notice.

Dated: September 9, 2015.

**Michael J. Toland,**

*Department of Commerce, Acting Freedom of Information/Privacy Act Officer.*

[FR Doc. 2015-23135 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-07-P**

**DEPARTMENT OF COMMERCE****National Telecommunications and Information Administration****First Responder Network Authority****First Responder Network Authority Board Meetings**

**AGENCY:** First Responder Network Authority (FirstNet), Commerce.

**ACTION:** Notice of public meetings.

**SUMMARY:** The Board of the First Responder Network Authority (FirstNet) will convene an open public meeting on October 2, 2015, preceded by open public meetings of the Board Committees on October 1, 2015.

**DATES:** On October 1, 2015 between 8 a.m. and 4:30 p.m. Eastern Daylight Time, there will be two open public meetings of FirstNet's four Board Committees. The first meeting is a joint meeting of the Governance and Personnel and Finance Committee and will be held between 8–11:30 a.m. Eastern Daylight Time. The second meeting is a joint meeting of the Technology and Consultation Committee and will be held between 1–4:30 p.m. The full FirstNet Board will hold an open public meeting on October 2, 2015 between 8 a.m. and 11 a.m. Eastern Daylight Time.

**ADDRESSES:** The meetings on October 1 and October 2, 2015 will be held at John Wesley Powell Federal Building, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192.

**FOR FURTHER INFORMATION CONTACT:** Uzoma Onyeije, Secretary, FirstNet, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192; telephone: (703) 648–4165; email: [uzoma.onyeije@firstnet.gov](mailto:uzoma.onyeije@firstnet.gov). Please direct media inquiries to Ryan Oremland at (703) 648–4114.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Board of FirstNet will convene an open public meeting on October 2, 2015, preceded by open public meetings of the Board Committees on October 1, 2015.

*Background:* The Middle Class Tax Relief and Job Creation Act of 2012 (Act), Public Law 112–96, 126 Stat. 156 (2012), established FirstNet as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs FirstNet to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Board is responsible for making strategic decisions regarding FirstNet's

operations. The FirstNet Board held its first public meeting on September 25, 2012.

*Matters to be Considered:* FirstNet will post detailed agendas of each meeting on its Web site, <http://www.firstnet.gov>, prior to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the Committees and the Board may involve commercial or financial information that is privileged or confidential, personnel matters, or other legal matters affecting FirstNet. As such, the Committee chairs and Board Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. § 1424(e)(2).

*Times and Dates of Meetings:* On October 1, 2015 between 8 a.m. and 4:30 p.m. Eastern Daylight Time, there will be two open public meetings of FirstNet's four Board Committees. The first meeting is a joint meeting of the Governance and Personnel and Finance Committee and will be held between 8–11:30 a.m. Eastern Daylight Time. The second meeting is a joint meeting of the Technology and Consultation Committee and will be held between 1–4:30 p.m. The full FirstNet Board will hold an open public meeting on October 2, 2015 between 8 a.m. and 11 a.m. Eastern Daylight Time.

*Place:* The meetings on October 1 and October 2, 2015 will be held at John Wesley Powell Federal Building, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192.

*Other Information:* These meetings are open to the public and press on a first-come, first-served basis. Space is limited. In order to get an accurate headcount, all expected attendees are asked to provide notice of intent to attend by sending an email to [BoardRSVP@firstnet.gov](mailto:BoardRSVP@firstnet.gov). If the number of RSVPs indicates that expected attendance has reached capacity, FirstNet will respond to all subsequent notices indicating that capacity has been reached and that in-person viewing may no longer be available but that the meeting may still be viewed by webcast as detailed below. For access to the meetings, valid government issued photo identification may be requested for security reasons.

The meetings are accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Uzoma Onyeije, Secretary, FirstNet, at (703) 648–4165 or [uzoma.onyeije@firstnet.gov](mailto:uzoma.onyeije@firstnet.gov), at least five (5) business days before the applicable meeting(s).

The meetings will also be webcast. Please refer to FirstNet's Web site at [www.firstnet.gov](http://www.firstnet.gov) for webcast instructions and other information. Viewers experiencing any issues with the live webcast may email [support@sparkstreetdigital.com](mailto:support@sparkstreetdigital.com) or call 202.684.3361 x9 for support. A variety of automated troubleshooting tests are also available via the "Troubleshooting Tips" button on the webcast player. The meetings will also be available to interested parties by phone. To be connected to the meetings in listen-only mode by telephone, please dial 888–997–9859 and passcode 3572169.

*Records:* FirstNet maintains records of all Board proceedings. Minutes of the Board Meeting and the Committee meetings will be available at [www.firstnet.gov](http://www.firstnet.gov).

Dated: September 10, 2015.

**Eli Veenendaal,**

*Attorney Advisor, First Responder Network Authority.*

[FR Doc. 2015–23391 Filed 9–16–15; 8:45 am]

**BILLING CODE 3510-TL-P**

**DEPARTMENT OF COMMERCE****International Trade Administration**

**[A–580–816]**

**Corrosion-Resistant Carbon Steel Flat Products From the Republic of Korea: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Administrative Review Pursuant to Court Decision**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce

**SUMMARY:** On August 31, 2015, the United States Court of International Trade (the Court) sustained the Department of Commerce's (Department) Final Remand Redetermination pertaining to the 19th administrative review of corrosion-resistant carbon steel flat products (CORE) from the Republic of Korea (Korea).<sup>1</sup>

Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in *Timken*,<sup>2</sup> as

<sup>1</sup> See *Dongbu Steel Co., Ltd. v. United States*, CIT Consol. Court No. 14–00098, Slip Op. 15–99 (August 31, 2015); Final Results of Redetermination Pursuant to Court Remand, Court No. 14–00098, dated July 24, 2015 (Final Remand Redetermination); and *Dongbu Steel Co. v. United States*, 61 F. Supp. 3d 1377 (Ct. Int'l Trade 2015) (*Remand Order*).

<sup>2</sup> See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

clarified by *Diamond Sawblades*,<sup>3</sup> the Department is notifying the public that the final judgment in this case is not in harmony with the Department's final results of the 19th administrative review of CORE from Korea, and that it is amending the final results with respect to Dongbu Steel Co., Ltd. (Dongbu) and Union Steel Manufacturing Co., Ltd. (Union Steel).<sup>4</sup> The period of review (POR) is August 1, 2011, through February 14, 2012.<sup>5</sup>

**DATES:** *Effective Date:* September 10, 2015.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Moore, AD/CVD Operations Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC, 20230; telephone: (202) 482-3692.

**SUPPLEMENTARY INFORMATION:**

**Background**

On September 26, 2012, the Department initiated an administrative review of the antidumping duty order on CORE from Korea for the period August 1, 2011, through July 31, 2012.<sup>6</sup> On March 19, 2013, as a result of the International Trade Commission's determination in the third sunset review, the Department published a notice that the antidumping duty order on CORE from Korea would be revoked, but that it would complete any pending reviews of entries made prior to February 14, 2012, the effective date of revocation.<sup>7</sup> For the *Preliminary Results*, published on September 9, 2013, the Department shortened the POR for the ongoing administrative review to reflect the effective date of revocation of the

antidumping order.<sup>8</sup> In its preliminary dumping calculations, the Department truncated the sales databases to conform to the shortened POR. However, in conducting the sales below cost and cost recovery tests to determine the pool of home market sales available for the calculation of normal value, the Department used the cost of production database submitted by Dongbu covering the original August 1, 2011, through July 31, 2012, review period. For the *Final Results*, the Department continued to use Dongbu's weighted-average cost data for the full-year POR in its antidumping calculations.<sup>9</sup> The Department also used Dongbu's weighted-average dumping margin as the rate for non-examined respondent Union Steel, because it was the only rate that was not zero, *de minimis*, or based on total facts available.<sup>10</sup>

Before the Court, Dongbu and Union Steel challenged the Department's determination to use the 12-month cost of production data in both the cost recovery and sales below cost tests, arguing that the language of the cost recovery test in section 773(b)(2)(D) of the Tariff Act of 1930, as amended (the Act) requires that prices be measured for cost recovery against the weighted-average cost of production for the shortened POR, and that the Department accordingly should have requested new cost data for the revised POR and recalculated the weighted-average dumping margin.<sup>11</sup> Dongbu and Union Steel further argued that the Department's use of costs outside the POR in the sales below cost test was unlawful because the statute requires that the cost of production "reasonably reflect the costs associated with the production and sale of the merchandise, during the period of review."<sup>12</sup>

In its *Remand Order*, the Court held that the language of the statute "unambiguously prohibited the Department from using cost data for a period other than the POR to calculate the weighted average cost of production for purposes of the cost recovery test," and that "[n]othing in the statutory framework contradicts the cost recovery test's plain language regarding the POR."<sup>13</sup> The Court rejected the

Department's remaining arguments regarding the cost recovery test provision.<sup>14</sup>

In addition, the Court agreed that the Department has discretion to include costs outside of the POR in conducting the sales below cost test, but found the Department's explanation as to why it included post-review period cost data inadequate, and remanded to the Department to "explain its decision in this case that the costs incurred after the POR reasonably reflect the costs of the product under review."<sup>15</sup>

After reopening the record to obtain cost of production data reflecting the revised POR from Dongbu, issuing a draft remand redetermination, and soliciting comments, the Department issued the Final Remand Redetermination on July 24, 2015. In the Final Remand Redetermination, the Department modified its dumping calculations by comparing Dongbu's home market sales against cost data from the revised POR to determine whether such sales were made at prices that would provide for the recovery of costs.<sup>16</sup> The Department relied on this same cost data in administering the sales below cost test for Dongbu.<sup>17</sup> Finally, the Department assigned Dongbu's revised dumping margin to Union Steel.<sup>18</sup>

**Timken Notice**

In *Timken*, 893 F.2d at 341, as clarified by *Diamond Sawblades*, the CAFC held that, pursuant to section 516A(e) of the Act, the Department must publish a notice of a court decision that is not "in harmony" with a Department determination and must suspend liquidation of entries pending a "conclusive" court decision. The Court's judgment sustaining the Final Remand Redetermination constitutes a final decision of the Court that is not in harmony with the Department's *Final Results*. This notice is published in fulfillment of the publication requirement of *Timken*. Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision. In the event the Court's ruling is not appealed or, if appealed, upheld by the CAFC, the Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on unliquidated entries of subject

<sup>3</sup> See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

<sup>4</sup> See *Corrosion-Resistant Carbon Steel Flat Products From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2011-2012*, 79 FR 17503 (March 28, 2014) (*Final Results*), and accompanying Issues and Decision Memorandum (I&D Memo).

<sup>5</sup> The period of review ends on February 14, 2012 because the antidumping duty order on CORE from Korea was revoked effective on this date. See *Corrosion-Resistant Carbon Steel Flat Products from Germany and the Republic of Korea: Revocation of Antidumping and Countervailing Duty Orders*, 78 FR 16832 (March 19, 2013) (*CORE Revocation*).

<sup>6</sup> See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 77 FR 59168 (September 26, 2012).

<sup>7</sup> See *Corrosion-Resistant Carbon Steel Flat Products from Germany and the Republic of Korea: Revocation of Antidumping and Countervailing Duty Orders*, 78 FR 16832 (March 19, 2013); *Determinations: Corrosion-Resistant Carbon Steel Flat Products from Germany and Korea*, 78 FR 15376 (March 11, 2013).

<sup>8</sup> See *Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Preliminary Results of Administrative Review*, 78 FR 55057 (September 9, 2013), and accompanying Preliminary Decision Memorandum (*Preliminary Results*).

<sup>9</sup> See *Final Results*, and accompanying I&D Memo at Comment 1.

<sup>10</sup> See *Final Results*, 79 FR at 17504 & n.11.

<sup>11</sup> See *Remand Order*, 61 F. Supp. 3d at 1381.

<sup>12</sup> *Id.*, at 1388.

<sup>13</sup> *Id.*, at 1384.

<sup>14</sup> *Id.*, at 1385-88.

<sup>15</sup> *Id.*, at 1388-90.

<sup>16</sup> See *Final Remand Redetermination* at 5.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*, at 6.

merchandise exported by the producers and/or exporters listed below at the rates listed below.

**Amended Final Results**

Because there is now a final court decision, the Department is amending the *Final Results* with respect to Dongbu and Union Steel, plaintiffs in this case. The revised weighted-average dumping margins for these producers/exporters during the period August 1, 2011, through February 14, 2012, are as follows:

WEIGHTED-AVERAGE DUMPING MARGINS	
Producer/Exporter	Weighted-average dumping margin (percent)
Dongbu .....	5.38
Union Steel .....	5.38

**Cash Deposit Requirements**

The Department notified CBP to discontinue the collection of cash deposits on entries of the subject merchandise, entered or withdrawn from warehouse, on or after February 14, 2012.<sup>19</sup> Therefore, no cash deposit requirements will be imposed in response to these amended final results.

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: September 10, 2015.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2015-23360 Filed 9-16-15; 8:45 am]

BILLING CODE 3510-DS-P

**DEPARTMENT OF COMMERCE**

**National Institute of Standards and Technology**

**Proposed Information Collection; Comment Request; National Institute of Standards and Technology (NIST), Generic Clearance for Usability Data Collections**

**AGENCY:** National Institute of Standards and Technology (NIST), Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information

collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before November 16, 2015.

**ADDRESSES:** Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at [jjessup@doc.gov](mailto:jjessup@doc.gov)).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to Amy Egan, Management Analyst, NIST, 100 Bureau Drive, MS 1710, Gaithersburg, MD 20899-1710, telephone 301-975-2819, or via email to [amy.egan@nist.gov](mailto:amy.egan@nist.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

This is a request to renew or extend the expiration date of this currently approved information collection.

In accordance with the Executive Order 12862, the National Institute of Standards and Technology (NIST), a non-regulatory agency of the Department of Commerce, proposes to conduct a number of data collection efforts—both quantitative and qualitative. The data collections will be designed to determine requirements and evaluate the usability and utility of NIST research for measurement and standardization work. These data collections efforts may include, but may not be limited to electronic methodologies, empirical studies, video and audio collections, interviews, and questionnaires. For example, data collection efforts may include the password generation study and the user perceptions of online privacy and security study. NIST will limit its inquiries to data collections that solicit strictly voluntary opinions or responses and will not collect information that is required or regulated. The results of the data collected will be used to guide NIST research. Steps will be taken to ensure anonymity of respondents in each activity covered under this request.

**II. Method of Collection**

NIST will collect this information by electronic means when possible, as well as by mail, fax, telephone and person-to-person interviews.

**III. Data**

*OMB Control Number:* 0693-0043.  
*Form Number:* None.

*Type of Review:* Regular submission (extension of a currently approved information collection.)

*Affected Public:* Individuals or households, State, local or tribal government, Federal government.

*Estimated Number of Respondents:* 8,500.

*Estimated Time per Response:* Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire may be 15 minutes or 2 hours to participate in an empirical study.

*Estimated Total Annual Burden Hours:* 5,000.

*Estimated Total Annual Cost to Public:* \$0.

**IV. Request for Comments**

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: September 11, 2015.

**Glenna Mickelson,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 2015-23295 Filed 9-16-15; 8:45 am]

BILLING CODE 3510-13-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**Proposed Information Collection; Comment Request; Vessel Monitoring System Requirements Under the Western and Central Pacific Fisheries Convention**

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing

<sup>19</sup> See *CORE Revocation*, 78 FR at 16833.



effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before November 16, 2015.

**ADDRESSES:** Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at [Jjessup@doc.gov](mailto:Jjessup@doc.gov)).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to Tom Graham, (808) 725-5032 or [Tom.Graham@noaa.gov](mailto:Tom.Graham@noaa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

This request is for an extension of a currently approved information collection. National Marine Fisheries Service (NMFS) has issued regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFCIA; 16 U.S.C. 6901 *et seq.*) to carry out the obligations of the United States under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention), including implementing the decisions of the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Commission). The regulations include a requirement for the owners and operators of U.S. vessels that fish for highly migratory species on the high seas in the Convention Area to carry and operate near real-time satellite-based position-fixing transmitters ("VMS units") at all times except when the vessel is in port. As part of this requirement, vessel owners and operators must transmit: (1) "on/off reports" to NMFS whenever the VMS unit is turned off while the vessel is in port, (2) "activation reports" to NMFS prior to the first use of a VMS unit, and (3) automatic "position reports" from the VMS unit to NOAA and the Commission as part of a vessel monitoring system (VMS) operated by the Commission (50 CFR 300.45). Under this information collection, it is expected that vessel owners and operators would also need to purchase, install, and occasionally maintain the VMS units.

The information collected from the vessel position reports is used by NOAA and the Commission to help ensure compliance with domestic laws and the Commission's conservation and management measures, and are necessary in order to the United States to satisfy its obligations under the Convention.

**II. Method of Collection**

Respondents may submit on/off reports by facsimile or email, and they may submit activation reports by mail, facsimile or email. Position reports are transmitted electronically and automatically from the VMS unit.

**III. Data**

*OMB Control Number:* 0648-0596.

*Form Number(s):* None.

*Type of Review:* Regular submission (extension of a currently approved collection).

*Affected Public:* Business or other for-profit organizations; individuals or households.

*Estimated Number of Respondents:* 78.

*Estimated Time per Response:* VMS unit purchase and installation, 1 hr; activation reports, 5 min; on/off reports, 5 min; VMS unit maintenance, 1 hr.

*Estimated Total Annual Burden Hours:* 192 hours.

*Estimated Total Annual Cost to Public:* \$78,000 in capital costs and \$58,111 in recordkeeping/reporting costs.

**IV. Request for Comments**

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: September 14, 2015.

**Sarah Brabson,**

*NOAA PRA Clearance Officer.*

[FR Doc. 2015-23337 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-22-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**RIN 0648-XE185**

**Pacific Island Fisheries; Public Meeting**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; public meeting.

**SUMMARY:** NMFS announces that the Center for Independent Experts will meet to review methods for reviewing modified integrated assessments (based on catch-MSY model) for data-poor stocks.

**DATES:** See **SUPPLEMENTARY INFORMATION** section for meeting dates and times.

**ADDRESSES:** The meeting will be held in the Pelagic Suite Conference Room, Western Pacific Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813.

**FOR FURTHER INFORMATION CONTACT:** Ben Richards, NMFS Pacific Islands Fisheries Science Center, (808) 725-5320 or [benjamin.richards@noaa.gov](mailto:benjamin.richards@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The meeting schedule and agenda are as follows:

1. *Tuesday, October 13, 2015 (9:30 a.m.–5 p.m.)*

- Introduction
- Background information—Objectives and Terms of Reference
- Coral reef fisheries in the Pacific Islands Region
- Data: Fishery-dependent data collection systems in the Pacific Islands, Coral Reef Ecosystem Division surveys, biological data, other data
- Discussion

2. *Wednesday, October 14, 2015 (8:30 a.m.–4 p.m.)*

- Review of modified integrated Catch-MSY stock assessment
- Discussion

3. *Thursday, October 15, 2015 (8:30 a.m.–4 p.m.)*

- Continue assessment review (1/2 day)
- Discussion
- Panel discussions (Closed)

4. *Friday, October 16, 2015 (8:30 a.m.–4 p.m.)*

- Panel discussions (1/2 day)
- Present results (afternoon)
- Adjourn

The agenda order may change. The meetings will run as late as necessary to

complete scheduled business. Although non-emergency issues not contained in this agenda may come up at the meeting for discussion, those issues may not be the subject of formal action during the meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the intent to take final action to address the emergency.

#### Special Accommodations

These meetings are physically accessible to people with disabilities. Direct requests for sign language interpretation or other auxiliary aids to Beth Lumsden, (808) 725-5330 or [beth.lumsden@noaa.gov](mailto:beth.lumsden@noaa.gov) at least 5 days prior to the meeting date.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: September 11, 2015.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2015-23335 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Proposed Information Collection; Comment Request; Mail Survey To Collect Economic Data From Federal Gulf of Mexico and South Atlantic For-Hire Permit Holders

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before November 16, 2015.

**ADDRESSES:** Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at [Jjessup@doc.gov](mailto:Jjessup@doc.gov)).

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to Christopher Liese, Industry Economist, SEFSC, NMFS, 75 Virginia Beach Drive, Miami FL 33149, (305) 365-4109 or [Christopher.Liese@noaa.gov](mailto:Christopher.Liese@noaa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Abstract

This request is for a new information collection.

The National Oceanic and Atmospheric Administration's (NOAA) Fisheries, Southeast Fisheries Science Center, proposes to collect very basic socioeconomic data from federally-permitted for-hire operators in the Gulf of Mexico and South Atlantic fisheries, using a mail sample survey. The National Marine Fisheries Service (NMFS) does not systematically collect information on for-hire trip prices and trip costs in the Southeast. The population consists of those for-hire operators who possess a federal for-hire permit for dolphin-wahoo, coastal migratory pelagics, snapper-grouper, or reef fish species in the South Atlantic or Gulf of Mexico. Each year we will sample approximately a third of the population. The two-page survey will be designed to collect basic data on trip revenues and trip costs as well as other related information. These data are needed to conduct socioeconomic analyses in support of management of the for-hire fishing industry and to satisfy legal requirements. The data will be used to assess how fishermen will be impacted by and respond to federal regulation likely to be considered by fishery managers.

##### II. Method of Collection

The information will be collected on paper using a mail survey.

##### III. Data

*OMB Control Number:* 0648-xxxx.

*Form Number(s):* None.

*Type of Review:* Regular (request for a new information collection).

*Affected Public:* Business or other for-profit organizations; individuals or households.

*Estimated Number of Respondents:* 1000.

*Estimated Time per Response:* 12 minutes.

*Estimated Total Annual Burden Hours:* 200 hours.

*Estimated Total Annual Cost to Public:* \$0 in recordkeeping/reporting costs.

## IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: September 14, 2015.

**Sarah Brabson,**

*NOAA PRA Clearance Officer.*

[FR Doc. 2015-23336 Filed 9-16-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

#### Record of Decision for the Final Supplemental Environmental Impact Statement for Guam and Commonwealth of the Northern Mariana Islands Military Relocation

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice.

**SUMMARY:** The Department of the Navy (DON), after carefully considering the environmental consequences of the proposed action, as well as strategic, operational, and training requirements, obligations under treaties and other international agreements, and cost, announces its decision to construct and operate a main base (cantonment area), a family housing area, a live-fire training range complex (LFTRC), and associated infrastructure on Guam to support the relocation of a substantially reduced number of Marines and dependents than previously analyzed in a 2010 Final Environmental Impact Statement (EIS) (Guam and Commonwealth of the Northern Mariana Islands (CNMI) Military Relocation; Relocating Marines from Okinawa, Visiting Aircraft Carrier Berthing, and Army Air and Missile Defense Task Force).

The proposed action will be accomplished as set out in Alternatives

E and 5 as identified in the 2015 Final Supplemental Environmental Impact Statement (SEIS) as the preferred alternatives. Alternatives E and 5 consist of a cantonment at Naval Computer and Telecommunications Station Finegayan (Finegayan) and family housing at Andersen Air Force Base (AAFB), and a LFTRC at AAFB—Northwest Field (NWF). The LFTRC also includes a stand-alone hand grenade range at Andersen South. Under these selected alternatives, the DON will be able to meet current and future DON and Department of Defense (DoD) training and operational requirements.

The Record of Decision (ROD) documents why the DoD has chosen to implement the preferred alternatives as described in the 2015 Final SEIS. The ROD includes descriptions and discussions of the anticipated environmental impacts of the proposed action. It also includes descriptions and discussions of all related actions and their anticipated impacts.

**FOR FURTHER INFORMATION CONTACT:** Director, Joint Guam Program Office Forward, P.O. Box 153246, Santa Rita, Guam 96915.

**SUPPLEMENTARY INFORMATION:** The complete text of the ROD is available for public viewing at [www.guambuildupeis.us](http://www.guambuildupeis.us). Hard copies of the ROD will be available at the following locations: University of Guam Robert F. Kennedy Memorial Library, Government Documents Tan Siu Lin Building, UOG Station, Mangilao, GU 96923 and Nieves M. Flores Memorial Library, 254 Martyr Street, Hagåtña, GU 96910.

Dated: September 9, 2015.

**N.A. Hagerty-Ford,**

*Commander, Office of the Judge Advocate General, U.S. Navy, Administrative Law Division, Federal Register Liaison Officer.*

[FR Doc. 2015–23244 Filed 9–16–15; 8:45 am]

**BILLING CODE 3810–FF–P**

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## DEPARTMENT OF EDUCATION

[Docket No. ED–2015–ICCD–0076]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Borrower Defenses Against Loan Repayment

**AGENCY:** Federal Student Aid (FSA), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is

proposing an extension of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before October 19, 2015.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2015–ICCD–0076. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202–4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Beth Grebeldinger (202) 377–4018.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* Borrower Defenses Against Loan Repayment.

*OMB Control Number:* 1845–0132.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* Individuals or Households.

*Total Estimated Number of Annual Responses:* 150,000.

*Total Estimated Number of Annual Burden Hours:* 150,000.

*Abstract:* This is a request to for an extension of the emergency clearance that was granted on this collection on June 5, 2015 to facilitate the continued collection of information from borrowers who believe they have cause to invoke the borrower defenses against repayment of a student loan as noted in regulation. The regulations for borrower defenses are specified in 34 CFR 685.206(c). The regulation states, in part, “(c)(1) [i]n any proceeding to collect on a Direct Loan, the borrower may assert as a defense against repayment, an act or omission of the school attended by the student that would give rise to a cause of action against the school under applicable State law.” Prior to 2015, the borrower defense identified above was rarely asserted by any borrowers and no specific methods of collecting information was defined or found necessary.

These processes are being offered to aid in preserving borrowers rights and to meet the fiduciary responsibilities of the federal student loan programs. These collections will allow the Department of Education to inform borrowers and loan servicers of the information needed to review and adjudicate requests for relief under borrower defenses regulations.

Dated: September 14, 2015.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–23346 Filed 9–16–15; 8:45 am]

**BILLING CODE 4000–01–P**

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## DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0111]

### Agency Information Collection Activities; Comment Request; Middle Grades Longitudinal Study of 2017–2018 (MGLS:2017) Recruitment for 2017 Operational Field Test

**AGENCY:** National Center for Education Statistics (NCES), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before November 16, 2015.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2015–ICCD–0111. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202–4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Kashka Kubzdela, 202–502–7411 or by email [kashka.kubzdela@ed.gov](mailto:kashka.kubzdela@ed.gov).

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use

of information technology. Please note that written comments received in response to this notice will be considered public records.

**Title of Collection:** Middle Grades Longitudinal Study of 2017–2018 (MGLS:2017) Recruitment for 2017 Operational Field Test.

**OMB Control Number:** 1850–0911.

**Type of Review:** A revision of an existing information collection.

**Respondents/Affected Public:** Individuals.

**Total Estimated Number of Annual Responses:** 1,224.

**Total Estimated Number of Annual Burden Hours:** 438.

**Abstract:** The Middle Grades Longitudinal Study of 2017–2018 (MGLS:2017) is the first study sponsored by the National Center for Education Statistics (NCES), within the Institute of Education Sciences (IES) of the U.S. Department of Education (ED), to follow a nationally-representative sample of students as they enter and move through the middle grades (grades 6–8). The data collected through repeated measures of key constructs will provide a rich descriptive picture of the academic experiences and development of students during these critical years and will allow researchers to examine associations between contextual factors and student outcomes. The study will focus on student achievement in mathematics and literacy along with measures of student socioemotional wellbeing and other outcomes. The study will also include a special sample of students with different types of disabilities that will provide descriptive information on their outcomes, educational experiences, and special education services. Baseline data for the MGLS:2017 will be collected from a nationally-representative sample of 6th grade students beginning in January 2018, with annual follow-ups beginning in January 2019 and in January 2020 when most of the students in the sample will be in grades 7 and 8, respectively. This request is to contact and recruit public school districts and public and private schools, beginning in January 2016, to participate in the MGLS:2017 Operational Field Test (OFT) which will take place from January to June 2017. The primary purpose of the OFT is to obtain information on recruiting, particularly for the targeted disability groups; obtaining a tracking sample that can be used to study mobility patterns in subsequent years; and testing protocols and administrative procedures. The OFT will inform the materials and procedures for the main study base year and follow-up data

collections. The base year data collection will begin in January 2018.

Dated: September 14, 2015.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–23338 Filed 9–16–15; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

### Meeting: National Board for Education Sciences

**AGENCY:** Institute of Education Sciences, ED.

**ACTION:** Announcement of an open meeting.

**SUMMARY:** This notice sets forth the schedule and proposed agenda of an upcoming meeting of the National Board for Education Sciences (NBES). The notice also describes the functions of the Committee. Notice of this meeting is required by Section 10(a) (2) of the Federal Advisory Committee Act and is intended to notify the public of their opportunity to attend the meeting.

**DATES:** The NBES meeting will be held on October 2, 2015, from 9 a.m. to 4:30 p.m. Eastern Standard Time.

**ADDRESSES:** 80 F Street NW., Large Board Room, Washington, DC 20001.

**FOR FURTHER INFORMATION CONTACT:** Ellie Pelaez, Designated Federal Official, NBES, U.S. Department of Education, 555 New Jersey Avenue NW., Room 600 E, Washington, DC 20208; phone: (202) 219–0644; fax: (202) 219–1402; email: [Ellie.Pelaez@ed.gov](mailto:Ellie.Pelaez@ed.gov).

**SUPPLEMENTARY INFORMATION:** NBES's Statutory Authority and Function: The National Board for Education Sciences is authorized by Section 116 of the Education Sciences Reform Act of 2002 (ESRA), 20 U.S.C. 9516. The Board advises the Director of the Institute of Education Sciences (IES) on, among other things, the establishment of activities to be supported by the Institute and the funding for applications for grants, contracts, and cooperative agreements for research after the completion of peer review. The Board also reviews and evaluates the work of the Institute.

**Meeting Agenda:** On October 2, 2015, starting at 9 a.m., the Board meeting will commence and members will approve the agenda. From 9:05 a.m. to 10:30 a.m., the Board will hear presentations from the Commissioners of the IES Centers for Education Research, Special Education Research, Education Evaluation and Regional Assistance, and

Education Statistics. This session will be followed by a question and answer period for board members, regarding the Commissioners' reports. A break will take place from 10:30 a.m. to 10:45 a.m.

The Board meeting will resume from 10:45 a.m. to 12 p.m. when the Board will discuss the IES Standards and Review Office. Anne Ricciuti, Deputy Director for Science, will provide opening remarks followed by a roundtable discussion with board members. The meeting will break for lunch from 12 p.m. to 1 p.m.

From 1 p.m. to 2:30 p.m., the board will participate in a discussion on the National Center for Education Statistics (NCES). Peggy Carr, Acting Commissioner, National Center for Education Statistics, will provide opening remarks, followed by a panel discussion with the Associate Commissioners of the National Center for Education Statistics. Roundtable discussion by board members will take place after the panel discussion. A break will take place from 2:30 p.m. to 2:45 p.m.

The meeting will resume at 2:45 p.m. to 4:15 p.m. when the Board will hold a panel discussion with National Center for Education Statistics stakeholders. Peggy Carr will provide opening remarks, followed by a panel discussion.

Closing remarks will take place from 4:15 p.m. to 4:30 p.m., with adjournment scheduled for 4:30 p.m.

*Submission of comments regarding the Board's policy recommendations:* There will not be an opportunity for public comment. However, members of the public are encouraged to submit written comments related to NBES to Ellie Pelaez (see contact information above) no later than September 23, 2015. A final agenda is available from Ellie Pelaez (see contact information above) and is posted on the Board Web site <http://ies.ed.gov/director/board/agendas/index.asp>.

*Access to Records of the Meeting:* The Department will post the official report of the meeting on the NBES Web site no later than 90 days after the meeting. Pursuant to the FACA, the public may also inspect the materials at 555 New Jersey Avenue NW., 6th Floor, Washington, DC, by emailing [Ellie.Pelaez@ed.gov](mailto:Ellie.Pelaez@ed.gov) or by calling (202) 219-0644 to schedule an appointment.

*Reasonable Accommodations:* The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice by or before

September 23, 2015. Although we will attempt to meet a request received after September 23, 2015, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

*Electronic Access to this Document:* The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

**Authority:** Section 116 of the Education Sciences Reform Act of 2002 (ESRA), 20 U.S.C. 9516

**Ruth Neild,**

*Deputy Director for Policy and Research, Delegated Duties of the Director, Institute of Education Sciences.*

[FR Doc. 2015-23392 Filed 9-16-15; 8:45 am]

**BILLING CODE P**

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## DEPARTMENT OF ENERGY

### Secretary of Energy Advisory Board Meeting; Correction

**AGENCY:** Department of Energy.

**ACTION:** Notice of open meeting; Correction.

**SUMMARY:** The Department of Energy (DOE), on September 10, 2015, published a notice of open meeting announcing an open meeting of the Secretary of Energy Advisory Board. Due to the scheduled transportation delays and security issues near the meeting venue, the meeting is being rescheduled. The date is now October 15, 2015, 8:30 a.m.–12:30 p.m. As a result, the language is being corrected in this notice.

#### Corrections

In the **Federal Register** of September 10, 2015, in FR DOC. 2015-22809, on pages 54558-54559, please make the following corrections:

In the **DATES** heading, third column, first and second lines, replace text with

“Thursday, October 15, 2015, 8:30 a.m.–12:30 p.m. (EDT)”.

In the **SUPPLEMENTARY INFORMATION** heading, *Tentative Agenda*: third column, twelfth line, please remove “September 25th” and replace with “October 15th.” And under Public Participation, twenty-fifth line, please remove “Monday, September 21, 2015”, and replace text with “Friday, October 9, 2015”.

On page 54559, first column, twenty-first line, please remove “September 25th” and replace text with “October 15th”.

Issued in Washington, DC, on September 11, 2015.

**LaTanya R. Butler,**

*Deputy Committee Management Officer.*

[FR Doc. 2015-23372 Filed 9-16-15; 8:45 am]

**BILLING CODE 6450-01-P**

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## DEPARTMENT OF ENERGY

### National Coal Council Meeting

**AGENCY:** Department of Energy.

**ACTION:** Notice of Open Meetings.

**SUMMARY:** This notice announces a meeting of the National Coal Council (NCC). The Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

**DATES:** Thursday, November 5, 2015, 8:45 a.m. to 12:15 p.m.

**ADDRESSES:** National Energy Technology Laboratory, 1501 Wallace Road, Pittsburgh, Pennsylvania 15129.

**FOR FURTHER INFORMATION CONTACT:** Dr. Robert J. Wright, U.S. Department of Energy, 4G-036/Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0001; Telephone: 202-586-0429.

**SUPPLEMENTARY INFORMATION:** *Purpose of the Council:* The National Coal Council provides advice and recommendations to the Secretary of Energy, on general policy matters relating to coal and the coal industry.

*Purpose of Meeting:* The 2015 Spring meeting of the National Coal Council.

*Tentative Agenda:*

1. Call to order and opening remarks by Jeff Wallace, Chair, National Coal Council
2. Remarks by Dr. Grace Bochenek, Director, National Energy Technology Laboratory, U.S. Department of Energy
3. Presentation by Dr. Sean Plasynski, Director Strategic Center for Coal, National Energy Technology Laboratory, U.S. Department of Energy

4. Presentation by Dr. Jared Moore, Independent Energy Researcher, Meridian Energy Policy on The Increasing Competitiveness of CCUS Generation Under Deep Decarbonization
5. Presentation by Dr. Robert Williams, Sr. Research Scientist & Associated Faculty, Princeton Environmental Institute, Princeton University on CO2 Capture Technology Cost Buydown in EOR Applications with Alternative Financing Mechanisms
6. Council Business:
  - a. Finance report by Finance Committee Chair Greg Workman
  - b. Coal Policy Committee report by Coal Policy Committee Chair Fred Palmer
  - c. Communications Committee report by Communications Committee Chair Holly Krutka
  - d. NCC Business Report by NCC Executive Vice President & COO Janet Gellici
7. Other business
8. Adjourn

Visiting NETL requires compliance with site safety and security requirements. Please see <http://www.netl.doe.gov/about/visiting-netl> for full details. Due to security requirements, attendees are requested to register in advance for the meeting at: <https://www.eiseverywhere.com/ereg/index.php?eventid=137597&>.

Transportation to NETL will be provided for meeting registrants from the Crowne Plaza Pittsburgh South hotel (164 Fort Couch Road, Pittsburgh, PA 15241). Bus departs hotel at 7:30 a.m. and 7:55 a.m. Return transportation will be provided at 1:15 p.m. following lunch and at 3:15 p.m. following a tour of NETL's facilities.

**Public Participation:** The meeting is open to the public. If you would like to file a written statement with the Council, you may do so either before or after the meeting. If you would like to make oral statements regarding any item on the agenda, you should contact Dr. Robert J. Wright, 202-586-0429 or [robert.wright@hq.doe.gov](mailto:robert.wright@hq.doe.gov) (email). You must make your request for an oral statement at least 5 business days before the meeting. Reasonable provision will be made to include oral statements on the scheduled agenda. The Chairperson of the Council will lead the meeting in a manner that facilitates the orderly conduct of business. Oral statements are limited to 10-minutes per organization and per person.

**Minutes:** A link to the transcript of the meeting will be posted on the NCC Web site at: <http://www.nationalcoalcoalition.org/>.

Issued at Washington, DC, on September 11, 2015.

**LaTanya R. Butler,**

*Deputy Committee Management Officer.*

[FR Doc. 2015-23371 Filed 9-16-15; 8:45 am]

**BILLING CODE 6450-01-P**

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

**AGENCY:** Department of Energy.

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge Reservation. The Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

**DATES:** Wednesday, October 14, 2015, 6:00 p.m.

**ADDRESSES:** Department of Energy Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37830.

**FOR FURTHER INFORMATION CONTACT:** Melyssa P. Noe, Federal Coordinator, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM-90, Oak Ridge, TN 37831. Phone (865) 241-3315; Fax (865) 576-0956 or email: [melyssa.noe@orem.doe.gov](mailto:melyssa.noe@orem.doe.gov) or check the Web site at <http://energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board>.

**SUPPLEMENTARY INFORMATION:** *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE-EM and site management in the areas of environmental restoration, waste management, and related activities.

#### Tentative Agenda

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer
- Comments from the DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency Liaisons
- Public Comment Period
- Presentation—Progress Made at East Tennessee Technology Park
- Additions/Approval of Agenda
- Motions/Approval of September 9, 2015 Meeting Minutes
- Status of Recommendations with DOE
- Committee Reports
- Federal Coordinator Report

#### • Adjourn

**Public Participation:** The EM SSAB, Oak Ridge, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Melyssa P. Noe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to the agenda item should contact Melyssa P. Noe at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

**Minutes:** Minutes will be available by writing or calling Melyssa P. Noe at the address and phone number listed above. Minutes will also be available at the following Web site: <http://energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board>.

Issued at Washington, DC, on September 11, 2015.

**LaTanya R. Butler,**

*Deputy Committee Management Officer.*

[FR Doc. 2015-23373 Filed 9-16-15; 8:45 am]

**BILLING CODE 6450-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 14706-000]

#### Empire State Hydro 303, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On August 26, 2015, Empire State Hydro 303, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Rock Bottom Dam Hydroelectric Project (project) to be located on the Susquehanna River, near the city of Binghamton, Broome County, New York. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A

preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) An existing 9-foot-high, 460-foot-long gravity dam; (2) a proposed concrete powerhouse approximately 100 feet long by 40 feet wide housing eight low-head, horizontal bulb turbines having a total installed capacity of 1,992 kilowatts; (3) a proposed concrete tailrace wall extending approximately 100 feet downstream; (4) a proposed 500-foot-long, 12,700-volt transmission line interconnecting with the local utility; and (5) appurtenant facilities. The proposed project would have an average annual generation of about 10 megawatt-hours.

**Applicant Contact:** Mr. Mark Boumansour, Gravity Renewables, Inc., 1401 Walnut Street, Suite 220, Boulder, CO 80302; phone: (303) 440-3378.

**FERC Contact:** Timothy Looney; phone: (202) 502-6096.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P-14706-000.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P-14706) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: September 10, 2015.

**Kimberly D. Bose,**

Secretary.

[FR Doc. 2015-23323 Filed 9-16-15; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2197-108]

#### Alcoa Power Generating, Inc.; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Request for a Temporary Variance from Minimum Flow and Reservoir Level Requirements—Article 33.

b. *Project No.:* 2197-108.

c. *Date Filed:* September 4, 2015.

d. *Applicant:* Alcoa Power Generating, Inc. (licensee).

e. *Name of Project:* Yadkin Hydroelectric Project.

f. *Location:* Davidson, Davie, Montgomery, Rowan, and Stanly counties, North Carolina.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Mark Gross, Vice President of Hydro Operations, (704) 422-5774, or [mark.gross@alcoa.com](mailto:mark.gross@alcoa.com).

i. *FERC Contact:* Alicia Burtner, (202) 502-8038, or [alicia.burtner@ferc.gov](mailto:alicia.burtner@ferc.gov).

j. *Deadline for filing comments, motions to intervene, protests, and recommendations is 30 days from the issuance date of this notice by the Commission.*

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at <http://www.ferc.gov/docs-filing/efiling.asp>. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments.

Please include the project number (P-2197-108) on any comments, motions, or recommendations filed.

k. *Description of Request:* The licensee requests a temporary variance from the requirements of license Article 33, which mandates the implementation of the Reservoir Operating Guides. The requirements, as amended in 1968, pertain to minimum flows and reservoir levels at the four project developments. The licensee is required to maintain a minimum 900 cubic feet per second (cfs) daily average flow and a 1,400 cfs weekly average minimum flow. Article 33 also stipulates a rule curve relating reservoir levels of the upstream High Rock reservoir to the downstream Badin (Narrows) reservoir level seasonally. The licensee indicates that, as a result of ongoing drought conditions throughout the watershed, it consulted with its Drought Management Team to determine alternative operating procedures to conserve water. The licensee requests that the weekly minimum flow requirement be reduced to a 1,200 cfs average, and it outlines additional modifications to daily and weekly minimum flows based on conditions, updated mid-month.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502-8371. This filing may also be viewed on the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), for TTY, call (202) 502-8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must

be received on or before the specified comment date for the particular application.

*o. Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to minimum flows and/or impoundment levels at the Yadkin Hydroelectric Project, which are the subject of the variance. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: September 10, 2015.

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. 2015-23320 Filed 9-16-15; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER15-2620-000]

#### Little Elk Wind Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Little Elk Wind Project, LLC's application for market-based rate authority, with an

accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 30, 2015.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: September 10, 2015.

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. 2015-23322 Filed 9-16-15; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER15-2631-000]

#### Odell Wind Farm, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Odell Wind Farm, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 30, 2015.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email



FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: September 10, 2015.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2015-23317 Filed 9-16-15; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER15-2634-000]

#### Robison Energy (Commercial) LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Robison Energy (Commercial) LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 30, 2015.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the

Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov). or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: September 10, 2015.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2015-23318 Filed 9-16-15; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Beverly Lock and Dam Water Power, Project No. 13404-002—Devola Lock and Dam Water Power Project, Project No. 13405-002—Malta/McConnelsville Lock and Dam Water Power Project, Project No. 13406-002—Lowell Lock and Dam Water Power Project, Project No. 13407-002—Philo Lock and Dam Water Power Project, Project No. 13408-002—Rokeby Lock and Dam Water Power Project, Project No. 13411-002]**

#### Notice of Proposed Restricted Service List for a Programmatic Agreement for Managing Properties Included in or Eligible for Inclusion in the National Register of Historic Places

Rule 2010 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure<sup>1</sup> provides that, to eliminate unnecessary expense or improve administrative efficiency, the Secretary may establish a restricted service list for a particular phase or issue in a proceeding. The restricted service list should contain the names of persons on the service list who, in the judgment of the decisional authority establishing the list, are active participants with respect to the phase or issue in the proceeding for which the list is established.

The Commission staff is consulting with the Ohio Historical Society (Ohio SHPO) and the Advisory Council on Historic Preservation (Advisory Council) pursuant to the Advisory Council's regulations, 36 CFR part 800, implementing section 106 of the National Historic Preservation Act, as amended, (54 U.S.C. 306108), to prepare

Programmatic Agreements for managing properties included in, or eligible for inclusion in, the National Register of Historic Places that could be affected by issuance of an original license for each of the following projects: (1) Beverly Lock & Dam Water Power Project No. 13404; (2) Devola Lock & Dam Water Power Project No. 13405; (3) Malta Lock & Dam Water Power Project No. 13406; (4) Lowell Lock & Dam Water Power Project No. 13407; (5) Philo Lock & Dam Water Power Project No. 13408; (6) and Rokeby Lock & Dam Water Power Project No. 13411.

The Programmatic Agreements, when executed by the Commission and the Ohio SHPO, would satisfy the Commission's section 106 responsibilities for all individual undertakings carried out in accordance with the licenses until the licenses expire or are terminated (36 CFR 800.13[e]). The Commission's responsibilities pursuant to section 106 for the projects would be fulfilled through the Programmatic Agreements, which the Commission staff proposes to draft in consultation with certain parties listed below. The executed Programmatic Agreements would be incorporated into any Order issuing a license for each project.

Clean River Power MR-3, LLC, Clean River Power MR-1, LLC, Clean River Power MR-5, LLC, Clean River Power MR-2, LLC, Clean River Power MR-7, LLC, and Clean River Power MR-6, LLC as applicants for the Beverly Lock and Dam Water Power Project, Devola Lock and Dam Water Power Project, Malta/McConnelsville Lock and Dam Water Power Project, Lowell Lock and Dam Water Power Project, Philo Lock and Dam Water Power Project, and Rokeby Lock and Dam Water Power Project, respectively, the Peoria Tribe Indians of Oklahoma, the Miami Tribe of Oklahoma, and the Hannahville Indian Community have expressed an interest in these proceedings and are invited to participate in consultations to develop the Programmatic Agreements. For purposes of commenting on the Programmatic Agreements, we propose to restrict the service list for Projects Nos. 13404, 13405, 12406, 13407, 13408, and 13411 as follows:

John Eddins or Representative, Advisory Council on Historic Preservation, 401 F Street NW., Suite 803, Washington, DC 2001-2637.

David Snyder or Representative, Ohio State Historic Preservation Office, Ohio History Connection, 800 E 17th Ave., Columbus, OH 43211.

Ramya Swaminathan or Representative, Clean River Power MR-3, LLC et al.,

<sup>1</sup> 18 CFR 385.2010.

745 Atlantic Avenue, 8th Floor,  
Boston, MA 02111.

Dave Anthony or Representative,  
Business & Government Affairs,  
Manager, Hannahville Indian  
Community, N14911 Hannahville B1  
Road, Wilson, MI 49896.

Logan Pappenfort, Section 106  
Representative, Peoria Tribe of  
Indians of Oklahoma, 118 S. Eight  
Tribes Trail, P.O. Box 1527, Miami,  
OK 74355.

George J. Strack, THPO, Miami Tribe of  
Oklahoma, P.O. Box 1326, Miami, OK  
74355.

Any person on the official service list for the above-captioned proceeding may request inclusion on the restricted service list, or may request that a restricted service list not be established, by filing a motion to that effect within 15 days of this notice date. In a request for inclusion, please identify the reason(s) why there is an interest to be included. Also please identify any concerns about historic properties, including Traditional Cultural Properties. If historic properties are to be identified within the motion, please use a separate page, and label it NON-PUBLIC Information.

The Commission strongly encourages electronic filing. Please file motions using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P-1256-031.

If no such motions are filed, the restricted service list will be effective at the end of the 15 day period. Otherwise, a further notice will be issued ruling on any motion or motions within the 15-day period.

Dated: September 10, 2015.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2015-23321 Filed X-XX; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 1267-108]

#### Greenwood County, South Carolina; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Type of Application*: Request for a Temporary Variance from Reservoir Level Requirements—Article 407.
- b. *Project No.*: 1267-108.
- c. *Date Filed*: August 14, 2015.
- d. *Applicant*: Greenwood County, South Carolina (licensee).
- e. *Name of Project*: Buzzards Roost Hydroelectric Project.
- f. *Location*: Greenwood, Laurens, and Newberry counties, South Carolina.
- g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)-825(r).
- h. *Applicant Contact*: Toby Chappell, County Manager, (864) 942-8596, or [tchappell@greenwoodsc.gov](mailto:tchappell@greenwoodsc.gov).
- i. *FERC Contact*: Joy Kurtz, (202) 502-6760, or [joy.kurtz@ferc.gov](mailto:joy.kurtz@ferc.gov).
- j. *Deadline for filing comments, motions to intervene, protests, and recommendations* is 30 days from the issuance date of this notice by the Commission.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at <http://www.ferc.gov/docs-filing/efiling.asp>. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments.

Please include the project number (P-1267-108) on any comments, motions, or recommendations filed.

k. *Description of Request*: The licensee requests a temporary variance from the requirements of license Article 407, which requires the licensee to maintain water levels in Lake Greenwood (*i.e.* reservoir) in accordance with the 1994 rule curve. Specifically, Article 407, as amended in 2010, requires the licensee to maintain a

reservoir elevation of 439 feet mean sea level (msl) between April 15 and November 1, and then gradually descend to 437 feet msl from November 1 to December 1, and then to 434.5 feet msl between December 1 and January 15, where it shall remain until January 31. Finally, between February 1 and April 15, the licensee must gradually increase the reservoir level from 434.5 to 439 feet msl. The licensee indicates that, as a result of ongoing drought conditions throughout the watershed, it cannot simultaneously maintain the reservoir level and release the minimum flows required by Article 408. Because priority must be given to provide the required minimum flow in order to protect aquatic resources downstream of the project, a temporary variance from Article 407 is needed until inflows into Lake Greenwood reach normal inflow rates, or until April 15, 2016, whichever occurs first.

l. *Locations of the Application*: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502-8371. This filing may also be viewed on the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), for TTY, call (202) 502-8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

*o. Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to impoundment levels at the Buzzards Roost Hydroelectric Project, which is the subject of the variance. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: September 10, 2015.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2015-23319 Filed 9-16-15; 8:45 am]

**BILLING CODE 6717-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-xxxx, 3060-0214, 3060-0113, 3060-0922, 3060-1065]

### Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications

Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before October 19, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, OMB, via email [Nicholas.A.Fraser@omb.eop.gov](mailto:Nicholas.A.Fraser@omb.eop.gov); and to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov). Include in the comments the OMB control number as shown in the "Supplementary Information" section below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Cathy Williams at (202) 418-2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <<http://www.reginfo.gov/public/do/PRAMain>>, (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently

under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

#### SUPPLEMENTARY INFORMATION:

*OMB Control Number:* 3060-xxxx.

*Title:* SDARS Political Broadcasting Requirements.

*Form Number:* N/A.

*Type of Review:* New collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents and Responses:* 1 respondent; 1 response.

*Estimated Time per Response:* 10 hours.

*Frequency of Response:* Recordkeeping requirement; on occasion reporting requirements; third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in 47 U.S.C. 309(a) and 307(a) of the Communications Act of 1934, as amended.

*Total Annual Burden:* 20 hours.

*Total Annual Cost:* No cost.

*Nature and Extent of Confidentiality:* Although the Commission does not believe that any confidential information will need to be disclosed in order to comply with the information collection requirements, applicants are free to request that materials or information submitted to the Commission be withheld from public inspection. (See 47 CFR 0.459 of the Commission's Rules.)

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* In 1997, the Commission imposed political broadcasting requirements on Satellite Digital Audio Broadcasting Service ("SDARS") licensees. See Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310-2360 MHz Frequency Band, 12 FCC Rcd 5754, 5792, para. 92 (1997) ("1997 SDARS Order"), FCC 97-70. The Commission stated that SDARS licensees should comply with the same substantive political debate provisions as broadcasters: The federal candidate access provision (47 U.S.C. Section 312(a)(7)) and the equal opportunities provision (47 U.S.C. Section 315). The 1997 SDARS Order imposes the following requirements on SDARS licensees:

Lowest unit charge: Similar to broadcasters, SDARS licensees must disclose any practices offered to commercial advertisers that enhance the value of advertising spots and different

classes of time. SDARS licensees must also calculate the lowest unit charge and are required to review their advertising records throughout the election period to determine whether compliance with this rule section requires that candidates receive rebates or credits. See 47 CFR 73.1942.

**Political file:** Similar to broadcasters, SDARS licensees must also keep and permit public inspection of a complete record (political file) of all requests for SDARS origination time made by or on behalf of candidates for public office, together with an appropriate notation showing the disposition made by the system of such requests, and the charges made, if any, if the request is granted. The disposition includes the schedule of time purchased, when the spots actually aired, the rates charged, and the classes of time purchased. Also, when free time is provided for use by or on behalf of candidates, a record of the free time provided is to be placed in the political file as soon as possible and maintained for a period of two years. See 47 CFR 73.1943.

**OMB Control Number:** 3060–0214.

**Title:** Sections 73.3526 and 73.3527, Local Public Inspection Files; Sections 76.1701 and 73.1943, Political Files.

**Form Number:** N/A.

**Type of Review:** Revision of a currently approved collection.

**Respondents:** Business or other for-profit entities; not for profit institutions; individuals or households.

**Number of Respondents and Responses:** 24,559 respondents; 63,235 responses.

**Estimated Time per Response:** 1–104 hours.

**Frequency of Response:** Recordkeeping requirement; on occasion reporting requirements; third party disclosure requirement.

**Obligation to Respond:** Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in Sections 151, 152, 154(i), 303, 307 and 308 of the Communications Act of 1934, as amended.

**Total Annual Burden:** 2,375,337 hours.

**Total Annual Cost:** \$882,631.

**Nature and Extent of Confidentiality:** Most of the documents comprising the public file consist of materials that are not of a confidential nature.

Respondents complying with the information collection requirements may request that the information they submit be withheld from disclosure. If confidentiality is requested, such requests will be processed in accordance with the Commission's rules, 47 CFR 0.459.

**Privacy Impact Assessment:** Should respondents submit any PII as part of the information collection requirements, the FCC has an existing system of records, FCC/MB–1, "Ownership of Commercial Broadcast Stations," that may partially cover this PII. In addition, the Commission has prepared a second system of records notice, FCC/MB–2, "Broadcast Station Public Inspection Files," that will cover the PII contained in the broadcast station public inspection files to be located on the Commission's Web site. The Commission is also drafting a PIA for the records covered by this SORN.

**Needs and Uses:** Satellite Radio (also referred to as "Satellite Digital Audio Radio Services" or "SDARS") licensees are required to comply with the Commission's EEO broadcast rules and policies, including public file obligations and periodic submissions to the Commission. See Applications for Consent to the Transfer of Control of Licenses, XM Satellite Radio Holdings Inc., Transferor, to Sirius Satellite Radio Inc., Transferee, 23 FCC Rcd 12348, 12426,) 174, and note 551 (2008) ("XM-Sirius Merger Order"). See also Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310–2360 MHz Frequency Band, 12 FCC Rcd 5754, 5791–92,) 91–92 (1997) ("SDARS Order"), FCC 97–70. This collection is being revised to reflect the burden associated with the EEO public file requirements.

**OMB Control Number:** 3060–0113.

**Title:** Broadcast EEO Program Report, FCC Form 396.

**Form Number:** FCC Form 396.

**Type of Review:** Revision of a currently approved collection.

**Respondents:** Business or other for-profit entities; not for profit institutions.

**Number of Respondents and Responses:** 2,001 respondents; 2,001 responses.

**Estimated Time per Response:** 1.5 hours.

**Frequency of Response:** On renewal reporting requirement.

**Obligation to Respond:** Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in Section 154(i) and 303 of the Communications Act of 1934, as amended.

**Total Annual Burden:** 3,002 hours.

**Total Annual Cost:** \$300,300.

**Nature and Extent of Confidentiality:** There is no need for confidentiality with this collection of information.

**Privacy Impact Assessment:** No impact(s).

**Needs and Uses:** The Broadcast Equal Employment Opportunity (EEO)

Program Report, FCC Form 396, is a device that is used to evaluate a broadcaster's EEO program to ensure that satisfactory efforts are being made to comply with FCC's EEO requirements. FCC Form 396 is required to be filed at the time of renewal of license by all AM, FM, TV, Low Power TV and International stations. Licensees in the Satellite Digital Audio Radio Service ("SDARS") also must file FCC Form 396.

The recordkeeping requirements for FCC Form 396 are covered under OMB control number 3060–0214.

**Revised Collection Requirement:** In 1997, the Commission determined that SDARS licensees must comply with the Commission's EEO requirements. See Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310–2360 MHz Frequency Band, 12 FCC Rcd 5754, 5791,) 91 (1997) ("1997 SDARS Order"), FCC 97–70. In 2008, the Commission clarified that SDARS licensees must comply with the Commission's EEO broadcast rules and policies, including the same recruitment, outreach, public file, Web site posting, record-keeping, reporting, and self-assessment obligations required of broadcast licensees, consistent with 47 CFR 73.2080, as well as any other Commission EEO policies. See Applications for Consent to the Transfer of Control of Licenses, SM Satellite Radio Holdings Inc., Transferor, to Sirius Satellite Radio Inc., Transferee, 23 FCC Rcd 12348, 12426,) 174, and note 551 (2008) ("XM-Sirius Merger Order").

The Commission is making this submission to the Office of Management and Budget for approval to add SDARS licensees to this information collection.

**OMB Control Number:** 3060–0922.

**Title:** Broadcast Mid-Term Report, FCC Form 397.

**Form Number:** FCC Form 397.

**Type of Review:** Revision of a currently approved collection.

**Respondents:** Business or other for-profit entities; not-profit institutions.

**Number of Respondents and Responses:** 1,181 respondents; 1,181 responses.

**Estimated Time per Response:** 0.5 hours.

**Frequency of Response:** Mid-point reporting requirement.

**Obligation to Respond:** Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in Sections 154(i) and 303 of the Communications Act, as amended.

**Total Annual Burden:** 591 hours.

**Total Annual Cost:** No cost.

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* The Broadcast Mid-Term Report (FCC Form 397) is required to be filed by each broadcast television station that is part of an employment unit with five or more full-time employees and each broadcast radio station that is part of an employment unit with more than ten full-time employees. It is a data collection device used to assess broadcast compliance with EEO outreach requirements in the middle of license terms that are eight years in duration. FCC Form 397 must also be filed by Satellite Digital Audio Radio Services (SDARS) licensees to assess compliance with EEO outreach requirements.

Revised Information Collection Requirements Which Require Approval and Review by the Office of Management and Budget (OMB): Satellite Radio (also referred to as "Satellite Digital Audio Radio Services" or "SDARS") licensees are required to comply with the Commission's EEO broadcast rules and policies. They must engage in the same recruitment, outreach, public file, Web site posting, record-keeping, reporting, and self-assessment obligations required of broadcast licensees, consistent with 47 CFR 73.2080, and are subject to the same EEO policies. See Applications for Consent to the Transfer of Control of Licenses, XM Satellite Radio Holdings Inc., Transferor, to Sirius Satellite Radio Inc., Transferee, 23 FCC Rcd 12348, 12426, 174, and note 551 (2008) ("XM-Sirius Merger Order").

See also Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310–2360 MHz Frequency Band, 12 FCC Rcd 5754, 5791–92, 91–92 (1997) ("SDARS Order"), FCC 97–70. This collection is being revised to reflect the burden associated with filing FCC Form 397 by SDARS licensees. Therefore, these respondents are being added as respondents to this collection. The form is not being revised.

*OMB Control Number:* 3060–1065.

*Title:* Section 25.701 of the Commission's Rules, Direct Broadcast Satellite Public Interest Obligations.

*Form Number:* N/A.

*Type of Review:* Reinstatement of a previously approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents and*

*Responses:* 2 respondents; 2 responses.

*Estimated Time per Response:* 1–10 hours.

*Frequency of Response:* Recordkeeping requirement; on occasion reporting requirement; one time reporting requirement; annual reporting requirement; Third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in Section 335 of the Communications Act of 1934, as amended.

*Total Annual Burden:* 50 hours.

*Total Annual Cost:* No cost.

*Nature and Extent of Confidentiality:* Although the Commission does not believe that any confidential information will need to be disclosed in order to comply with the information collection requirements, applicants are free to request that materials or information submitted to the Commission be withheld from public inspection. (See 47 CFR 0.459 of the Commission's Rules).

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* The Commission vacated an Order on Reconsideration, In the Matter of Implementation Of Section 25 Of The Cable Television Consumer Protection And Competition Act Of 1992, Direct Broadcast Satellite Public Interest Obligations, MM No. Docket 93–25 FCC 03–78, adopted April 9, 2003 and adopted in its place, in the same proceeding, a Second Order on Reconsideration of the First Report and Order, Sua Sponte Order on Reconsideration ("Second Order") and accompanying rules FCC 04–44, released March 25, 2004. The Second Order differs from the Order on Reconsideration with respect to two issues: (1) The political broadcasting requirements, and (2) the guidelines concerning commercialization of children's programming.

47 CFR 25.701(c)(1)(i)(C) states DBS providers may establish and define their own reasonable classes of immediately preemptible time so long as the differences between such classes are based on one or more demonstrable benefits associated with each class and are not based solely upon price or identity of the advertiser. Such demonstrable benefits include, but are not limited to, varying levels of preemption protection, scheduling flexibility, or associated privileges, such as guaranteed time sensitive make goods. DBS providers may not use class distinctions to defeat the purpose of the lowest unit charge requirement. All classes must be fully disclosed and made available to candidates.

47 CFR 25.701(c)(1)(i)(D) states DBS providers may establish reasonable

classes of preemptible with notice time so long as they clearly define all such classes, fully disclose them and make them available to candidates.

47 CFR 25.701(c)(1)(i)(E) states DBS providers may treat non preemptible and fixed position as distinct classes of time provided that they articulate clearly the differences between such classes, fully disclose them, and make them available to candidates.

47 CFR 25.701(c)(1)(i)(I) states DBS providers shall review their advertising records periodically throughout the election period to determine whether compliance with this section requires that candidates receive rebates or credits. Where necessary, DBS providers shall issue such rebates or credits promptly.

47 CFR 25.701(c)(1)(i)(M) states DBS providers must disclose and make available to candidates any make good policies provided to commercial advertisers. If a DBS provider places a make good for any commercial advertiser or other candidate in a more valuable program or daypart, the value of such make good must be included in the calculation of the lowest unit charge for that program or daypart.

47 CFR 25.701(c)(1)(ii) states at any time other than the respective periods set forth in paragraph (c)(1)(i) of this section, DBS providers may charge legally qualified candidates for public office no more than the charges made for comparable use of the facility by commercial advertisers. The rates, if any, charged all such candidates for the same office shall be uniform and shall not be rebated by any means, direct or indirect. A candidate shall be charged no more than the rate the DBS provider would charge for comparable commercial advertising. All discount privileges otherwise offered by a DBS provider to commercial advertisers must be disclosed and made available upon equal terms to all candidates for public office.

47 CFR 25.701(d) states each DBS provider shall keep and permit public inspection of a complete and orderly political file and shall prominently disclose the physical location of the file, and the telephonic and electronic means to access the file.

(1) The political file shall contain, at a minimum:

(i) A record of all requests for DBS origination time, the disposition of those requests, and the charges made, if any, if the request is granted. The "disposition" includes the schedule of time purchased, when spots actually aired, the rates charged, and the classes of time purchased; and

(ii) A record of the free time provided if free time is provided for use by or on behalf of candidates.

(2) DBS providers shall place all records required by this section in a file available to the public as soon as possible and shall be retained for a period of four years until December 31, 2006, and thereafter for a period of two years.

47 CFR 25.701(e)(3) requires DBS providers airing children's programming must maintain records sufficient to verify compliance with this rule and make such records available to the public. Such records must be maintained for a period sufficient to cover the limitations period specified in 47 U.S.C. 503(b)(6)(B).

47 CFR 25.701(f)(6) states that each DBS provider shall keep and permit public inspection of a complete and orderly record of:

(A) Quarterly measurements of channel capacity and yearly average calculations on which it bases its four percent reservation, as well as its response to any capacity changes;

(B) A record of entities to whom noncommercial capacity is being provided, the amount of capacity being provided to each entity, the conditions under which it is being provided and the rates, if any, being paid by the entity;

(C) A record of entities that have requested capacity, disposition of those requests and reasons for the disposition.

(ii) All records required by this paragraph shall be placed in a file available to the public as soon as possible and shall be retained for a period of two years.

The statutory authority which covers this information collection is contained in 47 U.S.C. 335 of the Communications Act of 1934, as amended.

#### Revised Information Collection Requirements:

The Commission is reinstating this collection into the Office of Management and Budget's (OMB's) inventory because after further evaluation the Commission has determined that this collection is still needed by the Commission because DBS providers make up the majority of their universe of respondents. Since this is the case, OMB approval is still need for this collection.

Federal Communications Commission.

#### Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015-23309 Filed 9-16-15; 8:45 am]

BILLING CODE 6712-01-P

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0999]

### Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before October 19, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, OMB, via email [Nicholas.A.Fraser@omb.eop.gov](mailto:Nicholas.A.Fraser@omb.eop.gov); and to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov). Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Cathy Williams at (202) 418-2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

#### SUPPLEMENTARY INFORMATION:

*OMB Control No.:* 3060-0999.

*Title:* Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

*Form Number:* FCC Form 655.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents:* 925 respondents; 925 responses.

*Estimated Time per Response:* 13.041081 hours per response (average).

*Frequency of Response:* On occasion and annual reporting requirements and third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151, 154(i), 157, 160, 201, 202, 208, 214, 301, 303, 308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

*Total Annual Burden:* 12,063 hours.

*OMB Control No.:* 3060-0999.

*Title:* Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

*Form Number:* FCC Form 655.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents:* 925 respondents; 925 responses.

*Estimated Time per Response:* 13.041081 hours per response (average).

*Frequency of Response:* On occasion and annual reporting requirements and third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151, 154(i), 157, 160, 201, 202, 208, 214, 301, 303, 308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

*Total Annual Burden:* 12,063 hours.

*Total Annual Cost:* No costs.

*Privacy Impact Assessment:* No impact(s).

*Total Cost:* No costs.

*Privacy Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* Information requested in the reports may include confidential information. However, covered entities are allowed to request that such materials submitted to the Commission be withheld from public inspection.

*Needs and Uses:* The Commission will submit this information collection as an extension to the Office of Management and Budget (OMB) after this 60-day comment period to obtain the full three year clearance for the collection. There is no change in number of respondents/responses, total annual burden hours, or total annual cost from the previously approved estimates. As part of the extension request, the Commission will submit certain non-substantive changes for approval, as described below.

The collection is necessary to implement certain disclosure requirements that are part of the Commission's wireless hearing aid compatibility rule. In a Report and Order in WT Docket No. 01-309, FCC 03-168, adopted and released in September 2003, implementing a mandate under the Hearing Aid Compatibility Act of 1988, the Commission required digital wireless phone manufacturers and service providers to make certain digital wireless phones capable of effective use with hearing aids, label certain phones they sold with information about their compatibility with hearing aids, and report to the Commission (at first every six months, then on an annual basis) on the numbers and types of hearing aid-compatible phones they were producing or offering to the public. These reporting requirements were subsequently amended on several occasions, and the existing, OMB-approved collection under this OMB control number includes these modifications.

As part of this extension request, the Commission is requesting approval of certain non-substantive changes to the

form and instructions. Changes to the form include updating the edition form date for the electronic form to reflect the current date, and adding certain additional language drawn from the instructions to the question on device disclosures through Public Web sites. In the instructions, the Commission is updating the edition form date to reflect the current date, updating a Web site link that has become inactive, adding certain informational text to make the instructions easier to understand, and updating figures as necessary to reflect the non-substantive changes in the form.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2015-23308 Filed 9-16-15; 8:45 am]

BILLING CODE 6712-01-P

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## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice to All Interested Parties of the Termination of the Receivership of 10303, Progress Bank of Florida, Tampa, Florida

*Notice is hereby given* that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Progress Bank of Florida, Tampa, Florida ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of Progress Bank of Florida on October 22, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: September 14, 2015.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2015-23349 Filed 9-16-15; 8:45 am]

BILLING CODE 6714-01-P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1640-FN]

#### Medicare Program; Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve the request from Doctors Hospital at Renaissance for an exception to the prohibition against expansion of facility capacity.

**DATES:** *Effective Date:* This notice is effective on September 11, 2015.

**FOR FURTHER INFORMATION CONTACT:** Patricia Taft, (410) 786-4561 or Teresa Walden, (410) 786-3755.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law—(1) prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

Section 1877(d)(2) of the Act provides an exception, known as the rural provider exception, for physician ownership or investment interests in rural providers. In order for an entity to qualify for the rural provider exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) and substantially all the DHS furnished by the entity must be furnished to individuals residing in a rural area.

Section 1877(d)(3) of the Act provides an exception, known as the hospital

ownership exception, for physician ownership or investment interests held in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to together as “the Affordable Care Act”) amended the hospital ownership and rural provider exceptions to the physician self-referral prohibition to impose additional restrictions on physician ownership and investment in hospitals. Since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding facility capacity unless it qualifies as an “applicable hospital” or “high Medicaid facility” (as defined in sections 1877(i)(3)(E), (F) of the Act and 42 CFR 411.362(c)(2), (3) of our regulations) and has been granted an exception to the facility expansion prohibition by the Secretary of the Department of Health and Human Services (the Secretary). Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with respect to the provider’s request for an exception. Section 1877(i)(3)(H) of the Act states that the Secretary shall publish in the **Federal Register** the final decision with respect to a request for an exception to the prohibition against facility expansion not later than 60 days after receiving a complete application.

## II. Exception Approval Process

On November 30, 2011, we published a final rule in the **Federal Register** (76 FR 74122, 74517 through 74525) that, among other things, finalized § 411.362(c), which specifies the process for submitting, commenting on, and reviewing a request for an exception to the prohibition on expansion of facility capacity. We published a subsequent final rule in the **Federal Register** on November 10, 2014 (79 FR 66770, 66987 through 66997) that made certain revisions. These revisions include, among other things, permitting the use of data from an external data source, as defined in our regulations, or from the Hospital Cost Report Information System (HCRIS) for specific eligibility criteria.

As stated in our regulations at § 411.362(c)(5), we solicit community

input on a request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities have 30 days to submit written comments on the request, which may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an “applicable hospital” or “high Medicaid facility,” as defined in § 411.362(c)(2) and (c)(3), respectively. We notify the hospital of comments received, and the hospital has 30 days after such notice to submit a rebuttal statement (§ 411.362(c)(5)(ii)). Section 411.362(c)(5) also specifies the timing for when CMS deems a request for an exception to the facility expansion prohibition complete.

If we grant the request for an exception, the expansion may occur only in facilities on the hospital’s main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to exceed 200 percent of the hospital’s baseline number of operating rooms, procedure rooms, and beds (§ 411.362(c)(6)).

## III. Public Response to Notice With Comment Period

On May 8, 2015, we published a notice in the **Federal Register** (80 FR 26566) entitled, “Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition.” In the May 8, 2015 notice, we stated that as permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital requested an exception to the prohibition on expansion of facility capacity:

*Name of Facility:* Doctors Hospital at Renaissance (DHR).

*Location:* 5501 South McColl Road, Edinburg, Texas 78539.

*Basis for Exception Request:* Applicable Hospital.

In the May 8, 2015 notice, we also solicited comments from individuals and entities in the community in which DHR is located.

We received 21 comments, 14 of which were variations of a form letter, and commenters generally opposed DHR’s request to expand.

One or more of the commenters raised questions or concerns regarding:

- Whether DHR’s request conforms to the procedural requirements set forth at § 411.362(c);
- Whether DHR demonstrated that it satisfied the population growth criterion using the data required under § 411.362(c)(2)(i);

- Whether the data source used by DHR to demonstrate satisfaction of the inpatient Medicaid admissions criterion at § 411.362(c)(2)(ii) was permissible;

- Whether DHR satisfied the non-discrimination criterion at § 411.362(c)(2)(iii);

- How a facility expansion by DHR would affect the community in which it is located; and

- The amount of increased facility capacity requested by DHR.

On June 16, 2015, as required by § 411.362(c)(5)(ii), we notified DHR that we received comments in response to the May 8, 2015 notice and that these comments were available for public viewing at <http://www.regulations.gov>. DHR submitted a rebuttal statement on July 15, 2015. The statement rebutted each of the commenters’ assertions regarding the applicable hospital eligibility criteria and addressed the concerns expressed by the commenters regarding an expansion by the hospital.

## IV. Decision

This final notice announces our decision to approve DHR’s request for an exception to the prohibition against expansion of facility capacity. As required by our current regulations and public guidance documents, DHR submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as an applicable hospital. Further, CMS considered the assertions of the commenters about DHR’s compliance with the procedural requirements set forth at § 411.362(c), the population growth criterion under § 411.362(c)(2)(i), the data source used by DHR to demonstrate satisfaction of the inpatient Medicaid admissions criterion at § 411.362(c)(2)(ii), and the non-discrimination criterion at § 411.362(c)(2)(iii). Following our review of the information provided by the commenters, we are not persuaded that DHR failed to satisfy one or more of the applicable hospital eligibility criteria or that its request failed to conform to our procedural requirements. Also, CMS cannot consider any concerns unrelated to the statutory and regulatory eligibility criteria when determining whether to grant an exception to a requesting hospital. In addition, if a hospital qualifies as either an applicable hospital or high Medicaid facility, CMS does not have the discretion to grant less than the requested increase in facility capacity.

In accordance with section 1877(i)(3) of the Act, we are granting DHR’s request for an exception to the prohibition against expansion of facility capacity based on the following criteria:



- DHR is located in Hidalgo County, which has a percentage increase in population that is at least 150 percent of the percentage increase in Texas' population during the most recent 5-year period for which data was available as of the date that DHR submitted its request;

- DHR has an annual percentage of total inpatient admissions under Medicaid that is equal to or greater than the average percentage with respect to such admissions for all hospitals located in Hidalgo County during the most recent 12-month period for which data are available as of the date that DHR submitted its request;

- DHR certified and provided satisfactory documentation that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

- DHR is located in Texas, which has an average bed capacity that is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submitted its request, contained data from a sufficient number of hospitals to determine Texas' average bed capacity and the national average bed capacity; and

- DHR has an average bed occupancy rate that is greater than the average bed occupancy rate in Texas during the most recent fiscal year for which HCRIS, as of the date that DHR submitted its request, contained data from a sufficient number of hospitals to determine its average bed occupancy rate and Texas' average bed occupancy rate.

In determining that DHR satisfied the Medicaid inpatient admissions, bed capacity and bed occupancy criteria, we deemed the HCRIS and Texas State Medicaid Agency data used by DHR to satisfy the standards set forth in the regulations published on November 10, 2014, for those criteria.

Our approval grants DHR's request to add a total of 551 operating rooms, procedure rooms, and beds for which DHR is licensed. Pursuant to § 411.362(c)(6), the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds. DHR certified that its baseline number of operating rooms, procedure rooms, and beds for which it was licensed as of March 23, 2010, was 551. Accordingly, we find that granting the additional 551 operating rooms, procedure rooms, and beds will not exceed the limitation on a permitted expansion.

**IV. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: September 4, 2015.

**Andrew M. Slavitt,**  
*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2015-23363 Filed 9-16-15; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Goal-Oriented Adult Learning in Self-Sufficiency Study

*OMB No.:* New Collection

*Description:* The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Goal-Oriented Adult Learning in Self-Sufficiency (GOALS) study. The purpose of the GOALS project is to address the nexus between the growing knowledge base in the psychological sciences and long-standing approaches to self-sufficiency programs targeted to adults and young adults. The project will explore the programmatic implications of existing research on psychological processes associated with goal-directed behaviors, including socio-emotional regulation and cognitive skills, executive functioning, and related areas. The project will synthesize current research on these topics; address how insights gained from research can be used to promote economic advancement among low-income populations, identify promising strategies, or strengthen underlying skills in these areas; and inform measurement of changes and developments in skill acquisition.

The proposed information collection activity consists of exploratory calls with program directors and administrators, semi-structured interviews with key program staff and community partner organization staff, and focus group discussions with program participants. ACF seeks to gain an in-depth, systematic understanding of program administration and implementation, service delivery and operation, outputs and outcomes, and identify promising practices and other areas for further study.

*Respondents:* Key program directors and administrators, program staff and community partner organization staff, and program participants at selected program sites.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Exploratory telephone call semi-structured interview—program directors and administrators .....	24	12	1	1	12
Site visit semi-structured interview—program staff and community partner organization staff .....	180	90	1	1.25	113
Site visit group discussion—program participants .....	84	42	1	1.25	53

*Estimated Total Annual Burden Hours:* 178.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for

Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should

be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the

collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*ACF Reports Clearance Officer.*

[FR Doc. 2015-23353 Filed 9-16-15; 8:45 am]

BILLING CODE 4184-07-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-3287]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Small Business Qualification and Certification

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3602 and Form FDA 3602A, which will allow domestic and foreign applicants to certify that they qualify as a small business and pay certain medical device user fees at reduced rates.

**DATES:** Submit either electronic or written comments on the collection of information by November 16, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All

comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Medical Device User Fee Small Business Qualification and Certification—OMB Control Number 0910-0508—Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107-250) amends the Federal Food, Drug, and Cosmetic Act, to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2015 (80 FR 46033), announcing fees for fiscal year (FY) 2016. To avoid harming small

businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a small business. This means there are two levels of fees; a standard fee and a reduced or waived small business fee. You can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than \$100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours, and the total must be no more than \$100 million. If your gross receipts or sales are no more than \$30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the small business criteria (Form FDA 3602, "FY 2016 MDUFMA Small Business Qualification Certification—For a Business Headquartered in the United States"). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a small business within the meaning of MDUFMA.

The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid (Form FDA 3602A, "FY 2016 MDUFMA Foreign Small Business Qualification Certification—For a Business Headquartered Outside the United States"). Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, \$100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected. In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a

certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a “National Taxing Authority Certification”, must: Be in English; be from the national taxing authority of the country in which the business is headquartered; provide the business’ gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; provide the dates during which the reported receipts or sales were collected; and bear the

official seal of the national taxing authority.

Both Forms FDA 3602 and FDA 3602A are available in the guidance document, “FY 2016 Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff, and Foreign Governments” available on the Internet at: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.pdf>. This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help

prospective applicants understand what they need to do to meet the small business criteria for FY 2016.

The estimated burden is based on the number of applications received in the last 3 years and includes time required to collect the required information. Based on our experience with Form FDA 3602, FDA believes it will take each respondent 1 hour to complete the form. Based on our experience with Form FDA 3602A, FDA also believes that it will take each respondent 1 hour to complete.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA form no.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—FY 2016 MDUFA Small Business Qualification and Certification For a Business Headquartered in the United States .....	3,600	1	3,600	1	3,600
FDA 3602A—FY 2016 MDUFA Foreign Small Business Qualification and Certification For a Business Headquartered Outside the United States .....	1,400	1	1,400	1	1,400
Total .....					5,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 11, 2015.  
**Leslie Kux**,  
*Associate Commissioner for Policy.*  
 [FR Doc. 2015–23331 Filed 9–16–15; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2012–D–0429]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for

public comment in response to the notice. This notice solicits comments on FDA’s meetings with tobacco manufacturers, importers, researchers, and/or investigators relating to their plans to conduct research to inform the regulation of tobacco products, or support the development or marketing of tobacco products.

**DATES:** Submit either electronic or written comments on the collection of information by November 16, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques, when appropriate, and other forms of information technology.

### Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

(OMB Control Number 0910-0731)—  
*Extension*

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market particular products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate. This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in a meeting request,
- How and when to submit a request, and
- What information FDA recommends persons submit prior to a meeting.

This guidance describes two collections of information: (1) The submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance as a level 2 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115).

*Meeting Requests:* Section IV.E of the guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the

following information be included in the meeting request:

1. Product name and FDA-assigned Submission Tracking Number (if applicable);
2. Product category (e.g., cigarettes, smokeless tobacco) (if applicable);
3. Product use (indicate for consumer use or for further manufacturing);
4. Contact information for the authorized point of contact for the company requesting the meeting;
5. The topic of the meeting being requested;
6. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
7. A draft list of the specific objectives/outcomes expected from the meeting;
8. A preliminary proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s);
9. A draft list of specific questions, grouped by discipline (e.g., chemistry, clinical, nonclinical);
10. A list of all individuals (including titles and responsibilities) who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator;
11. The approximate date on which supporting documentation (i.e., the meeting information package) will likely be received by FDA; and
12. Suggested dates and times for the meeting (note that generally a meeting will be scheduled for 1 hour).

This information will be used by the Agency to: (1) Determine the utility of the meeting, (2) identify Agency staff necessary to discuss proposed agenda items, and (3) schedule the meeting.

*Meeting Information Packages:* An individual submitting a meeting information package to FDA in advance of a meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the individual or FDA to be discussed at the meeting. As stated in section IV.K of the guidance, FDA recommends that meeting information packages generally include

updated information from the meeting request (see items 1 through 8 in section III.A of this document) and:

1. Product composition and design (as applicable);
2. Manufacturing and process control data summary (as applicable);
3. Nonclinical data summary (as applicable);
4. Clinical data summary (as applicable);
5. Behavioral and product use data summary (as applicable);
6. User and nonuser perception data summary (as applicable); and
7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):
  - a. Study objective(s),
  - b. Study hypotheses,
  - c. Study design,
  - d. Study population (inclusion/exclusion criteria, comparison group(s)),
  - e. Human subject protection information, including Institutional Review Board information,
  - f. Primary and secondary endpoints (definition and success criteria),
  - g. Sample size calculation,
  - h. Data collection procedures,
  - i. Duration of follow up and baseline and follow up assessments, and
  - j. Data analysis plan(s).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. For the information that was previously submitted in the meeting request, the information package should provide updated information that reflects the most current and accurate information available.

*Description of Respondents:* The respondents to this collection of information are manufacturers, importers, researchers, and investigators of tobacco products who seek to meet with FDA to discuss their plans regarding the development or marketing of a tobacco product.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers .....	67	1	67	10	670
Meeting Information Packages					
Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers .....	67	1	67	18	1,206
Total .....					1,876

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents for meeting requests in Table 1 of this document is based on the number of meeting requests to be received over the next 3 years.

In the next three years of this collection, FDA estimates that 67 pre-application meetings will be requested. The number is not expected to change, as the public is more experienced in submitting applications for substantial equivalence, requests for non-substantial equivalence, etc.

Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting requests in Table 1 of this document to be 67 (50 year 1 requests + 100 year 2 requests + 50 year 3 requests divided by 3). The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by this guidance to be submitted with a meeting request is estimated to be approximately 10 hours each, and the total burden hours are 670 hours (10 hours preparation/ mailing times 67 average respondents per year). Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA's estimate of the number of respondents for compiling meeting information packages in Table 1 of this document is based on 67 respondents each preparing copies of their information package and submitting them to FDA, for a total of 1,206 hours annually. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package as recommended by the guidance, is estimated to be approximately 18 hours per information package. Based on FDA's experience, the Agency expects

that it will take respondents 1,206 hours of time (67 respondents times 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is 1,876 hours (67 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).

Dated: September 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-23332 Filed 9-16-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0021]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe; Notification Procedure

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Notification Procedure for Substances Generally Recognized as Safe (GRAS).

**DATES:** Submit either electronic or written comments on the collection of information by November 16, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170.36 and 570.36**

(OMB Control Number 0910–0342)—  
Extension

Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for “food additives”;

section 201(s) of the FD&C Act (21 U.S.C. 321(s)) provides an exclusion to the definition of “food additive” and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. In the **Federal Register** of April 17, 1997 (62 FR 18938), we published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify us about a view of a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. Under an interim policy announced in the proposed rule, we invited manufacturers to submit notices of their independent determinations for review under the framework of the proposed rule during the period between issuance of the proposal and any final rule based on the proposal. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice.

To assist respondents in submissions to our Center for Food Safety and Applied Nutrition (CFSAN), we developed Form FDA 3667 entitled “Generally Recognized as Safe Notice.”

The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted. For submissions to our Center for Veterinary Medicine (CVM), respondents may continue to send GRAS notices in letter format to the Agency, as instructed in our **Federal Register** notice of June 4, 2010 (75 FR 31800).

Presently, we have committed to issuing a final rule regarding “Substances Generally Recognized as Safe” in 2016, as part of a settlement agreement with the Center for Food Safety, which filed a lawsuit in 2014 seeking to vacate our 1997 proposed rule.

*Description of Respondents:* The respondents to this collection of information are manufacturers of substances used in food and feed.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR part	FDA Form No. <sup>2</sup>	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.36 (CFSAN) .....	FDA 3667 <sup>3</sup> .....	40	1	40	150	6,000
570.36 (CVM) .....	N/A .....	20	1	20	150	3,000
Total .....	.....	.....	.....	.....	.....	9,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Only CFSAN uses Form FDA 3667.

<sup>3</sup> Form FDA 3667 may be submitted electronically via the ESG.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
170.36(c)(v) (CFSAN) .....	40	1	40	15	600
570.36(c)(v) (CVM) .....	20	1	20	15	300
Total .....	.....	.....	.....	.....	900

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: September 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-23334 Filed 9-16-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 19, 2015, from 8 a.m. to 1 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

*Contact Person:* Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, [ODAC@fda.hhs.gov](mailto:ODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* Information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) ABT-414, application submitted by AbbVie, Inc., and (2) Lenvatinib, application submitted by Eisai, Inc.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before November 4, 2015. Oral presentations from the public will be scheduled between approximately 9:05 a.m. to 9:35 a.m., and 11:30 a.m. to 12 noon. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 27, 2015. Time allotted for each presentation may be limited. If the number of registrants

requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 28, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Lauren D. Tesh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 14, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-23366 Filed 9-16-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Alliance for Innovation on Maternal and Child Health Cooperative Agreement

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of Single-Case Deviation from Competition Requirement for the Alliance for Innovation on Maternal and Child Health Cooperative Agreement at the Association of State and Territorial Health Officials, Grant Number UC4MC28036.

**SUMMARY:** HRSA announces the award of a program expansion supplement in the amount of \$100,000 for the Alliance for Innovation on Maternal and Child Health (AIM) cooperative agreement. The purpose of the AIM cooperative agreement, as stated in the funding

opportunity announcement (FOA), is to expand access to care for the maternal and child health (MCH) populations through the following program focus areas: (1) Ensuring continuity of coverage and care for pregnant women and children; (2) improving systems of care for children with special health care needs; and (3) promoting the use of Bright Futures Guidelines for all children. The program expansion supplement will provide funds to the Association of State and Territorial State Health Officials (ASTHO), the cooperative agreement awardee, during the budget period of September 30, 2015, through September 29, 2016, to provide targeted technical assistance to two States at risk for rapid transmission of HIV and Hepatitis C virus (HCV) through injection drug use, to build capacity and expand access to care, document and share best practices with other State Health Officials also seeking to prevent HIV and HCV infection through injection drug use.

**SUPPLEMENTARY INFORMATION:** Intended Recipient of the Award: The Association of State and Territorial Health Officials  
*Amount of the Non-Competitive Award:* \$100,000  
*CFDA Number:* 93.110  
*Current Project Period:* 9/30/2014–9/29/2017  
*Period of Supplemental Funding:* 9/30/2015–9/29/2016

**Authority:** Social Security Act, Title V, § 501(a)(2) (42 U.S.C. 701(a)(2)).

**Justification:** On April 24, 2015, the Governor of Indiana declared a public health disaster emergency in Scott County, Indiana, attributable to the HIV

epidemic in that county. On the same day, the Centers for Disease Control and Prevention issued a Health Alert Network Advisory to inform other public health departments and healthcare providers of the possibility of HIV outbreaks among persons who inject drugs and to provide guidance to assist in the identification and prevention of such outbreaks. As of August 28, 2015, the Indiana outbreak is now 181 (177 confirmed and 4 presumptive positive) adult and adolescent HIV infections, including a small number of pregnant women. Though there are HIV prevention best practices to inform States, additional innovative practices are needed to reach women of child-bearing age, adolescents, and young adults within high risk counties, which do not routinely access health care.

As stated in the FOA, the Alliance for Innovation on Maternal and Child Health (AIM) is a Maternal and Child Health Bureau (MCHB) collaborative program of awardee organizations for the purpose of expanding access to care for the maternal and child health (MCH) populations. Per the FOA, AIM Collaborative Engagement awardees are responsible for engaging key State agencies and offices (*i.e.*, Public Health and Medicaid) in AIM activities and raising awareness of best practices.

In 2014, following objective review of its application, HRSA awarded the Association of State and Territorial Health Officials (ASTHO) cooperative agreement funding as an AIM Collaborative Engagement program. If approved, this would be the first

program expansion supplement for this cooperative agreement.

ASTHO is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, the District of Columbia, and over 100,000 public health professionals these agencies employ. As part of its AIM cooperative agreement, ASTHO identifies and disseminates best practices to meet the needs of MCH populations. At the time of the FOA and application, expanding access to care among high risk populations to prevent HIV infection through injection drug use was not yet identified as a need of MCH populations. As such, the FOA and application did not address it.

To meet this emerging need, ASTHO submitted a prior approval request to expand the scope of its AIM cooperative agreement award to work with States at risk for rapid transmission of HIV and HCV through injection drug use. ASTHO, working with MCHB, would provide targeted technical assistance to two states to build capacity and expand access to care among high risk populations to prevent HIV and HCV infection through injection drug use. ASTHO would also document and share best practices and other technical assistance resources from the two targeted states to its network of State Health Officials.

**FOR FURTHER INFORMATION CONTACT:** Sylvia Sosa, MSc, Office of Policy and Planning, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W25D, Rockville, Maryland 20857; [ssosa@hrsa.gov](mailto:ssosa@hrsa.gov).

Grantee/organization name	Grant number	State	FY 2015 Authorized funding level	FY 2015 Estimated supplemental funding
The Association of State and Territorial Health Officials .....	UC4MC28036 .....	VA .....	\$350,000	\$100,000

Dated: September 11, 2015.

**James Macrae,**  
*Acting Administrator.*

[FR Doc. 2015-23357 Filed 9-16-15; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Centers of Excellence in Maternal and Child Health in Education, Science, and Practice Program**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of Single-Case Deviation from Competition Requirements for Program Expansion Supplement Request for Centers of Excellence in Maternal and Child Health in

Education, Science, and Practice program Award to the University of Washington, Grant Number T76MC00011.

**SUMMARY:** HRSA announces the award of a program expansion supplement in the amount of \$40,000 for the Centers of Excellence in Maternal and Child Health (MCH) in Education, Science, and Practice grant. The purpose of the Centers of Excellence in MCH program is for the training of graduate and post-graduate public health professionals in an interdisciplinary MCH setting. The purpose of this notice is to award supplemental funds to conduct a rigorous evaluation of the Pediatric



Obesity Collaborative Improvement and Innovation Network (CoIIN) to spread evidence-based practices, and to translate knowledge into practice by the University of Washington, the awardee who serves as the Centers of Excellence in MCH, during the budget period of June 1, 2015, through May 31, 2016.

**SUPPLEMENTARY INFORMATION:**

*Intended Recipient of the Award:* University of Washington  
*Amount of Each Non-Competitive Award:* \$40,000  
*Period of Supplemental Funding:* 6/1/2015–5/31/2016  
*CFDA Number:* 93.110

**Authority:** Social Security Act as amended, Title V, Section 501(a)(2) (42 U.S.C. 701(a)(2))

**Justification:** The purpose of the Centers of Excellence in MCH program is for the training of graduate and post-graduate public health professionals in an interdisciplinary MCH setting. The Centers of Excellence in MCH program supports HRSA’s Maternal and Child Health Bureau’s (MCHB) mission to provide national leadership and to work, in partnership with states, communities, public-private partners, and families to strengthen the MCH infrastructure and build the knowledge and human resources in order to assure continued improvement in the health,

safety, and well-being of the MCH population, which includes all U.S. women, infants, children, youth and their families, including fathers and children with special health care needs (CSHCN). It does so by training current and future workforce in applied research and state-of-the-art public health management, planning, and leadership principles to promote healthier children, families, and communities and in the identification and solution of current MCH problems while anticipating the challenges of the future. It assures a prominent focus on MCH content and competencies such as inter-professional practice, systems integration, and quality improvement within schools of public health.

In the summer of 2014, MCHB initiated a CoIIN on Pediatric Obesity in collaboration with the University of Washington and the Association of State Public Health Nutritionists (ASPHN). The work on this project (by the University of Washington) was funded through an administrative supplement in fiscal year (FY) 2014 to a previous grant, and the amount provided only allowed the grantee and its subcontractor to engage a limited number of steps in the CoIIN process.

This supplement will allow the University of Washington, in

collaboration with ASPHN, to complete the final phases of the evaluation component for the previously initiated Pediatric Obesity CoIIN. The goal of this CoIIN project is to apply quality improvement methodologies through a CoIIN framework to support state Title V agencies and others leverage for state MCH program capacity to reduce childhood obesity rates on a population level. Specifically, state teams are working to affect systems changes through the adoption of policies and practices in early care and education settings that support healthy weight behaviors and are using the CoIIN model to gather best practices, promote evidence-based strategies, and increase nutrition resources provided to young children and their families. A rigorous evaluation of this CoIIN is a critical and essential component in order to spread evidence-based practices—including qualitative and quantitative process and outcome measures—and translate knowledge into practice.

**FOR FURTHER INFORMATION CONTACT:**

Denise Sofka, RD, MPH, Division of Maternal and Child Health Workforce Development, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W55, Rockville, Maryland 20857; [DSofka@hrsa.gov](mailto:DSofka@hrsa.gov).

Grantee/organization name	Grant number	State	FY 2015 authorized funding level	FY 2015 estimated supplemental funding
University of Washington .....	T76MC00011 .....	WA .....	\$350,000	\$40,000

Dated: September 11, 2015.

**James Macrae,**

*Acting Administrator.*

[FR Doc. 2015-23356 Filed 9-16-15; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Bridging the Word Gap Competition Challenge**

**AGENCY:** Health Resources and Services Administration (HRSA, Department of Health and Human Services (HHS)).

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), announces the funding

opportunity for the Bridging the Word Gap Incentive Prize Challenge.

MCHB is sponsoring the Word Gap Challenge (Challenge) to spur innovative solutions to promote the early language environment and address the “word gap,” the large difference in exposure to language for children from low-income families as compared to children from higher-income families. This Challenge will reward the development and testing of scalable innovations that drive behavior change among parents and caregivers.

The goal of the Challenge is to develop a low-cost, scalable technologically-based intervention that drives parents and caregivers to talk and engage in more back-and-forth interactions with their young children (ages 0–4).

This Challenge, structured in three phases, with a narrowing of applicants through each phase to result in one final winner, will reach a diverse population of innovators and solvers, including

coders, public health experts, individuals affiliated with academic institutions, research and development communities in the private sector, and others.

All submissions will be evaluated; separate prizes will be awarded for each of the three phases below.

- Phase 1: Design
- Phase 2: Development and Small Scale Testing
- Phase 3: Scaling

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (COMPETES Act, *Pub. L. 111-358*).

Estimated dates for each phase are as follows:

- Phase 1: Effective on September 30, 2015
- Phase 1 Submission ends: December 31, 2015, 11:59 p.m. ET
- Phase 1 Judging Period: January 1–January 31, 2016

Phase 1 Winners Announced: February 10, 2016  
 Phase 2 Begins: February 11, 2016  
 Phase 2 Submission Period Ends: July 11, 2016  
 Phase 2 Judging Period: July 12–August 12, 2016  
 Phase 2 Winners Announced: August 20, 2016  
 Phase 3 Begins: August 21, 2016  
 Phase 3 Submission Period Ends: February 21, 2017  
 Phase 3 Winner Announced: March 1, 2017

**FOR FURTHER INFORMATION CONTACT:**

Jessie Buerlein, MSW, 301–443–8931, or James Resnick, 301–443–3222.

**SUPPLEMENTARY INFORMATION:**

**Subject of Challenge Competition**

There is evidence that socioeconomic status (SES) is a strong indicator of school achievement, and that children from lower SES backgrounds exhibit a delay in early literacy skills, a slower vocabulary acquisition rate, and lower school readiness rates.<sup>1</sup> Once American children enter kindergarten, there is a significant, prevalent gap between children from higher versus lower SES backgrounds in average oral language skills,<sup>2</sup> referred to as the “word gap.” There is also growing evidence that early language exposure for children may not only have a significant influence on language development and school achievement, but on the overall trajectory of children’s lives, including later academic and occupation success.<sup>3</sup> Existing literature reveals several key themes in addressing the language gap, including the significant role of the caregiver in the home, and the effectiveness of engaging parents in language interventions.<sup>4</sup> A significant influence on children’s language development is the context of parenting and parent responsiveness to children’s early language acquisition.<sup>5</sup> Research in

this area shows that both the quality and quantity of speech spoken at home during daily interactions influences the relationship between SES and child language skills at school entry.<sup>6</sup> However, research also shows that interventions engaging parents and increasing their knowledge of child development and the importance of child-directed talk may be an effective route to preventing and addressing the SES language gap.<sup>7</sup>

The research base has improved markedly over the last two decades, making a strong case that addressing the word gap is a critical social challenge that may help promote equitable opportunity for all children. The frequency and quality of child-directed talk and back and forth interactions between children and their parents have consequences for what is learned and is associated with significant disparities in vocabulary size, school readiness, and long-term educational outcomes.

Technologies now exist to support low-cost, broadly scalable approaches to helping parents and caregivers focus on the early language environment, and the technical expertise exists to address the issue in creative ways. This challenge aims to cultivate an environment to attract a broad array of innovators from outside disciplines to propose inventive, creative, and effective ideas to address the word gap by encouraging higher frequency and higher quality interaction between parents/caregivers and children. This is an opportunity for applicants to get national visibility, by the leading experts and organizations in the field, for new ideas on solving this problem of national importance. This is also an opportunity for applicants to access testing environments and design expertise as they move forward through the Challenge phases.

When developing submissions, participants should consider the context of the user. The submission should be easily utilized by those of diverse cultural, socioeconomic, and literacy level backgrounds, including parents and children who are dual language speakers.

**Eligibility Rules for Participating in the Competition**

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules

promulgated by the Health Resources and Services Administration and the U.S. Department of Health and Human Services.

(2) Shall have complied with all the requirements under this section.

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(4) May not be a federal entity or federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) May not be employees of HRSA or any other company, organization, or individual involved with the design, production, execution, judging, or distribution of the Challenge and their immediate family (*i.e.*, spouse, parents and step-parents, siblings and step-siblings, and children and step-children) and household members (*i.e.*, people who share the same residence at least 3 months out of the year).

(7) In the case of a federal grantee, may not use federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) In the case of a federal contractor, may not use federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

(9) Shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made equitably available to all individuals and entities participating in the competition.

(10) Must agree to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

(11) Must also agree to indemnify the federal government against third party claims for damages arising from or related to competition activities.

(12) Shall not be currently on the Excluded Parties List (<https://www.epls.gov/>).

<sup>1</sup> Suskind D., Kuhl, P., Leffel, K.R., Landry, S., Cunha, F., & Necherman, K.M. (2013). *Bridging the early language gap: A plan for scaling up*. (A White Paper prepared for the White House meeting on “Bridging the Thirty-Million-Word Gap”).

<sup>2</sup> Rowe, M.L., Suskind, D., & Hoff, E. (2013) *Early language gaps: Sources and solutions*. (A White Paper prepared for the White House meeting on “Bridging the Thirty-Million-Word Gap”).

<sup>3</sup> Suskind D., Kuhl, P., Leffel, K.R., Landry, S., Cunha, F., & Necherman, K.M. (2013). *Bridging the early language gap: A plan for scaling up*. (A White Paper prepared for the White House meeting on “Bridging the Thirty-Million-Word Gap”).

<sup>4</sup> Roberts, M.Y., & Kaiser, A.P. (2011). The effectiveness of parent-implemented language interventions: A meta-analysis. *American Journal of Speech-Language Pathology*, 20, 180–199.

<sup>5</sup> Suskind D., Kuhl, P., Leffel, K.R., Landry, S., Cunha, F., & Necherman, K.M. (2013). *Bridging the early language gap: A plan for scaling up*. (A White Paper prepared for the White House meeting on “Bridging the Thirty-Million-Word Gap”).

<sup>6</sup> Hoff, E. (2009) *Do vocabulary differences explain achievement gaps and can vocabulary-targeted interventions close them?* (Prepared for the National Research Council workshop on the Role of Language in Education.)

<sup>7</sup> *Ibid.*

## Submission Requirements

The Challenge has three phases.

### Phase 1—Design

The first stage of the prize competition aims to attract a large set of ideas and innovators. The target product of the first stage will be the conceptualization of the most promising innovations to help support parental and caregiver behavior change around the early language environment. The submissions should aim to demonstrate that the proposed intervention will be accessible across diverse backgrounds and easily implemented by users.

The Phase 1 Submission shall include:

1. A comprehensive description of the proposed intervention in 5 pages or less, including:

- a. A one-paragraph executive summary that clearly states the question to be solved;
- b. Background information linking the evidence to support the intervention;
- c. A descriptive analysis of how the applicant arrived at their idea;
- d. Descriptions of the methods and technologies involved in implementation of the intervention; and

2. An assessment describing the applicant's ability to execute the proposed solution in Phase 2 and 3.

### Phase 2—Development and Small Scale Testing

The winners of Phase 1 of the prize competition will then advance to a second stage focused on prototyping the intervention, and testing the effectiveness of the intervention. Using support from the Phase 1 prize funding, intervention developers will test the efficacy of their models to show that the proposed intervention demonstrates an impact on the outcomes of interest for children and families. The applicants should demonstrate both the evidence base for the intervention and its usability. Mentors will be made available to help solvers design appropriate testing methodologies and learn more about the evidence base.

### Phase 3—Scaling

The winners of Phase 2 will move to the final phase of the Word Gap Incentive Prize, which will involve testing the most promising models at greater scale through rollout at the program or community level. This will test the scalability of the device at low-cost, the feasibility of implementation, and the impact on the intended outcomes. Applicants will be assisted in matching their submission with a community or program.

## Registration Process for Participants

Participants can find out more information at <https://www.challenge.gov/list/>.

### Prizes

- Total: Up to \$300,000 in Prizes
  - Phase 1: 7–10 winners, up to \$10,000 each
  - Phase 2: 3–5 winners; up to \$25,000 each
  - Phase 3: 1 winner; up to \$100,000

### Payment of the Prizes

Prize will be paid by HRSA's Maternal and Child Health Bureau.

### Basis for Winner Selection

The challenge entries will be de-identified and then will be judged by a review panel composed of HHS employees and experts in compliance with the requirements of the COMPETES Act and the Department of Health and Human Services judging guidelines: <http://www.hhs.gov/idealab/wp-content/uploads/2014/04/HHS-COMPETITION-JUDGING-GUIDELINES.pdf>. The review panel will make selections based upon the following criteria:

#### Phase 1

In Phase 1, proposed interventions to be judged on the following criteria:

#### Accessibility

- Is the proposed intervention able to be easily utilized by parents of diverse economic, social, and cultural backgrounds? Is it functional across disciplines/users?

#### Measurability

- How easily will the proposed intervention be evaluated in order to determine its efficacy (in both lab testing and in the real world)? Is the proposed intervention measurable among various audiences?

#### Sustainability

- Is the proposed intervention "sticky?" Does it fit into daily life? Is it fun to use?

#### Impact

- Does the applicant present a theory or explanation of how the proposed intervention would inspire behavior change?

#### Phase 2

In Phase 2, interventions will be judged on the following criteria:

#### Impact

- How did the intervention impact target outcomes for parents/caregivers and children? What did the data show?

#### Evidence base

- Is the intervention grounded in existing science related to the word gap, behavior change, etc.?

#### Sustainability

- Was the intervention "sticky" among users? Did users want to continuously engage with the program?

#### Implementation

- How feasible is the intervention? How much support for implementation will the intervention require (estimated financial and time commitment)?

#### Phase 3

In Phase 3, interventions will be judged on the following criteria:

#### Impact

- How effective was the intervention when implemented at scale? Did the impacts on parents/caregivers from Phase 2 remain consistent?

#### Implementation

- How feasible was the intervention on a larger scale? How much support for implementation did the model require (financial and time commitment)? How challenging was the actual program implementation?

#### Scalability

- How costly was the intervention in a real-world setting? How likely are cost efficiencies for program delivery at greater scale? Can the device be used in existing platforms?

In order for an entry to be eligible to win this Challenge, it must meet the following requirement:

#### Additional Information

General Conditions: HRSA reserves the right to cancel, suspend, and/or modify the contest, or any part of it, for any reason, at HRSA's sole discretion.

The interventions submitted across all phases should not use the HHS or HRSA logos or official seals in the submission, and must not claim endorsement.

#### Intellectual Property

- Each entrant retains full ownership and title in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement.
- By participating in the challenge, each entrant hereby irrevocably grants to HRSA a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publically perform, publically display, and use the submission for internal HHS business and to the extent necessary to

administer the challenge, and to publically perform and publically display the submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

- **Record Retention and FOIA:** All materials submitted to HRSA as part of a submission become HRSA records and cannot be returned. Any confidential commercial information contained in a submission should be designated at the time of submission. Submitters will be notified of any Freedom of Information Act requests for their submissions in accordance with 45 CFR 5.65.

Dated: September 14, 2015.

**James Macrae,**

*Acting Administrator.*

[FR Doc. 2015-23358 Filed 9-16-15; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

*Date:* October 8, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

*Contact Person:* Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, 301-435-1850, [limc4@csr.nih.gov](mailto:limc4@csr.nih.gov).

*Name of Committee:* Oncology 1-Basic Translational Integrated Review Group; Cancer Genetics Study Section.

*Date:* October 14, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

*Contact Person:* Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301-451-0132, [bloomm2@mail.nih.gov](mailto:bloomm2@mail.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Chronic Dysfunction and Integrative Neurodegeneration Study Section.

*Date:* October 15, 2015–October 16, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Wyndham Grand Chicago Riverfront Hotel, 71 E Wacker Drive, Chicago, IL 60601.

*Contact Person:* Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301-435-1785, [kondratyevad@csr.nih.gov](mailto:kondratyevad@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Brain Injury and Neurovascular Pathologies Study Section.

*Date:* October 15–16, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Wyndham Grand Chicago Riverfront Hotel, 71 E Wacker Drive, Chicago, IL 60601.

*Contact Person:* Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301-435-1254, [yakovleva@csr.nih.gov](mailto:yakovleva@csr.nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group; Tumor Cell Biology Study Section.

*Date:* October 15–16, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

*Contact Person:* Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301-408-9850, [morrowcs@csr.nih.gov](mailto:morrowcs@csr.nih.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

*Date:* October 15–16, 2015.

*Time:* 8:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco, 700 F Street NW., Washington, DC 20001.

*Contact Person:* Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040-A, MSC 7850, Bethesda, MD 20892, 301-435-1235, [geoffreys@csr.nih.gov](mailto:geoffreys@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Liver Pathobiology and Toxicology.

*Date:* October 15, 2015.

*Time:* 12:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mushtaq A. Khan, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301-435-1778, [khanm@csr.nih.gov](mailto:khanm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: SBIR/STTR Serious STEM Games.

*Date:* October 19, 2015.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, [ruvinsr@csr.nih.gov](mailto:ruvinsr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Enabling Bioanalytical and Imaging Technologies.

*Date:* October 20, 2015.

*Time:* 8:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Washington, DC Downtown, 1199 Vermont Ave NW., Washington, DC 20005.

*Contact Person:* Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301-435-0229, [kenneth.ryan@nih.hhs.gov](mailto:kenneth.ryan@nih.hhs.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Urologic and Urogynecologic Applications.

*Date:* October 22, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza Washington National Airport, 1489 Jefferson Davis Hwy, Arlington, VA 22202.

*Contact Person:* Ryan G. Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301-435-1501, [morrisr@csr.nih.gov](mailto:morrisr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowship: Immunology.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr, Room 4203, Bethesda, MD 20817, (301) 435-3566, [alok.mulky@nih.gov](mailto:alok.mulky@nih.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Synapses, Cytoskeleton and Trafficking Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 11:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Pier 2620 Hotel Fisherman's Wharf, 2620 Jones Street, San Francisco, CA 94133.

*Contact Person:* Christine A. Piggee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7850, Bethesda, MD 20892, 301-435-0657, [christine.piggee@nih.gov](mailto:christine.piggee@nih.gov).

*Name of Committee:* Immunology Integrated Review Group; Immunity and Host Defense Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301-435-1506, [jakesse@mail.nih.gov](mailto:jakesse@mail.nih.gov).

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Nanotechnology Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* James J. Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301-806-8065, [lijames@csr.nih.gov](mailto:lijames@csr.nih.gov).

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

*Contact Person:* William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435-1726, [greenbergwa@csr.nih.gov](mailto:greenbergwa@csr.nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton McLean Tyson's Corner, 7920 Jones Branch Drive, McLean, VA 22102.

*Contact Person:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Genes, Genomes,

and Genetics IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, MSC 7890, Bethesda, MD 20892, 301 435-2514, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Gastrointestinal Mucosal Pathobiology Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910.

*Contact Person:* Aiping Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 2188, MSC7818, Bethesda, MD 20892-7818, (301) 435-0682, [zhaoa2@csr.nih.gov](mailto:zhaoa2@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Developmental Brain Disorders Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW., Washington, DC 20036.

*Contact Person:* Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301-408-9866, [manospa@csr.nih.gov](mailto:manospa@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Myocardial Ischemia and Metabolism Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

*Contact Person:* Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301-435-5575, [hamannkj@csr.nih.gov](mailto:hamannkj@csr.nih.gov).

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.

*Date:* October 22–23, 2015.

*Time:* 8:30 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 500-5829, [sechu@csr.nih.gov](mailto:sechu@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-14-166: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

*Date:* October 22, 2015.

*Time:* 10:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Chiayeng Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Room 5213, MSC 7852, Bethesda, MD 20892, 301-435-2397, [chiayeng.wang@nih.gov](mailto:chiayeng.wang@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-12-259: Lymphatics in Health and Disease in the Digestive, Urinary, Cardiovascular and Pulmonary Systems.

*Date:* October 22, 2015.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Mushtaq A. Khan, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301-435-1778, [khanm@csr.nih.gov](mailto:khanm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR13-392: Computational Methods for Functional Variants in Mental Disorders.

*Date:* October 22, 2015.

*Time:* 12:00 p.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Washington, 1515 Rhode Island Ave NW., Washington, DC 20005.

*Contact Person:* Barbara J. Thomas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2218, MSC 7890, Bethesda, MD 20892, 301-435-0603, [bthomas@csr.nih.gov](mailto:bthomas@csr.nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular, Molecular and Integrative Reproduction Study Section.

*Date:* October 23, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco Baltimore, 2 N Charles Street, Baltimore, MD 21201.

*Contact Person:* Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301-435-0229, [hunnicuttgr@csr.nih.gov](mailto:hunnicuttgr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 13-293: Gut Microbiota-Derived Factors in the Integrated Physiology and Pathophysiology of Diseases within NIDDK's mission.

*Date:* October 23, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910.

*Contact Person:* Aiping Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 2188, MSC7818, Bethesda, MD 20892-7818, (301) 435-0682, [zhaoa2@csr.nih.gov](mailto:zhaoa2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Bioinformatics in Surgical Sciences, Imaging and Independent Living.

*Date:* October 23, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301-237-9870, [xuguofen@csr.nih.gov](mailto:xuguofen@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group; Vector Biology Study Section.

*Date:* October 23, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard Philadelphia Downtown, 21 North Juniper Street, Philadelphia, PA 19107.

*Contact Person:* Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301-402-5671, [zhengli@csr.nih.gov](mailto:zhengli@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA-CA-15-006: Big Data to Knowledge (BD2K) Advancing Biomedical Science Using Crowdsourcing and Interactive Digital Media (UH2).

*Date:* October 23, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Raymond Jacobson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301-996-7702, [jacobsonrh@csr.nih.gov](mailto:jacobsonrh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; AREA Review: Immunology.

*Date:* October 23, 2015.

*Time:* 10:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Alok Mulky, Scientific Review Officer, Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr, Room 4203, Bethesda, MD 20817, (301) 435-3566, [alok.mulky@nih.gov](mailto:alok.mulky@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Genes Genomes and Disease.

*Date:* October 23, 2015.

*Time:* 11:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Richard A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435-1219, [currieri@csr.nih.gov](mailto:currieri@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Adult Psychopathology.

*Date:* October 23, 2015.

*Time:* 2:00 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301-500-5829, [sechu@csr.nih.gov](mailto:sechu@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Gene Variants in Drug Response.

*Date:* October 23, 2015.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Savvas Makrides, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 2200, Bethesda, MD 20892, 301-435-2514, [makridess@mail.nih.gov](mailto:makridess@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 11, 2015.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-23299 Filed 9-16-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5830-C-07]

### 60-Day Notice of Proposed Information Collection; Legal Instructions Concerning Applications for Full Insurance Benefits—Assignment of Multifamily Mortgages to the Secretary; Correction of Web Site Address for Form

**AGENCY:** Office of the General Counsel, HUD.

**ACTION:** Notice.

**SUMMARY:** On September 10, 2015, HUD published in the **Federal Register** a notice seeking approval from the Office of Management and Budget (OMB) for the information collection described in the September 10, 2015, notice. The September 10, 2015, notice provided a web address where the existing information collection document and proposed to be changed could be found, but the web address was incorrect. This document provides the corrected webaddress, which is <http://portal.hud.gov/hudportal/documents/huddoc?id=leginstrfullinsben.pdf>. All remaining information in the September 10, 2015, is unchanged.

**FOR FURTHER INFORMATION CONTACT:** For information about this technical correction, Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10282, Washington, DC 20410-0500, telephone (202) 708-3055 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** On September 10, 2015, at 80 FR 54581, HUD published in the **Federal Register** a notice seeking approval from the Office of Management and Budget (OMB) on the information collection, as proposed to be revised, in HUD's Legal Instructions Concerning Applications for Full Insurance Benefits—Assignment of Multifamily Mortgage. To assist interested parties in understanding the information that HUD proposed to change in this document, HUD cited to a web address where the current document could be found. However, the web address was incorrect. The correct web address is <http://portal.hud.gov/hudportal/documents/huddoc?id=leginstrfullinsben.pdf>. All other information in the September 10, 2015, notice remains unchanged.

Dated: September 14, 2015.

**Camille E. Acevedo,**

*Associate General Counsel for Regulations and Legislation.*

[FR Doc. 2015-23362 Filed 9-16-15; 8:45 am]

**BILLING CODE 4210-67-P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

[FWS-HQ-IA-2015-N179;  
FXIA16710900000-156-FF09A30000]

**Endangered Species; Marine Mammals; Issuance of Permits**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of issuance of permits.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA).

**ADDRESSES:** Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358-2281; or email [DMAFR@fws.gov](mailto:DMAFR@fws.gov).

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358-2104

(telephone); (703) 358-2281 (fax); [DMAFR@fws.gov](mailto:DMAFR@fws.gov) (email).

**SUPPLEMENTARY INFORMATION:** On the dates below, as authorized by the provisions of the ESA (16 U.S.C. 1531 *et seq.*), as amended, and/or the MMPA, as amended (16 U.S.C. 1361 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) The application was filed in good faith, (2) The granted permit would not operate to the disadvantage of the endangered species, and (3) The granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

**ENDANGERED SPECIES**

Permit number	Applicant	Receipt of application <b>Federal Register</b> notice	Permit issuance date
24385B .....	University of Pennsylvania School of Medicine	79 FR 15768; March 21, 2014 .....	August 13, 2014.
24407B .....	Connecticut Zoological Society .....	79 FR 24445; April 30, 2014 .....	September 5, 2014.
30341B .....	Dallas World Aquarium .....	79 FR 26452; May 8, 2014 .....	November 25, 2014.
34712B .....	Louisiana State University Museum of Natural Science.	79 FR 36090; June 25, 2014 .....	November 5, 2014.
32491B .....	Southwick's Zoo .....	79 FR 36090; June 25, 2014 .....	January 26, 2015.
24200B .....	Zoological Society of San Diego .....	79 FR 52038; September 2, 2014 .....	October 20, 2014.
701789 .....	Binder Park Zoo .....	79 FR 65980; November 6, 2014 .....	June 23, 2015.
003005 .....	Louisiana State University .....	79 FR 72007; December 4, 2014 .....	June 23, 2015.
10866B .....	Ox Ranch .....	80 FR 255; January 5, 2015 .....	June 15, 2015.
50631B .....	Minnesota Zoological Gardens .....	80 FR 3249; January 22, 2015 .....	April 3, 2015.
18705B .....	Jordan Mercer .....	80 FR 3249; January 22, 2015 .....	April 2, 2015.
751619 .....	Charles Mercer dba NBJ Zoological Park .....	80 FR 3249; January 22, 2015 .....	June 5, 2015.
53174B .....	Disney's Animal Kingdom .....	80 FR 16694; March 30, 2015 .....	June 3, 2015.
19311B .....	Adrian Cieslak .....	80 FR 24961; May 1, 2015 .....	June 24, 2015.
63973B .....	Jeffery Dobbins .....	80 FR 24961; May 1, 2015 .....	June 30, 2015.
57198B .....	Alaska Department of Fish and Game .....	80 FR 28296; May 18, 2015 .....	July 9, 2015.
52803B .....	North Carolina State University .....	80 FR 28296; May 18, 2015 .....	July 8, 2015.
65614B .....	Terry Small .....	80 FR 30263; May 27, 2015 .....	July 9, 2015.
52662B .....	Norton-Brown Herbarium, University of Maryland.	80 FR 30263; May 27, 2015 .....	June 29, 2015.
177999 .....	Lori Snook .....	80 FR 33541; June 12, 2015 .....	July 15, 2015.
676511 .....	Virginia Zoological Park .....	80 FR 33541; June 12, 2015 .....	July 23, 2015.
801652 .....	U.S. Geological Survey, Alaska Science Center.	80 FR 33541; June 12, 2015 .....	July 15, 2015.
64739B .....	Andrew Gwynn .....	80 FR 33541; June 12, 2015 .....	July, 27, 2015.
63962B .....	Disney's Animal Kingdom .....	80 FR 33541; June 12, 2015 .....	July 30, 2015.
54288B .....	Stanford University .....	80 FR 33541; June 12, 2015 .....	August 13, 2015.
60999B .....	Wildlife Conservation Society .....	80 FR 33541; June 12, 2015 .....	July 21, 2015.
53974B .....	Kingsley Rodrigo .....	80 FR 36554; June 25, 2015 .....	June 25, 2015.
64252B .....	University of Pennsylvania/School of Veterinary Medicine.	80 FR 36554; June 25, 2015 .....	August 13, 2015.
61389B .....	Exotic Feline Breeding Compound, Inc. ....	80 FR 36554; June 25, 2015 .....	August 31, 2015.
789828 .....	Point Defiance Zoo & Aquarium .....	80 FR 36554; June 25, 2015 .....	August 11, 2015.
69019B .....	Kyle Witwer .....	80 FR 39795; July 10, 2015 .....	August 17, 2015.
48384B .....	Hurricane Aviaries, Inc. ....	80 FR 39795; July 10, 2015 .....	August 20, 2015.
58979B .....	California Academy of Sciences .....	80 FR 43791; July 23, 2015 .....	August 24, 2015.
71117B .....	Mark Corry .....	80 FR 46042; August 3, 2015 .....	September 4, 2015.

**MARINE MAMMALS**

Permit number	Applicant	Receipt of application <b>Federal Register</b> notice	Permit issuance date
59492B .....	British Broadcasting Corporation—Ocean .....	80 FR 30263; May 27, 2015 .....	August 31, 2015.
59633B .....	Melissa McKinney .....	80 FR 43790; July 23, 2015 .....	September 4, 2015.

### Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358-2281.

#### Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2015-23307 Filed 9-16-15; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-HQ-IA-2015-N180:  
FXIA1671090000-156-FF09A30000]

### Endangered Species; Receipt of Applications for Permit

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of applications for permit.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

**DATES:** We must receive comments or requests for documents on or before October 19, 2015.

**ADDRESSES:** Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358-2281; or email [DMAFR@fws.gov](mailto:DMAFR@fws.gov).

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358-2104 (telephone); (703) 358-2281 (fax); [DMAFR@fws.gov](mailto:DMAFR@fws.gov) (email).

#### SUPPLEMENTARY INFORMATION:

#### I. Public Comment Procedures

*A. How do I request copies of applications or comment on submitted applications?*

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**.

Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

*B. May I review comments submitted by others?*

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) along with Executive Order 13576, “Delivering an Efficient, Effective, and Accountable Government,” and the President’s Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and

Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

#### III. Permit Applications

##### *Endangered Species*

Applicant: Michael Braun, Smithsonian Institute of Natural History, Washington, DC; PRT-70015B

The applicant requests a permit to import biological samples from wild-caught red siskin (*Carduelis cucullata*) from Guyana for the purpose of scientific research.

Applicant: Houston Zoo, INC., Houston, TX; PRT-63550B

The applicant requests a permit to import three captive-bred African wild dog, (*Lycyaon pictus pictus*), for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 1-year period.

Applicant: Alaska Department of Fish and Game, Juneau, AK; PRT-43954A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for wood bison (*Bison bison athabasca*) to enhance the species propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Rare Species Conservatory Foundation, Loxahatchee, FL; PRT-756101

The applicant requests amendment of a captive-bred wildlife registration under 50 CFR 17.21(g) to add red siskin (*Carduelis cucullata*) to enhance the species propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Six Flags Discovery Kingdom, Vallejo, CA; PRT-676508

The applicant requests amendment of a captive-bred wildlife registration under 50 CFR 17.21(g) to add the following species to enhance species propagation or survival: African penguin (*Spheniscus demersus*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Richard Papapietro, Saratoga, CA; PRT-74210B

The applicant requests a permit to import sport-hunted trophies of three



male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: David Florance, Carlisle, PA; PRT-74205B

The applicant requests a permit to import sport-hunted trophies of two male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

**Brenda Tapia,**

*Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.*

[FR Doc. 2015-23306 Filed 9-16-15; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Office of the Secretary

[156D0102DM DS61100000  
DLSN00000.000000 DX61101]; [OMB Control  
Number 1094-0001]

### Proposed Renewal of Information Collection: The Alternatives Process in Hydropower Licensing

**AGENCY:** Office of Environmental Policy and Compliance, Office of the Secretary, Interior.

**ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Environmental Policy and Compliance, Office of the Secretary, Department of the Interior is announcing its intention to request renewal for the collection of information for Alternatives Process in Hydropower Licensing. This collection request has been forwarded to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and the expected burden and cost.

**DATES:** OMB has up to 60 days to approve or disapprove the information collection request, but may respond after 30 days; therefore, public comments should be submitted to OMB by October 19, 2015, in order to be assured of consideration.

**ADDRESSES:** Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the

Department of Interior (1094-0001), by telefax at (202) 395-5806 or via email to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov). Also, please send a copy of your comments to Shawn Alam, Office of Environmental Policy and Compliance, U.S.

Department of the Interior, MS 2462-MIB, 1849 C Street, NW., Washington, DC 20240, or send an email to [Shawn\\_Alam@ios.doi.gov](mailto:Shawn_Alam@ios.doi.gov). Additionally, you may telefax them to him at (202) 208-6970. Individuals providing comments should reference Alternatives Process in Hydropower Licensing.

**FOR FURTHER INFORMATION CONTACT:** To receive a copy of the information collection request, contact Dr. Shawn Alam at (202) 208-5465. You may also contact Dr. Shawn Alam electronically at [Shawn\\_Alam@ios.doi.gov](mailto:Shawn_Alam@ios.doi.gov). To see a copy of the entire ICR submitted to OMB, go to: <http://www.reginfo.gov/public/do/PRAMain>.

### SUPPLEMENTARY INFORMATION:

#### I. Abstract

The OMB regulations at 5 CFR part 1320, which implement the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*, require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8 (d)).

On March 31, 2015, the Departments of Agriculture, the Interior, and Commerce published revised interim final rule they originally published in November 2005 at 7 CFR part 1, 43 CFR part 45, and 50 CFR part 221, to implement section 241 of the Energy Policy Act of 2005 (EP Act), Public Law 109-58, which the President signed into law on August 8, 2005. Section 241 of the EP Act added a new section 33 to the Federal Power Act (FPA), 16 U.S.C. 823d, that allowed the license applicant or any other party to the license proceeding to propose an alternative to a condition or prescription that one or more of the Departments develop for inclusion in a hydropower license issued by the Federal Energy Regulatory Commission (FERC) under the FPA. This provision required that the Department of Agriculture, the Department of the Interior, and the Department of Commerce collect the information covered by 1094-0001.

Under FPA section 33, the Secretary of the Department involved must accept the proposed alternative if the Secretary determines, based on substantial evidence provided by a party to the license proceeding or otherwise available to the Secretary, (a) that the alternative condition provides for the

adequate protection and utilization of the reservation, or that the alternative prescription will be no less protective than the fishway initially proposed by the Secretary, and (b) that the alternative will either cost significantly less to implement or result in improved operation of the project works for electricity production.

In order to make this determination, the regulations require that all of the following information be collected: (1) A description of the alternative, in an equivalent level of detail to the Department's preliminary condition or prescription; (2) an explanation of how the alternative: (i) If a condition, will provide for the adequate protection and utilization of the reservation; or (ii) if a prescription, will be no less protective than the fishway prescribed by the bureau; (3) an explanation of how the alternative, as compared to the preliminary condition or prescription, will: (i) Cost significantly less to implement; or (ii) result in improved operation of the project works for electricity production; (4) an explanation of how the alternative or revised alternative will affect: (i) Energy supply, distribution, cost, and use; (ii) flood control; (iii) navigation; (iv) water supply; (v) air quality; and (vi) other aspects of environmental quality; and (5) specific citations to any scientific studies, literature, and other documented information relied on to support the proposal.

This notice of proposed renewal of an existing information collection is being published by the Office of Environmental Policy and Compliance, Department of the Interior, on behalf of all three Departments, and the data provided below covers anticipated responses (alternative conditions/prescriptions and associated information) for all three Departments.

#### II. Data

(1) Title: 7 CFR part 1; 43 CFR part 45; 50 CFR part 221; the Alternatives Process in Hydropower Licensing.

*OMB Control Number:* 1094-0001.

*Current Expiration Date:* November 30, 2015.

*Type of Review:* Information Collection Renewal.

*Affected Entities:* Business or for-profit entities.

*Estimated annual number of respondents:* 5.

*Frequency of responses:* Once per alternative proposed.

(2) Annual reporting and recordkeeping burden:

*Total annual reporting per response:* 500 hours.

*Total number of estimated responses:*

5.

*Total annual reporting:* 2,500 hours.  
(3) Description of the need and use of the information: The purpose of this information collection is to provide an opportunity for license parties to propose an alternative condition or prescription to that proposed by the Federal Government for inclusion in the hydropower licensing process.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on the collection of information was published on May 7, 2015 (88 FR 26290). No comments were received. This notice provides the public with an additional 30 days in which to comment on the proposed information collection activity.

### III. Request for Comments

The Departments invite comments on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agencies, including whether the information will have practical utility;

(b) The accuracy of the agencies' estimate of the burden of the collection of information and the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology.

"Burden" means the total time, effort, and financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install, and use technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, and to complete and review the collection of information; and to transmit or otherwise disclose the information.

It is our policy to make all comments available to the public for review. Before including Personally Identifiable Information (PII), such as your address, phone number, email address, or other personal information in your comment(s), you should be aware that your entire comment (including PII) may be made available to the public at

any time. While you may ask us in your comment to withhold PII from public view, we cannot guarantee that we will be able to do so.

If you wish to view any comments received, you may do so by scheduling an appointment with the Office of Environmental Policy and Compliance by calling (202) 208-3891. A valid picture identification is required for entry into the Department of the Interior.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

**Willie R. Taylor,**

*Director, Office of Environmental Policy and Compliance.*

[FR Doc. 2015-23393 Filed 9-16-15; 8:45 am]

**BILLING CODE 4334-63-P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS-WASO-NRNHL-19228;  
PPWOCRADIO, PCU00RP14.R50000]**

### National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before August 29, 2015. Pursuant to section 60.13 of 36 CFR Part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202-371-6447. Written or faxed comments should be submitted by October 2, 2015. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: September 3, 2015.

**J. Paul Loether,**

*Chief, National Register of Historic Places/  
National Historic Landmarks Program.*

## CALIFORNIA

### Kern County

National Farm Workers Association  
Headquarters, (Latinos in 20th Century  
California MPS) 102 Albany St., Delano,  
15000715

### Solano County

LCS-102 (landing craft support), 7th &  
Nimitz Sts., Vallejo, 15000716

## DISTRICT OF COLUMBIA

### District of Columbia

Emory United Methodist Church, 6100  
Georgia Ave. NW., Washington, 15000717  
Grant Circle Historic District, 4-33 Grant Cir.,  
NW., Washington, 15000718  
Heurich-Parks House, 3400 Massachusetts  
Ave. NW., Washington, 15000719

## IOWA

### Clinton County

Washington Junior High School and Jefferson  
Grade School, 751 2nd Ave., S., Clinton,  
15000720

### Davis County

Bloomfield Public Library, 107 N. Columbia,  
Bloomfield, 15000721

### Dubuque County

Old Main Street Historic District (Boundary  
Increase and Additional Documentation),  
(Dubuque, Iowa MPS) Main St. between W.  
1st & 4th Sts., Dubuque, 15000722  
Seminary Hill Residential Historic District,  
(Dubuque, Iowa MPS) Clarke Dr., N. Main  
& Madison Sts., Madison Park, Dubuque,  
15000723  
Upper Iowa Street Historic District,  
(Dubuque, Iowa MPS) Iowa St. between W.  
11th & 12th Sts., Dubuque, 15000724  
Washington Residential Historic District,  
(Dubuque, Iowa MPS) 1100-1900 blks.  
White, Jackson & Washington Sts.  
Dubuque, 15000725

### Franklin County

St. John's Danish Evangelical Lutheran  
Church Historic District, 1207 Indigo Ave.,  
Hampton, 15000726

### Jefferson County

Gobble and Heer—Spurgeons Building, 51 E.  
Broadway, Fairfield, 15000727

### Linn County

Grant Vocational High School, 346 2nd Ave.,  
SW., Cedar Rapids, 15000728

### Wapello County

St. Joseph Hospital Historic District, 312 E.  
Alta Vista & 317 Vanness Aves., Ottumwa,  
15000729

### Webster County

Fort Dodge Junior High School, 416 S. 10th  
St., Fort Dodge, 15000730

Fort Dodge Senior High School, 1015 5th Ave. N., Fort Dodge, 15000731

#### MASSACHUSETTS

##### Middlesex County

North Town Hall, 31 Princeton St., Chelmsford, 15000732

#### NEW JERSEY

##### Essex County

Banister, James A., Company Shoe Factory, 370–386 Orange St., Newark, 15000733

#### PENNSYLVANIA

##### Philadelphia County

Bethel Burying Ground, 405–425 Queen St., Philadelphia, 15000734

Friends Housing Cooperative, Bounded by Fairmount Ave., 8th, Franklin & Brown Sts., Philadelphia, 15000735

#### SOUTH CAROLINA

##### Jasper County

Sinclair Service Station, 10782 Jacob Smart Blvd., Ridgeland, 15000736

#### VERMONT

##### Franklin County

Community Baptist Church and Parsonage, (Religious Buildings, Sites and Structures in Vermont MPS) 2 & 10 Mountain Rd., Montgomery, 15000737

A request for removal has been received for the following resource:

#### INDIANA

##### Miami County

Paw Paw Creek Bridge No. 52, Paw Paw Pike, Chili, 83000008

[FR Doc. 2015–23326 Filed 9–16–15; 8:45 am]

BILLING CODE 4312–51P

## DEPARTMENT OF THE INTERIOR

### National Park Service

[NPS–WASO–NRNHL–19204; PPWOCRADIO, PCU00RP14.R50000]

### National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before August 22, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye

St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by October 2, 2015. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: September 1, 2015.

#### J. Paul Loether,

Chief, National Register of Historic Places/  
National Historic Landmarks Program.

#### CALIFORNIA

##### San Mateo County

Dielmann, John, House, 1020 Main St., Redwood City, 15000681

Offerman, John, House, 1018 Main St., Redwood City, 15000682

#### DISTRICT OF COLUMBIA

##### District of Columbia

U.S. Department of Agriculture Cotton Annex, 300 12th St., SW., Washington, 15000683

#### HAWAII

##### Hawaii County

Honokaa People's Theatre, 45–3574 Mamane St., Honokaa, 15000684

Hotel Honokaa Club, 45–3480 Mamane St., Honokaa, 15000685

#### KANSAS

##### Barton County

Great Bend Army Air Field Hangar, (World War II-Era Aviation-Related Facilities of Kansas) 9047 6th St., Great Bend, 15000686

Norden Bombsight Storage Vaults, (World War II-Era Aviation-Related Facilities of Kansas) 9047 6th St., Great Bend, 15000687

##### Bourbon County

Fulton High School and Grade School, (Public Schools of Kansas MPS) 408 W. Osage St., Fulton, 15000688

##### Ellis County

Papes Barn, (Agriculture-Related Resources of Kansas MPS) 890 Ellis Ave., Ellis, 15000689

##### Lincoln County

Evangelical Lutheran School, 308 N. Indiana St., Sylvan Grove, 15000690

##### Riley County

Kimble, Francis Byron (Barney), House, (Late 19th and Early 20th Century Residential Resources in Manhattan, Kansas MPS), 720 Poyntz Ave., Manhattan, 15000691

#### Stafford County

Martin Cemetery, US 50, 1/4 mi. W. of US 281, St. John, 15000692

#### LOUISIANA

##### East Baton Rouge Parish

Sharp, John and Amelia, House, 7585 Willow Grove Blvd., Baton Rouge, 15000693

##### Lafayette Parish

Freetown—Port Rico Historic District, Roughly bounded by E. University, Lee & Lucille Aves., Garfield, Coolidge & Taft Sts., Jefferson Blvd., Lafayette, 15000694

##### Livingston Parish

Brown Hotel and Cafe, 114 N. Range Ave., Denham Springs, 15000695

##### Orleans Parish

Jones, Henry, Cottage, 2409–2411 D'Abadie St., New Orleans, 15000696

Standard Coffee Company Warehouse and Factory, 450 Mandeville St., New Orleans, 15000697

##### Tensas Parish

Routhwood Elementary School, 217 Lombardo St., Newellton, 15000698

##### Terrebonne Parish

Houma Historic District (Boundary Increase and Decrease), 7717, 7719, 7725, 7801–09, 7815–17, 7819 W. Main, 407, 425, 507 Rousell, 7910, 7932, 7936, 7942 W. Park Ave., Houma, 15000699

##### Vermilion Parish

Beard Congregational Church, 402 Granger St., Erath, 15000700

#### MICHIGAN

##### Marquette County

Holy Family Orphanage, 600 Altamont St., Marquette, 15000701

##### Wayne County

Cleveland, Elizabeth, Intermediate School, (Public Schools of Detroit MPS) 13322 Conant St., Detroit, 15000702

#### MISSOURI

##### St. Louis County

U.S. Army Publications Distribution Center, 1655 Woodson Rd., Overland, 15000704

#### SOUTH CAROLINA

##### Charleston County

Huger, Cleland Kinloch and Burnet R. Maybank, House, 8 Legare St., Charleston, 15000705

##### Greenville County

Fulmer, James A., House, 303 N. Main St., Fountain Inn, 15000706

Greenville Elks Lodge, 18 E. North St., Greenville, 15000707

##### Spartanburg County

Converse Mill, 200 High St., Spartanburg, 15000709

**TEXAS****Dallas County**

Lamar—McKinney Bridge, (Road Infrastructure of Texas, 1866–1965 MPS) Across Trinity R. at Continental Ave., Dallas, 15000708

**WISCONSIN****Brown County**

Nicolet High School, 111 3rd St., De Pere, 15000703

**Door County**

HANOVER (schooner) Shipwreck, (Great Lakes Shipwreck Sites of Wisconsin MPS) 1.75 mi. NW. of Fish Cr., Gibraltar, 15000710

UCESS (scow schooner) Shipwreck, (Great Lakes Shipwreck Sites of Wisconsin MPS) .13 mi. SW. of Whitefish Dunes State Park, Sevastopol, 15000711

**Manitowoc County**

PATHFINDER (schooner) Shipwreck, (Great Lakes Shipwreck Sites of Wisconsin MPS) 2.6 mi. N. of Rawley Point Lighthouse, Two Creeks, 15000712

**Marinette County**

Brown, Mary and Harry, House, 1931 Riverside Ave., Marinette, 15000713  
[FR Doc. 2015–23316 Filed 9–16–15; 8:45 am]

**BILLING CODE 4312–51–P**

**INTERNATIONAL TRADE COMMISSION**

**[Investigation Nos. 701–TA–540–544 and 731–TA–1283–1290 (Preliminary)]**

**Cold-Rolled Steel Flat Products From Brazil, China, India, Japan, Korea, Netherlands, Russia, and the United Kingdom****Determinations**

On the basis of the record<sup>1</sup> developed in the subject investigations, the United States International Trade Commission (“Commission”) determines,<sup>2</sup> pursuant to the Tariff Act of 1930 (“the Act”), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of cold-rolled steel flat products from Brazil, China, India, Japan, Korea, Russia, and the United Kingdom, provided for in subheadings 7209.15, 7209.16, 7209.17, 7209.18, 7209.25, 7209.26, 7209.27, 7209.28, 7209.90, 7210.70, 7211.23, 7211.29, 7211.90, 7212.40, 7225.50, 7225.99, and 7226.92 of the Harmonized Tariff Schedule of the United States, that are allegedly sold in the United States at less than fair value (“LTFV”), and by imports of cold-

rolled steel flat products that are allegedly subsidized by the governments of Brazil, China, Korea, and Russia. The Commission also determines, pursuant to the Act, that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of cold-rolled steel flat products that are allegedly subsidized by the government of India.

The Commission further determines that imports of cold-rolled steel flat products from the Netherlands are negligible pursuant to section 771(24) of the Act, and its investigation with regard to cold-rolled steel flat products from this country is thereby terminated pursuant to section 733(a)(1) of the Act.

**Commencement of Final Phase Investigations**

Pursuant to section 207.18 of the Commission’s rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission’s rules, upon notice from the Department of Commerce (“Commerce”) of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

**Background**

On July 28, 2015, AK Steel Corporation (West Chester, Ohio), ArcelorMittal USA LLC (Chicago, Illinois), Nucor Corporation (Charlotte, North Carolina), Steel Dynamics, Inc. (Fort Wayne, Indiana), and United States Steel Corporation (Pittsburgh, Pennsylvania) filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized

imports of cold-rolled steel flat products from Brazil, China, India, Korea, and Russia and LTFV imports of cold-rolled steel flat products from Brazil, China, India, Japan, Korea, Netherlands, Russia, and the United Kingdom. Accordingly, effective July 28, 2015, the Commission, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation Nos. 701–TA–540–544 and antidumping duty investigation Nos. 731–TA–1283–1290 (Preliminary).

Notice of the institution of the Commission’s investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of August 3, 2015 (80 FR 46047). The conference was held in Washington, DC, on August 18, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on September 11, 2015. The views of the Commission are contained in USITC Publication 4564 (September 2015), entitled *Cold-Rolled Steel Flat Products from Brazil, China, India, Japan, Korea, Netherlands, Russia, and the United Kingdom: Investigation Nos. 701–TA–540–544 and 731–TA–1283–1290 (Preliminary)*.

By order of the Commission.

Issued: September 11, 2015.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2015–23325 Filed 9–16–15; 8:45 am]

**BILLING CODE 7020–02–P**

**INTERNATIONAL TRADE COMMISSION**

**[Investigation No. 337–TA–926]**

**Certain Marine Sonar Imaging Systems, Products Containing the Same, and Components Thereof; Commission Determination to Review a Final Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest and Bonding**

**AGENCY:** U.S. International Trade Commission.

<sup>1</sup> The record is defined in sec. 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

<sup>2</sup> Commissioner F. Scott Kieff not participating.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination (“ID”) issued by the presiding administrative law judge (“ALJ”) on July 13, 2015, finding a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), as to certain asserted patent claims in this investigation.

**FOR FURTHER INFORMATION CONTACT:** Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on 202–205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on August 21, 2014, based on a complaint filed by Johnson Outdoors Inc. of Racine, Wisconsin and Johnson Outdoors Marine Electronics, Inc. of Eufaula, Alabama (collectively, “Johnson Outdoors”). 79 FR 49536 (Aug. 21, 2014). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain marine sonar imaging systems, products containing the same, and components thereof by reason of infringement of one or more of claims 1, 2, 17, 25, 26, 31, 32, 35, 36, 41–43, 53, and 56 of U.S. Patent No. 7,652,952 (“the ’952 patent”); claims 1, 5, 7, 8, 21, 22, 24, 25, 28, and 29 of U.S. Patent No. 7,710,825 (“the ’825 patent”); and claims 14, 18, 21–23, 25, and 33 of U.S. Patent No. 7,755,974 (“the ’974 patent”). *Id.* The notice of investigation named the following respondents: Garmin International, Inc.; Garmin North America, Inc.; Garmin USA, Inc. all of Olathe, Kansas; and Garmin Corporation of New Taipei City, Taiwan

(collectively, “Garmin”). *Id.* The Office of Unfair Import Investigations is not a party to the investigation.

On January 30, 2015, the parties entered into a stipulation that the domestic industry requirement was met. The parties also agreed to a stipulation regarding importation of Garmin accused products. That same day, Johnson Outdoors filed two unopposed motions for summary determination: (1) That Garmin’s importation and sales satisfy the importation requirement and (2) that Johnson Outdoors satisfies the domestic industry requirement. On March 24, 2015, the ALJ granted Johnson Outdoors’ summary determination motions in Order Nos. 14 and 15, respectively. The Commission determined not to review. *See* Notice of Commission Determination Not to Review Two Initial Determinations Granting Unopposed Motions for Summary Determinations of Importation and the Existence of a Domestic Industry That Practices the Asserted Patents (April 22, 2015).

On July 13, 2015, the ALJ issued his final ID, finding a violation of section 337 by Garmin in connection with claims 14, 18, 21, 22, 23, and 33 of the ’974 patent. The ALJ found no violation of section 337 in connection with the asserted claims of the ’952 and ’825 patents; and claim 25 of the ’974 patent. Specifically, the ALJ found that the Commission has subject matter jurisdiction, *in rem* jurisdiction over the accused products, and *in personam* jurisdiction over Garmin. ID at 21. The ALJ further found that the accused products infringe asserted claims 14, 18, 21, 22, 23, and 33 of the ’974 patent but do not infringe the asserted claims of the ’952 and ’825 patents or claim 25 of the ’974 patent. *See* ID at 55–57, 58–59, 60–62. The ALJ also found that Garmin failed to establish by clear and convincing evidence that the asserted claims of the ’952, ’825, or ’974 patents were anticipated or rendered obvious by the cited prior art references. *See id.* at 68–80, 89–100. Finally, the ALJ found that the ’952, ’825, and ’974 patents are not unenforceable due to inequitable conduct and that the ’952 patent is not invalid under 35 U.S.C. 102(f) for derivation. ID at 80–83, 100–109.

On July 27, 2015, Garmin filed a petition for review of the ID. That same day, Johnson Outdoors filed a contingent petition for review of the ID. On August 4, 2015, the parties filed responses to the petitions.

Having examined the record of this investigation, including the ALJ’s final ID, the petitions for review, and the responses thereto, the Commission has

determined to review the final ID on all issues petitioned.

The parties are requested to provide any comments they may have as to the Commission’s proposed construction below with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in a response to the following:

If the Commission were to construe the claim term “mounted to a boat” to mean “proximately secured to the boat in a fixed manner,” please discuss any impact this construction may have on the ID’s findings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission’s action. *See* Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United

States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

**Written Submissions:** The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. Complainants are further requested to supply the names of known importers of the Garmin products at issue in this investigation. The written submissions and proposed remedial orders must be filed no later than close of business on September 21, 2015. Reply submissions must be filed no later than the close of business on September 28, 2015. Such submissions should address the ALJ's recommended determinations on remedy and bonding. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-926") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf)). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents

for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: September 11, 2015.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2015-23329 Filed 9-16-15; 8:45 am]

**BILLING CODE 7020-02-P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

[OMB Control No. 1219-0011]

#### Revision of a Currently Approved Collection; Respirable Coal Mine Dust Sampling

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for public comments.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Respirable Coal Mine Dust Sampling.

**DATES:** All comments must be received on or before November 16, 2015.

**ADDRESSES:** Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

• *Federal E-Rulemaking Portal:* <http://www.regulations.gov>. Follow the

on-line instructions for submitting comments for docket number MSHA-2015-0022.

• *Regular Mail:* Send comments to USDOL-MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202-5452.

• *Hand Delivery:* USDOL-Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202-5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

**FOR FURTHER INFORMATION CONTACT:** Sheila McConnell, Acting Director, Office of Standards, Regulations, and Variances, MSHA, at [MSHA.information.collections@dol.gov](mailto:MSHA.information.collections@dol.gov) (email); 202-693-9440 (voice); or 202-693-9441 (facsimile).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Chronic exposure to respirable coal mine dust causes lung diseases including coal workers' pneumoconiosis (CWP), emphysema, silicosis, and chronic bronchitis, known collectively as "black lung." These diseases are debilitating and can result in disability and premature death. While considerable progress has been made in lowering dust levels since 1970 and, consequently, lowering the prevalence rate of black lung among coal miners, severe forms of black lung continue to be identified. Information from the federally funded Coal Workers' Health Surveillance Programs administered by the National Institute for Occupational Safety and Health (NIOSH) clearly indicates that black lung remains a key occupational health risk among our nation's coal miners. According to NIOSH, 933 or 3.7 percent of the 25,558 underground coal miners x-rayed between January 2003 and September 2011 were found to have CWP. Also, in FY 2011, over 28,600 former coal miners and the dependents of miners received \$417 million in "black lung" benefits. Since inception of the federal Black Lung Benefits Program in 1970, over \$45 billion in total benefits have been paid out to former miners and their dependents.

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty to protect the safety and health of miners. Further, Section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the

protection of life and prevention of injuries in coal or other mines. This Information Collection 1219-0011 reflects requirements of MSHA's final rule, Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors (79 FR 24814; May 1, 2014) related to respirable coal mine dust sampling in effect on February 1, 2016, and respirable dust standards in effect on August 1, 2016.

MSHA's standards in 30 CFR parts 70, 71, and 90 require each mine operator of an underground coal mine, surface coal mine and, surface work areas of an underground coal mine, and each coal mine operator who employs a Part 90 miner, to protect miners from exposure to excessive respirable coal mine dust levels. Parts 70 and 71 require each coal mine operator to continuously maintain the average concentration of respirable coal mine dust in the mine atmosphere where miners normally work or travel at or below 1.5 milligrams per cubic meter ( $\text{mg}/\text{m}^3$ ). This standard is reduced using the formula 10 divided by the percent of quartz when the respirable dust contains more than 5 percent quartz. Overexposure to respirable coal mine dust containing quartz has been associated with silicosis (black lung). These lung diseases are irreversible and may be fatal, but they are preventable. Parts 70 and 71 also require each coal mine operator to continuously maintain the average concentration of respirable dust in intake airways at underground mines at or below  $0.5 \text{ mg}/\text{m}^3$ .

If a Part 90 miner is employed at the mine, the coal mine operator is required to continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift to which the Part 90 miner in the active workings of the mine is exposed at or below  $0.5 \text{ mg}/\text{m}^3$ . This standard is also reduced if more than 5 percent quartz is found in the mine atmosphere during each shift to which the Part 90 miner is exposed.

MSHA's standards require that coal mine operators sample respirable coal mine dust quarterly and submit these samples to MSHA for analysis to determine if the mine is complying with the applicable dust standards. Underground coal mine operators must sample: The Designated Occupation (DO) and Other Designated Occupation (ODO) in each Mechanized Mining Unit (MMU) under 30 CFR 70.208 and each Designated Area (DA) at locations specified in the operator's approved mine ventilation plan under 30 CFR 70.209. In addition, Designated Work Positions (DWP) at surface coal mines and surface work areas of underground

coal mines must be sampled under 30 CFR 71.206. Furthermore, each part 90 miner must be sampled under 30 CFR 90.207.

Sampling, General and Technical Requirements under Parts 70, 71, and 90: Section 70.201(b)(2) requires that DAs identified by the underground coal mine operator be sampled quarterly only with an approved Coal Mine Dust Personal Sampling Unit (CMDPSU) unless the operator notifies the District Manager in writing that only an approved Continuous Personal Dust Monitor (CPDM) will be used for all DA sampling at the mine. With respect to DWP sampling, section 71.201(a) requires each mine operator of a surface coal mine and each mine operator of an underground coal mine with surface work areas who is sampling on the surface to sample with an approved CMDPSU, however, the operator may use an approved CPDM if the operator notifies the District Manager in writing that only an approved CPDM will be used for all DWP sampling at the mine. MSHA does not expect underground coal mine operators to use the CPDM to conduct DA sampling underground, or DWP sampling on the surface area of the underground mine. Also, MSHA does not expect surface coal mine operators to use the CPDM to conduct DWP sampling. Thus, there are no notifications to the MSHA District Manager and therefore no burdens to operators for sections 70.201(b)(2) and 71.201(a).

Sections 70.201(e), 71.201(d), and 90.201(f) require that coal mine operators make records showing the length of: Each production shift for each MMU; each normal work shift for each DWP; and each shift for each part 90 miner respectively. These provisions also require that the records be retained for at least six months, made available for inspection by authorized representatives of the Secretary and, except in the case of part 90 miners, by the representative of miners. The records must also be submitted to the District Manager when requested in writing.

Section 70.211(c)(5) requires that, when CPDMs are used for sampling, underground coal mine operators print, sign and post a paper record (Dust Data Card) with the shift length. Under section 90.209(c)(5), when CPDMs are used for sampling, coal mine operators must print, sign and provide to each part 90 miner a Dust Data Card with the shift length. Under sections 70.210(c) and 71.207(c), if using a CMDPSU, the operator must complete a dust card, which includes recording the shift length.

There are no separate burdens shown for recording shift lengths for sections 70.201(e) for underground coal mines and 90.201(f) related to part 90 miners when sampling is conducted because records of shift length are accounted for under sections 70.211(c) and 90.209(c) when a CPDM Dust Data Card is printed and signed. However, burdens for recording shift lengths when sampling is not conducted are shown under sections 70.201(e) and 90.201(f).

For surface work areas of underground coal mines and surface coal mines, there is no burden shown for section 71.201(d) when DWP sampling is conducted because records of shift length are accounted for under section 71.207(c) when a CMDPSU Dust Data Card is completed. However, the burden for recording shift length when sampling is not conducted is shown under section 71.201(d).

Sections 70.201(f), 71.201(e), and 90.201(g) require that upon request from the District Manager, the operator must submit the date and time any respirable dust sampling required by part 70, 71, or 90 will begin. The mine operator must submit this information to MSHA at least 48 hours prior to scheduled sampling. In addition, under section 71.201(f), a mine operator may request, in writing, that the rain restriction for a normal work shift as defined in section 71.2 be waived by the District Manager.

Sections 70.210(d), 71.207(d), and 90.208(d) require that all operator samples be considered to be taken to fulfill the sampling requirements of parts 70, 71, and 90, respectively, unless the sample has been identified in writing by the operator to the District Manager, prior to the intended sampling shift, as a sample to be used for another purpose.

Section 70.201(g) requires that to establish a normal production shift, the operator must record the amount of run-of-mine material produced by each MMU during each shift to determine the average production for the most recent 30 production shifts or for all production shifts if fewer than 30 shifts of production data are available. It also requires that the production records must be retained for at least six months and be made available for inspection by authorized representatives of the Secretary and the representative of miners.

Sections 70.201(j) and 90.201(j) allow the mine operator of an anthracite mine that uses the full box, open breast, or slant breast mining method to use either a CPDM or a CMDPSU for respirable coal mine dust sampling required under part 70 or part 90. However, if the mine operator chooses not to use a CPDM, he

must notify the District Manager in writing of this decision. To estimate the full cost impact upon coal mine operators, MSHA assumed that these operators will use the CPDM for the required sampling. Therefore, no burden was estimated at this time for these operators to notify the District Manager of their choice not to use the CPDM. Operators may reevaluate whether to use the CPDM. Therefore, future updates to this package may result in a burden for these provisions.

Sampling under Parts 70, and 71: Sections 70.205(b)(2) and 71.205(b)(2) require that if a CMDPSU is used to sample respirable coal mine dust, each approved sampling device must be examined each shift by a person certified in sampling during the last hour of operation to assure that the sampling device is operating properly and at the proper flowrate. If the proper flowrate is not maintained, the respirable dust sample must be transmitted to MSHA with a notation by the certified person on the back of the Dust Data Card stating that the proper flowrate was not maintained. Other events occurring during the collection of respirable coal mine dust samples that may affect the validity of the sample, such as dropping of the sampling head assembly onto the mine floor, must also be noted on the back of the Dust Data Card. The burdens for these requirements are included in the burdens estimated to complete the Dust Data Cards under sections 70.210(c) and 71.207(c).

Quarterly Sampling Requirements for Parts 70, 71, and 90: Quarterly sampling requirements are in section 70.208 for MMUs, section 70.209 for DAs, and section 90.207 for part 90 miners. Sections 70.208(e)(3), 70.209(c)(3), and 90.207(c)(3) require that when a valid representative sample meets or exceeds the ECV that corresponds to the applicable standard and particular sampling device used for either an MMU or DA, respectively, or that corresponds to the applicable standard and particular sampling device used for part 90 miner sampling, the operator must make, upon implementation of corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine

for at least 1 year and be made available for inspection by authorized representatives of the Secretary and, except for part 90 miners, the representative of miners. Also, the records must be made available for inspection by the affected part 90 miner who was sampled.

Sections 70.208(h)(3), 70.209(f)(3), and 90.207(f)(3) require that mine operators, upon issuance of a citation for violation of the applicable standard for either an MMU, DA, or part 90 miner, respectively, must make, upon implementation of the corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and, except for part 90 miners, the representative of miners. Also, the records must be made available for inspection by the affected part 90 miner who was sampled.

DWPs at surface coal mines and surface work areas of underground coal mines must be sampled quarterly under section 71.206. Under section 71.206(d), operators with multiple work positions that are specified in section 71.206(c)(2) and (c)(3) must sample the DWP exposed to the greatest respirable dust concentration in each work position performing the same activity or task at the same location at the mine and exposed to the same dust generation source. Each operator must provide the District Manager with a list identifying the specific work positions where DWP samples will be collected for: Active mines; new mines; and DWPs with a change in operational status that increases or reduces the number of active DWPs.

Section 71.206(e) requires that each DWP sample must be taken on a normal work shift. If a normal work shift is not achieved, the respirable dust sample must be transmitted to MSHA with a notation by the person certified in sampling on the back of the Dust Data Card stating that the sample was not taken on a normal work shift. Section 71.207(c) requires that a person certified in sampling properly complete the Dust Data Card that is provided by the manufacturer for each filter cassette. The card must have an identification

number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and include that person's MSHA Individual Identification Number (MIIN). A separate burden has not been included for section 71.206(e) since MSHA assumed that any notations can be made at the same time that the Dust Data Card is completed under section 71.207(c).

Section 71.206(h)(3) requires that when a valid representative sample taken in accordance with this section meets or exceeds the ECV that corresponds to the applicable standard and particular sampling device used, the operator must make, upon implementation of the corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and the representative of miners. There are no separate burden estimates projected for section 71.206(h)(3). MSHA assumed that surface samples that meet or exceed the applicable ECV will result in a citation, and this burden appears under section 71.206(k)(3).

Section 71.206(k)(3) requires that upon issuance of a citation for violation of the applicable standard, the operator must make, upon implementation of the corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and the representative of miners.

Transmission of Respirable Coal Mine Dust Samples by the Operator under Parts 70, 71, and 90: Sections 70.210(a) and 71.207(a) require that if a CMDPSU



is used to sample, the operator must transmit within 24 hours after the end of the sampling shift all samples collected to fulfill the requirements of part 70, 71, or 90, including control filters, in containers provided by the manufacturer of the filter cassette to: Respirable Dust Processing Laboratory, Pittsburgh Safety and Health Technology Center, Cochran Mill Road, Building 38, P.O. Box 18179, Pittsburgh, Pennsylvania 15236-0179, or to any other address designated by the District Manager.

Sections 70.210(c) and 71.207(c) require that a person certified in sampling properly complete the Dust Data Card that is provided by the manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and include that person's MSHA Individual Identification Number (MIIN). Respirable dust samples with data cards not properly completed may be voided by MSHA.

Sections 70.210(f), 71.207(f), and 90.208(f) require that if a CPDM is used to sample, the person certified in sampling must validate, certify and transmit electronically to MSHA within 24 hours after the end of each sampling shift all sample data file information collected and stored in the CPDM, including the sampling status conditions encountered when sampling. All CPDM data files transmitted electronically to MSHA must be maintained by the operator for at least 12 months.

The burdens for sections 70.210(a), (c), and (f), 71.207(a) and (c), and 90.208(f) are included in the burdens for sections 70.210, 71.207, and 90.208. Section 71.207(f) pertains only to using the CPDM. However, operators of surface coal mines and operators of surface work areas of underground coal mines are only required to use the CPDM for part 90 miner sampling, and MSHA does not expect them to use the CPDM to conduct DWP sampling. Thus, the burden for section 71.207(f) is accounted for in the burden for section 90.208(f).

Report to the Operator of Respirable Dust Samples; Post or Provide Results and Report under Parts 70, 71, and 90: Sections 70.211(b) and 71.208(b) require that upon receipt of the sampling report that contains sampling results from MSHA, the operator must post the data for at least 31 days on the mine bulletin board. Sections 70.211(c) and 71.208(c)

require, if using a CPDM, the person certified in sampling, within 12 hours after the end of each sampling shift, to print, sign, and post on the mine bulletin board a paper record (Dust Data Card) of each sample run. This hard-copy record must include the data entered when the sample run was first programmed and the following: The mine identification number; the locations within the mine or the DWP at the mine from which the samples were taken; the concentration of respirable dust, expressed as an equivalent concentration reported and stored for each sample; the sampling status conditions encountered for each sample; and the shift length. Section 71.208(c) requires that when CPDMs are used for DWP sampling, underground coal mine operators that have surface work areas and surface coal mine operators print, sign, and post a paper record (Dust Data Card) with the shift length and other information regarding sampling for each location sampled under Part 71. MSHA does not expect that the CPDM will be used for DWP sampling by underground coal mine operators on the surface area of the underground mine, or by surface coal mine operators. Therefore, no burden was estimated at this time for Section 71.208(c).

For part 90 miners, section 90.209(b) requires that upon receipt of the sampling report from MSHA, the operator must provide a copy to the part 90 miner only. Section 90.209(c) requires that if using a CPDM, the person certified in sampling must print, sign, and provide to each part 90 miner, a paper record (Dust Data Card) of the sample run within one hour after the start of the part 90 miner's next work shift. This hard copy record must include the data entered when the sample run was first programmed, and the following: The mine identification number; the location within the mine from which the sample was taken; the concentration of respirable dust, expressed as an equivalent concentration reported and stored for each sample; the sampling status conditions encountered for each sample; the shift length; and the part 90 miner's MSHA Individual Identification Number (MIIN).

Operational Status Changes under Parts 70, 71, and 90: Sections 70.212(a), 71.209(a), and 90.210 require that if there is a change in operational status that affects the respirable dust sampling requirements of part 70, 71, or 90, respectively, the operator must report the change in operational status of the mine, MMU, DA, DWP, or part 90 miner (such as the part 90 miner entering a

terminated, injured or ill status, or returning to work) to the MSHA District Office or to any other MSHA office designated by the District Manager. Status changes must be reported in writing or electronically within 3 working days after the status change has occurred.

Revised Dust Control Parameters in the Mine Ventilation Plan in Response to Violations of the Applicable Standard under Part 70: Sections 70.208(i)(2) and 70.209(g)(2) provide that a citation for violation of the applicable standard shall be terminated by MSHA when the operator has submitted to the District Manager revised dust control parameters as part of the mine ventilation plan applicable to the MMU, or the DA, respectively, in the citation and such changes have been approved by the District Manager. The revised parameters must reflect the control measures used by the operator to abate the violation.

Dust Control Plan Provisions in Response to Violations of the Applicable Standard under Part 71: Section 71.300(a) requires that the operator must submit to the District Manager for approval a written respirable dust control plan applicable to the DWP identified in the citation within 15 calendar days after the termination date of a citation for violation of the applicable standard. The respirable dust control plan and revisions must be suitable to the conditions and the mining system of the coal mine and be adequate to continuously maintain respirable dust within the applicable standard at the DWP identified in the citation.

Section 71.300(a)(1) requires that the mine operator must notify the representative of miners at least 5 days prior to submission to MSHA of a respirable dust control plan and any revision to a dust control plan. If requested, the mine operator must provide a copy to the representative of miners at the time of notification.

Section 71.300(a)(3) requires that a copy of the proposed respirable dust control plan, and a copy of any proposed revision, submitted for Agency approval must be posted on the mine bulletin board at the time of submittal. The proposed plan or proposed revision must remain posted until it is approved, withdrawn, or denied.

Under section 71.301(d)(1), the approved respirable dust control plan and any revisions must be provided upon request to the representative of the miners by the operator following notification of approval.

Under section 71.301(d)(3), the plan or revisions must be posted on the mine bulletin board within 1 working day following notification of approval and remain posted for the period that the plan is in effect.

Under section 71.301(e), the operator may review respirable dust control plans and submit proposed revisions to such plans to the District Manager for approval.

Dust Control Plan Provisions in Response to Violations of the Applicable Standard under Part 90: Section 90.300(a) requires that if an operator abates a violation of the applicable standard by reducing the respirable dust level in the position of the part 90 miner, the operator must submit to the District Manager for approval a written respirable dust control plan for the part 90 miner in the position identified in the citation within 15 calendar days after the citation is terminated. The respirable dust control plan and revisions thereof must be suitable to the conditions and the mining system of the coal mine and be adequate to continuously maintain respirable dust within the applicable standard for that part 90 miner.

Section 90.301(d) requires the operator to provide a copy of the current respirable dust control plan to the part 90 miner.

Under section 90.301(e), the operator may review respirable dust control plans and submit proposed revisions to such plans to the District Manager for approval.

Mine Ventilation Plan, Revisions, Notify Miners' Representatives, Provide Copy, and Posting: Section 75.370(a)(3)(i) requires underground coal mine operators to notify the miners' representative at least 5 days prior to submission of mine ventilation plan and any revision and, if requested, provide a copy to the miners' representative at the time of notification. Section 75.370(a)(3)(iii) and (f)(3) require the operator to post a copy of the proposed plan and any proposed revision, and the MSHA-approved plan and any revisions, respectively, on the mine bulletin board. In addition, section 75.370(f)(1) requires the operator to provide a copy of the MSHA-approved plan and any revisions to the miners' representative, if requested.

## II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Respirable Coal Mine Dust Sampling. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The information collection request will be available on <http://www.regulations.gov>. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on [www.regulations.gov](http://www.regulations.gov) and [www.reginfo.gov](http://www.reginfo.gov).

The public may also examine publicly available documents at USDOL-Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202-5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

## III. Current Actions

This request for collection of information contains provisions for Respirable Coal Mine Dust Sampling. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

*Type of Review:* Revision of a currently approved collection.

*Agency:* Mine Safety and Health Administration.

*OMB Number:* 1219-0011.

*Affected Public:* Business or other for-profit.

*Number of Respondents:* 1,035.

*Frequency:* On occasion.

*Number of Responses:* 1,704,366.

*Annual Burden Hours:* 94,478 hours.

*Annual Respondent or Recordkeeper Cost:* \$40,967.

*MSHA Forms:* Miner Operator Dust Data Card.

Comments submitted in response to this notice will be summarized and

included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

**Sheila McConnell,**

*Certifying Officer.*

[FR Doc. 2015-23330 Filed 9-16-15; 8:45 am]

**BILLING CODE 4510-43-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2015-0220]

### Seismic Design Classification for Nuclear Power Plants

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft regulatory guide; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG-1315, "Seismic Design Classification for Nuclear Power Plants." The DG describes a method that the NRC staff considers acceptable for use in identifying and classifying those features of light-water-reactor (LWR) nuclear power plants that must be designed to withstand the effects of the safe-shutdown earthquake (SSE). DG-1315 is proposed revision 5 of Regulatory Guide (RG) 1.29.

**DATES:** Submit comments by November 16, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specified subject):

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0220. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN-12H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on accessing information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Yiu Law, Office of New Reactors, telephone: 301-415-0523, email: [Yiu.Law@nrc.gov](mailto:Yiu.Law@nrc.gov) or Edward O'Donnell, Office of Nuclear Regulatory Research, telephone: 301-415-3317, email: [Edward.ODonnell@nrc.gov](mailto:Edward.ODonnell@nrc.gov). Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Obtaining Information and Submitting Comments**

#### *A. Obtaining Information*

Please refer to Docket ID NRC-2015-0220 when contacting the NRC about the availability of information regarding this document. You may obtain publically-available information related to this document by the following methods:

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0220.

- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The DG is electronically available in ADAMS under Accession No. ML15061A048.

- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

#### *B. Submitting Comments*

Please include Docket ID NRC-2015-0220 in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submissions. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

### **II. Additional Information**

The NRC is issuing for public comment a DG in the NRC's “Regulatory Guide” series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

The DG, entitled, “Seismic Design Classification for Nuclear Power Plants,” is temporarily identified by its task number, DG-1315. DG-1315 is proposed revision 5 of RG 1.29. The guide describes a method that the staff of the NRC considers acceptable for use in identifying and classifying those features of LWR nuclear power plants that must be designed to withstand the effects of the SSE.

This DG does not present new regulatory requirements, but is intended to clarify content in Section C, “Staff Regulatory Guidance,” by (1) addition of a reference to the definition of the reactor coolant pressure boundary in section 50.2 of Title 10 of the *Code of Federal Regulations* (CFR), and (2) a reorganization of systems and subsystems to add clarity to the staff guidance. It also adds a reference to a related international standard, and it was reformatted to align with current program guidance for regulatory guides.

### **III. Backfitting and Issue Finality**

DG-1315 describes a method that the staff of the NRC considers acceptable for use in identifying and classifying those features of LWR nuclear power plants that must be designed to withstand the effects of the SSE. Issuance of this DG, if finalized, would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and would not otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the “Implementation” section of this DG, the NRC has no current intention to impose this guided,

if finalized, on holders of current operating licenses or combined licenses.

This DG may be applied to applications for operating licenses, combined licenses, early site permits, and certified design rules docketed by the NRC as of the date of issuance of the final regulatory guide, as well as future applications submitted after the issuance of the regulatory guide. Such action would not constitute backfitting as defined in the Backfit Rule or be otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in part 52.

Dated at Rockville, Maryland, this 14th day of September, 2015.

For the Nuclear Regulatory Commission.

**Thomas H. Boyce,**

*Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2015-23365 Filed 9-16-15; 8:45 am]

**BILLING CODE 7590-01-P**

## **NUCLEAR REGULATORY COMMISSION**

[NRC-2015-0102]

### **Information Collection: Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations Other Than Conventional Residences Receiving Such Patients**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed information collection; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a proposed collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, “Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations other than Conventional Residences Receiving Such Patients.”

**DATES:** Submit comments by October 19, 2015.

**ADDRESSES:** Submit comments directly to OMB reviewer at: Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150-XXXX), NEOB-10202, Office of Management and Budget, Washington, DC 20503;

telephone: 202-395-7315, email: [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:**

Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6258; email: [INFOCOLLECTS.Resource@NRC.GOV](mailto:INFOCOLLECTS.Resource@NRC.GOV).

**SUPPLEMENTARY INFORMATION:**

**I. Obtaining Information and Submitting Comments**

*A. Obtaining Information*

Please refer to Docket ID NRC-2015-0102 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- Federal rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0102. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2015-0102 on this Web site.

- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML15209A593. The supporting statement available in ADAMS under Accession No. ML15209A605.

- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- NRC's Clearance Officer: A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6258; email: [INFOCOLLECTS.Resource@NRC.GOV](mailto:INFOCOLLECTS.Resource@NRC.GOV).

*B. Submitting Comments*

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your

comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

**II. Background**

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a proposed collection of information to OMB for review entitled, "Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations other than Conventional Residences Receiving Such Patients." The NRC hereby informs potential responses that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on Tuesday, May 19, 2015 (80 FR 28715).

1. *The title of the information collection:* Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations other than Conventional Residences Receiving Such Patients.

2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.

3. *Type of submission:* New.

4. *The form number, if applicable:* N/A.

5. *How often the collection is required or requested:* One-time.

6. *Who will be required or asked to respond:* Institutions that treat thyroid cancer patients with I-131 and the thyroid cancer patients who have been treated.

7. *The estimated number of annual responses:* 5,175 (175 for treating institutions and 5000 for individuals).

8. *The estimated number of annual respondents:* 5,175.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 1,675 (175 hours for treating institution and 1500 hours for individuals).

10. *Abstract:* Although most patients return to their home after receiving diagnostic or therapeutic of Iodine-131, some patients released by the licensee may stay at another location (such as a hotel) for a few days. However, the extent of this practice is unclear. The same uncertainty exists regarding patients returning to nursing homes and other institutional settings. Therefore, one of the main objectives of this study is to obtain reliable statistical data that provides good estimates of the prevalence of these practices. The second objective is to determine, by measurements, the external and internal doses received by members of the general public at hotels, nursing homes, or other institutional settings that receive treated patients immediately after their release.

Dated at Rockville, Maryland, this 14th day of September, 2015.

For the Nuclear Regulatory Commission.

**Tremaine Donnell,**

*NRC Clearance Officer, Office of Information Services.*

[FR Doc. 2015-23367 Filed 9-16-15; 8:45 am]

**BILLING CODE 7590-01-P**

**NUCLEAR REGULATORY COMMISSION**

[NRC-2015-0214]

**Independent Assessment of Nuclear Material Control and Accounting Systems**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft regulatory guide; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG-5049, "Independent Assessment of Nuclear Material Control and Accounting Systems." This DG provides guidance from experience gained since the regulatory guide was initially published in June 1975. In particular, the guidance for performing independent assessments has been expanded to include process monitoring and item monitoring for Category I fuel cycle facilities, and to include guidance for uranium enrichment facilities. In addition, this revision addresses changes in Material Control & Accounting (MC&A) terminology; for

example, the term “management review” has been replaced by “independent assessment,” and “material unaccounted for” by “inventory difference.”

**DATES:** Submit comments by November 16, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specified subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2015–0214. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Glenn Tuttle, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–7230, email: [Glenn.Tuttle@nrc.gov](mailto:Glenn.Tuttle@nrc.gov), or Mekonen Bayssie, Office of Nuclear Regulatory Research, telephone: 301–415–1699, email: [Mekonen.Bayssie@nrc.gov](mailto:Mekonen.Bayssie@nrc.gov); U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Obtaining Information and Submitting Comments**

#### *A. Obtaining Information*

Please refer to Docket ID NRC–2014–0214 when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2015–0214.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The DG is electronically available in ADAMS under Accession No. ML14310A339.

- *NRC’s PDR:* You may examine and purchase copies of public documents at the NRC’s PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

#### *B. Submitting Comments*

Please include Docket ID NRC–2015–0214 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov> as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

### **II. Additional Information**

The NRC is issuing for public comment a DG in the NRC’s “Regulatory Guide” series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC’s regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

The DG entitled “Independent Assessment of Nuclear Material Control and Accounting Systems” is a proposed revision temporarily identified by its task number, DG–5049. This DG is proposed Revision 1 of Regulatory Guide (RG) 5.51, “Management Review of Nuclear Material Control and Accounting Systems.”

This DG provides guidance that conforms with revisions to 10 CFR part 74, “Material Control and Accounting of Special Nuclear Material,” as well as incorporates experience gained since the RG was initially published in June 1975. In particular, the guidance for performing independent assessments has been expanded to include process monitoring and item monitoring for Category I fuel cycle facilities, and to include guidance for uranium enrichment facilities. In addition, this revision addresses changes in MC&A terminology since the RG was published in 1975; for example, the term “management review” has been replaced by “independent assessment,” and “material unaccounted for” by “inventory difference.”

### **III. Backfitting**

This DG provides guidance on recordkeeping and reporting requirements with respect to material control and accounting, as set forth in 10 CFR part 74. The regulatory position held in this guidance demonstrates the method that the NRC staff finds acceptable for an applicant or licensee to meet the requirements of the underlying NRC regulations. The issuance of the guidance in this DG is not backfitting, as that term is defined in 10 CFR 70.76, 72.62, or 76.76, because information collection and reporting requirements with respect to material control and accounting are not included within the scope of the NRC’s backfitting protections.

Dated at Rockville, Maryland, this 11th day of September, 2015.

For the Nuclear Regulatory Commission.

**Thomas H. Boyce,**

*Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2015–23290 Filed 9–16–15; 8:45 am]

**BILLING CODE 7590–01–P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75902; File No. SR-BATS-2015-74]

### Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees To Adopt a Tape B Volume Tier

September 11, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 9, 2015, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act<sup>3</sup> and Rule 19b-4(f)(2) thereunder,<sup>4</sup> which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend its fees and rebates applicable to Members<sup>5</sup> of the Exchange pursuant to Rule 15.1(a) and (c) ("Fee Schedule") to adopt a Tape B Volume Tier.

The text of the proposed rule change is available at the Exchange's Web site at [www.batstrading.com](http://www.batstrading.com), at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

Currently, the Exchange offers a rebate of \$0.0020 per share as the standard rebate for orders with fee code B, which applies to orders that add liquidity to the Exchange in Tape B securities. The Exchange also offers various tiers that provide Members with the opportunity to earn higher rebates by meeting certain volume metrics, including the Cross-Asset Tape B Tier which provides a \$0.0031 per share rebate to a Member's orders with a fee code of B for which the Member: (1) Has a Tape B Step-Up Add TCV<sup>6</sup> from February 2015 that is equal to or greater than 0.06%; and (2) has an Options Market Maker Add TCV<sup>7</sup> that is equal to or greater than 0.75% on the BATS Options.

The Exchange is proposing to adopt a new tier in footnote 13 titled "Tape B Volume Tier." Under the Tape B Volume Tier, the Exchange is proposing to provide a \$0.0027 per share rebate to a Member's orders with a fee code of B for which the Member's Tape B ADAV as a percentage of TCV is equal to or greater than 0.08%. As is the case with any other rebates on the fee schedule, to the extent that a Member qualifies for higher rebates than those provided under the proposed Tape B Volume Tier, the higher rebates shall apply.

###### Implementation Date

The Exchange proposes to implement this amendment to its Fee Schedule immediately.<sup>8</sup>

<sup>6</sup> As provided in the fee schedule, for purposes of BATS Equities pricing, "Tape B Step-Up Add TCV" means ADAV in Tape B securities as a percentage of TCV in the relevant baseline month subtracted from current ADAV in Tape B securities as a percentage of TCV.

<sup>7</sup> As provided in the fee schedule, for purposes of BATS Equities pricing, "Options Market Maker Add TCV" for purposes of equities pricing means ADAV resulting from Market Maker orders as a percentage of TCV, using the definitions of ADAV, Market Maker and TCV as provided under the Exchange's fee schedule for BATS Options.

<sup>8</sup> The Exchange initially filed the proposed fee change on August 31, 2015 (SR-BATS-2015-66). On September 2, 2015, the Exchange withdrew that filing and submitted filing SR-BATS-2015-70. On that same day, the Exchange withdrew SR-BATS-2015-70 and submitted SR-BATS-2015-72. On September 9, 2015, the Exchange withdrew SR-BATS-2015-72 and submitted this filing.

###### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,<sup>9</sup> in general, and furthers the objectives of Section 6(b)(4),<sup>10</sup> in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

Volume-based rebates and fees such as the proposed Tape B Volume Tier have been widely adopted by equities and options exchanges and are equitable because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and introduction of higher volumes of orders into the price and volume discovery processes.

The Exchange believes that the proposal to add a Tape B Volume Tier is a reasonable, fair and equitable, and not unfairly discriminatory allocation of fees and rebates because it will provide Members with an additional incentive to reach certain thresholds on both [sic] the Exchange in Tape B securities. Such pricing programs thereby reward a Member's growth pattern in Tape B securities and such increased volume increases potential revenue to the Exchange, and will allow the Exchange to continue to provide and potentially expand the incentive programs operated by the Exchange. Further, the proposed changes will result in Members receiving either the same or an increased rebate than they would currently receive. The Exchange also notes that the proposed Tape B Volume Tier is similar to pricing tier already employed by the Exchange as well as on

<sup>9</sup> 15 U.S.C. 78f.

<sup>10</sup> 15 U.S.C. 78f(b)(4).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A)(ii).

<sup>4</sup> 17 CFR 240.19b-4(f)(2).

<sup>5</sup> A Member is defined as "any registered broker or dealer that has been admitted to membership in the Exchange." See Exchange Rule 1.5(n).

other exchanges, including EDGX Exchange, Inc. (“EDGX”), which maintains a Tape B Step Up tier to incentivize added liquidity in Tape B securities.<sup>11</sup>

#### *B. Self-Regulatory Organization’s Statement on Burden on Competition*

The Exchange does not believe its proposed amendments to its Fee Schedule would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed changes represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange’s competitors. Additionally, Members may opt to disfavor the Exchange’s pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange does not believe that the proposed new tier would burden competition, but instead, enhances competition, as they [sic] are intended to increase the competitiveness of and draw additional volume to the Exchange. As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if the deem fee structures to be unreasonable or excessive. The proposed changes are generally intended to enhance the rebates for liquidity added to the Exchange, which is intended to draw additional liquidity to the Exchange. The Exchange does not believe the proposed tier would burden intramarket competition as they [sic] would apply to all Members uniformly.

#### *C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)

of the Act<sup>12</sup> and paragraph (f) of Rule 19b–4 thereunder.<sup>13</sup> At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission’s Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR–BATS–2015–74 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2015–74. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from

submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2015–74, and should be submitted on or before October 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>14</sup>

**Brent J. Fields,**  
*Secretary.*

[FR Doc. 2015–23286 Filed 9–16–15; 8:45 am]

**BILLING CODE 8011–01–P**

## **SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34–75899; File No. SR–NSCC–2015–803]

### **Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Advance Notice To Enhance NSCC’s Margining Methodology as Applied to Family-Issued Securities of Certain NSCC Members**

September 11, 2015.

Pursuant to section 806(e)(1) of title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010<sup>1</sup> (“Clearing Supervision Act”) and Rule 19b–4(n)(1)(i)<sup>2</sup> under the Securities Exchange Act of 1934 (“Act”), notice is hereby given that on August 14, 2015, National Securities Clearing Corporation (“NSCC”) filed with the Securities and Exchange Commission (“Commission”) the advance notice SR–NSCC–2015–803 (“Advance Notice”) as described in Items I and II below, which Items have been prepared by NSCC.<sup>3</sup> The Commission is publishing this notice to solicit comments on the Advance Notice from interested persons.

#### **I. Clearing Agency’s Statement of the Terms of Substance of the Advance Notice**

This Advance Notice consists of amendments to NSCC’s Rules & Procedures (“Rules”) in order to enhance NSCC’s margining methodology as applied to family-issued

<sup>14</sup> 17 CFR 200.30–3(a)(12).

<sup>1</sup> 12 U.S.C. 5465(e)(1).

<sup>2</sup> 17 CFR 240.19b–4(n)(1)(i).

<sup>3</sup> On August 14, 2015, NSCC filed this Advance Notice as a proposed rule change (SR–NSCC–2015–003) with the Commission pursuant to section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), and Rule 19b–4, 17 CFR 240.19b–4. A copy of the proposed rule change is available at <http://www.dtcc.com/legal/sec-rule-filings.aspx>.

<sup>11</sup> See EDGX fee schedule, footnote 2.

<sup>12</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>13</sup> 17 CFR 240.19b–4(f).

securities of those NSCC Members<sup>4</sup> that are placed on NSCC's "Watch List", *i.e.* those Member [sic] who present a heightened credit risk to NSCC or have demonstrated higher risk related to their ability to meet settlement, as more fully described below.

## II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the Advance Notice and discussed any comments it received on the Advance Notice. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections A and B below, of the most significant aspects of such statements.

### (A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

In November 2013, NSCC engaged in outreach to its Members by providing those Members with a description of the proposal and the results of an impact study showing the potential impact of this proposal on Members' Clearing Fund required deposits. NSCC did not receive any written comments relating to this proposal in response to this outreach. NSCC will notify the Commission of any written comments received by NSCC.

### (B) Advance Notice Filed Pursuant to Section 806(e) of the Payment, Clearing and Settlement Supervision Act

#### Description of Change

NSCC is proposing to enhance its margin methodology as applied to the family-issued securities of its Members that are on its Watch List<sup>5</sup> by excluding these securities from the volatility component, or "VaR" charge, and then charging an amount calculated by multiplying the absolute value of the long net unsettled positions in that Member's family-issued securities by a percentage that is no less than 40%. The haircut rate to be charged would be

<sup>4</sup> Terms not defined herein are defined in the Rules, available at [http://dtcc.com/-/media/Files/Downloads/legal/rules/nscs\\_rules.pdf](http://dtcc.com/-/media/Files/Downloads/legal/rules/nscs_rules.pdf).

<sup>5</sup> As part of its ongoing monitoring of its membership, NSCC utilizes an internal credit risk rating matrix to rate its risk exposures to its Members based on a scale from 1 (the strongest) to 7 (the weakest). Members that fall within the higher risk rating categories (*i.e.* 5, 6, and 7) are considered on NSCC's "Watch List", and may be subject to enhanced surveillance or additional margin charges, as permitted under NSCC's Rules. See Section 4 of Rule 2B and section I(B)(1) of Procedure XV of NSCC's Rules, *supra* Note 1 [sic].

determined based on the Member's rating on the credit risk rating matrix and the type of family-issued security submitted to NSCC. Fixed income securities that are family-issued securities would be charged a haircut rate of no less than 80% for firms that are rated 6 or 7 on the credit risk rating matrix, and no less than 40% for firms that are rated 5 on the credit risk rating matrix; and equity securities that are family-issued securities would be charged a haircut rate of 100% for firms that are rated 6 or 7 on the credit risk rating matrix, and no less than 50% for firms that are rated 5 on the credit risk rating matrix. NSCC would have the authority to adjust these haircut rates from time to time within these parameters as described in Procedure XV of NSCC's Rules without filing a proposed rule change with the Commission pursuant to section 19(b)(1) of the Act,<sup>6</sup> and the rules thereunder, or an advance notice with the Commission pursuant to section 806(e)(1) of the Clearing Supervision Act,<sup>7</sup> and the rules thereunder.

#### Anticipated Effect on and Management of Risk

As a central counterparty, NSCC occupies an important role in the securities settlement system by interposing itself between counterparties to financial transactions and thereby reducing the risk faced by participants and contributing to global financial stability. The effectiveness of a central counterparty's risk controls and the adequacy of its financial resources are critical to achieving these risk-reducing goals. In that context, NSCC continuously reviews its margining methodology in order to ensure the reliability of its margining in achieving the desired coverage. In order to be most effective, NSCC must take into consideration the risk characteristics specific to certain securities when margining those securities.

Among the various risks that NSCC considers when evaluating the effectiveness of its margining methodology are its counterparty risks and identification and mitigation of "wrong-way" risk, particularly specific wrong-way risk, defined as the risk that an exposure to a counterparty is highly likely to increase when the creditworthiness of that counterparty deteriorates.<sup>8</sup> NSCC has identified an

exposure to wrong-way risk when it acts as central counterparty to a Member with respect to positions in securities that are issued by that Member or that Member's affiliate. These positions are referred to as "family-issued securities." In the event that a Member with unsettled long positions in family-issued securities defaults, NSCC would close out those positions following a likely drop in the credit-worthiness of the issuer, possibly resulting in a loss to NSCC.

Therefore, the overall impact of NSCC's proposal, as described above, on risks presented by NSCC would be to reduce NSCC's exposure to this type of wrong-way risk by enhancing its margin methodology as applied to the family-issued securities of its Members that are on its Watch List, and present a heightened credit risk to the clearing agency or have demonstrated higher risk related to their ability to meet settlement. NSCC believes a reduction in its exposures to wrong-way risk through a margining methodology that more effectively capture [sic] the risk characteristics of these positions would contribute to the goal of maintaining financial stability in the event of a Member default and reduce systemic risk overall. Because NSCC Members that are on its Watch List present a heightened credit risk to the clearing agency or have demonstrated higher risk related to their ability to meet settlement, NSCC believes that this charge would more effectively capture the risk characteristics of these positions and can help mitigate NSCC's exposure to wrong-way risk.

NSCC will continue to evaluate its exposures to wrong-way risk, specifically wrong-way risk presented by family-issued securities, including by reviewing the impact of expanding the application of the proposed margining methodology to the family-issued securities of those Members that are not on the Watch List. NSCC is proposing to apply the enhanced margining methodology to the family-issued securities of Members that are on the Watch List at this time because, as stated above, these Members present a heightened credit risk to the clearing agency or have demonstrated higher risk related to their ability to meet settlement. As such, there is a clear and more urgent need to address NSCC's exposure to wrong-way risk presented by these firms' family-issued securities. However, any future change to the margining methodology as applied to the family-issued securities of Members

<sup>6</sup> 15 U.S.C. 78s(b)(1).

<sup>7</sup> 12 U.S.C. 5465(e)(1).

<sup>8</sup> See *Principles for financial market infrastructures*, issued by the Committee on Payment and Settlement Systems and the Technical Committee of the International Organization of

Securities Commissions 47 n.65 (April 2012), available at <http://www.bis.org/publ/cpss101a.pdf>.



that are not on the Watch List would be subject to a separate proposed rule change pursuant to section 19(b)(1) of the Act,<sup>9</sup> and the rules thereunder and an advance notice pursuant to section 806(e)(1) of the Clearing Supervision Act,<sup>10</sup> and the rules thereunder.

*Consistency with the Clearing Supervision Act.* The objectives and principles of section 805(b)(1) of the Clearing Supervision Act specify the promotion of robust risk management, promotion of safety and soundness, reduction of systemic risks and support of the stability of the broader financial system.<sup>11</sup> Rule 17Ad-22(b)(1), promulgated under the Act, requires NSCC to measure its credit exposures to its participants at least once a day and limit its exposures to potential losses from defaults by its participants under normal market conditions so that the operations of the clearing agency would not be disrupted and non-defaulting participants would not be exposed to losses that they cannot anticipate or control.<sup>12</sup> Rule 17Ad-22(b)(2), promulgated under the Act, requires NSCC to use risk-based models for setting margin requirements.<sup>13</sup>

By enhancing the margin methodology as applied to the family-issued securities of its Members that are on its Watch List the proposal would assist NSCC in collecting margin that more accurately reflects the risk characteristics of these securities, thereby limiting NSCC's exposures to potential losses from defaults by these Members under normal market conditions. By more closely capturing the risk characteristics of these positions, the proposed enhancement to the margining methodology would also assist NSCC in its continuous efforts to ensure the reliability and effectiveness of its risk-based margining methodology. In this way, the proposal would help NSCC, as a central counterparty, maintain effective risk controls, contributing to the goal of maintaining financial stability in the event of a Member default. Therefore, NSCC believes the proposal is consistent with the requirements of section 805(b)(1) of the Clearing Supervision Act and Rule 17Ad-22(b)(1) and (2), promulgated under the Act, cited above.

### III. Date of Effectiveness of the Advance Notice, and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. NSCC shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing NSCC with prompt written notice of the extension. The proposed change may be implemented in less than 60 days from the date the Advance Notice is filed, or the date further information requested by the Commission is received, if the Commission notifies NSCC in writing that it does not object to the proposed change and authorizes NSCC to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

NSCC shall post notice on its Web site of proposed changes that are implemented.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the Advance Notice is consistent with the Clearing Supervision Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NSCC-2015-803 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NSCC-2015-803. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the Advance Notice that are filed with the Commission, and all written communications relating to the Advance Notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's Web site (<http://dtcc.com/legal/sec-rule-filings.aspx>). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NSCC-2015-803 and should be submitted on or before October 8, 2015.

By the Commission.

**Brent J. Fields,**  
Secretary.

[FR Doc. 2015-23283 Filed 9-16-15; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31819; 812-14416]

### Pomona Investment Fund, et al.; Notice of Application

September 11, 2015.

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Notice of an application under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 18(c) and 18(i) of the Act and for an order pursuant to section 17(d) of the Act and rule 17d-1 under the Act.

**SUMMARY OF APPLICATION:** Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares ("Shares") and to impose asset-based distribution and service fees and contingent deferred sales loads ("CDSCs").

<sup>9</sup> 15 U.S.C. 78s(b)(1).

<sup>10</sup> 12 U.S.C. 5465(e)(1).

<sup>11</sup> 12 U.S.C. 5464(b)(1).

<sup>12</sup> 17 CFR 240.17Ad-22(b)(1).

<sup>13</sup> 17 CFR 240.17Ad-22(b)(2).

**APPLICANTS:** Pomona Investment Fund (the "Fund"), Pomona Management LLC (the "Adviser") and Voya Investments Distributor, LLC (the "Distributor").

**FILING DATES:** The application was filed on January 13, 2015, and amended on May 28, 2015 and August 10, 2015.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 6, 2015, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090; Applicants, c/o Michael Granoff, Pomona Management LLC, 780 3rd Avenue, New York, New York 10017.

**FOR FURTHER INFORMATION CONTACT:** Deepak T. Pai, Senior Counsel, at (202) 551-6876 or Mary Kay Frech, Branch Chief, at (202) 551-6821 (Division of Investment Management, Office of Investment Company Regulation).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

### Applicants' Representations

1. The Fund is a non-diversified closed-end management investment company registered under the Act and organized as a Delaware statutory trust. The Adviser, a Delaware limited liability company, is registered as an investment adviser under the Investment Advisers Act of 1940 and serves as investment adviser to the Fund. The Distributor, a broker-dealer registered under the Securities Exchange Act of 1934 ("1934 Act"), acts as principal underwriter of the Fund. The Distributor is under common control with the Adviser and is an

affiliated person, as defined in section 2(a)(3) of the Act, of the Adviser.

2. The Fund is engaged in a continuous public offering of Shares pursuant to its currently effective registration statement under the Securities Act of 1933 ("Securities Act").<sup>1</sup> The Fund's Shares are not listed on any securities exchange and are not traded on an over-the-counter system such as Nasdaq. Applicants do not expect that any secondary market will develop for the Fund's Shares.

3. The Fund currently issues a single class of Shares (the "Class A") at net asset value per share ("NAV"), subject to a front-end sales load and an asset-based distribution and services fee. The Fund proposes to offer multiple classes of Shares (each a "New Class") at NAV and may also charge a front-end sales load and an annual asset-based distribution and/or service fee. Each class of Shares would comply with the provisions of rule 12b-1 under the Act, as if the rule applied to closed-end management investment companies.

4. In order to provide a limited degree of liquidity to shareholders, the Fund may from time to time offer to repurchase Shares at their then-current NAV in accordance with rule 13e-4 under the 1934 Act. Repurchases of the Fund's Shares will be made at such times, in such amounts and on such terms as may be determined by the Fund's board of trustees (the "Board") in its sole discretion.<sup>2</sup> The Adviser expects that it will generally recommend to the Board that the Fund offer to repurchase Shares from shareholders quarterly.

5. Applicants request that the order also apply to any continuously-offered registered closed-end management investment company existing now or in the future for which the Adviser or the Distributor, or any entity controlling, controlled by, or under common control with the Adviser or the Distributor, acts as investment adviser or principal underwriter, and which provides periodic liquidity with respect to its Shares through tender offers conducted

<sup>1</sup> Shares of the Fund will only be sold to "accredited investors," as defined in Regulation D under the Securities Act.

<sup>2</sup> For Class A, a 2% early repurchase fee will be charged by the Fund with respect to any repurchase of Shares from a shareholder at any time prior to the one-year anniversary of the shareholder's purchase of the respective Shares. Any early repurchase fee, and the Fund's waiver of, scheduled variation in, or elimination of, such early repurchase fee, will equally apply to all shareholders of the Fund, regardless of class, consistent with section 18 of the Act and rule 18f-3 thereunder. To the extent the Fund determines to waive, impose scheduled variations of, or eliminate the early repurchase fee, it will do so consistently with the requirements of rule 22d-1 under the Act.

pursuant to rule 13e-4 under the 1934 Act (collectively with the Fund, the "Funds").<sup>3</sup>

6. Applicants represent that any asset-based distribution and/or service fees will comply with the provisions of rule 2830(d) of the Conduct Rules of the National Association of Securities Dealers, Inc. ("NASD Conduct Rule 2830").<sup>4</sup> Applicants also represent that the Fund will disclose in its prospectus, the fees, expenses and other characteristics of each class of Shares offered for sale by the prospectus, as is required for open-end, multiple class funds under Form N-1A. As if it were an open-end management investment company, the Fund will disclose fund expenses in shareholder reports, and disclose in its prospectus any arrangements that result in breakpoints in, or elimination of, sales loads.<sup>5</sup> Each Fund and the Distributor will also comply with any requirements that may be adopted by the Commission or FINRA regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements as if those requirements applied to the Fund and the Distributor.<sup>6</sup>

7. The Fund will allocate all expenses incurred by it among the various classes of Shares based on net assets of the Fund attributable to each such class, except that the NAV and expenses of each class will reflect the expenses associated with the distribution fees paid pursuant to a plan adopted in compliance with rule 12b-1 of that class (if any), shareholder servicing fees attributable to a particular class (as well as transfer agency fees, if any) and any other incremental expenses particular to that class. Expenses of the Fund allocated to a particular class of the

<sup>3</sup> Any Fund relying on this relief will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each investment company presently intending to rely on the requested order is listed as an applicant.

<sup>4</sup> Any references to NASD Conduct Rule 2830 include any successor or replacement Financial Industry Regulatory Authority ("FINRA") rule to NASD Conduct Rule 2830.

<sup>5</sup> See Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release).

<sup>6</sup> See Confirmation Requirements and Point of Sale Disclosure Requirements for Transactions in Certain Mutual Funds and Other Securities, and Other Confirmation Requirement Amendments, and Amendments to the Registration Form for Mutual Funds, Investment Company Act Release No. 26341 (Jan. 29, 2004) (proposing release).

Fund's Shares will be borne on a pro rata basis by each outstanding Share of that class. Applicants state that the Fund will comply with the provisions of rule 18f-3 under the Act as if it were an open-end investment company.

8. In the event the Funds impose a CDSC, applicants will comply with the provisions of rule 6c-10 under the Act, as if that rule applied to closed-end management investment companies. With respect to any waiver of, scheduled variation in, or elimination of the CDSC, the Fund will comply with the requirements of rule 22d-1 under the Act as if the Fund were an open-end investment company.

### Applicants' Legal Analysis

#### *Multiple Classes of Shares*

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of Shares of the Fund may be prohibited by section 18(c).

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that permitting multiple classes of the Fund may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

3. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Fund to issue multiple classes of Shares.

4. Applicants submit that the proposed allocation of expenses and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed system would permit the Fund to facilitate the distribution of Shares through diverse distribution channels and would provide investors with a broader choice of shareholder

options. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f-3 under the Act. Applicants state the Fund will comply with the provisions of rule 18f-3 as if it were an open-end investment company.

#### *CDSCs*

5. Applicants believe that the requested relief meets the standards of section 6(c) of the Act. Rule 6c-10 under the Act permits open-end investment companies to impose CDSCs, subject to certain conditions. Applicants state that any CDSC imposed by the Fund will comply with rule 6c-10 under the Act as if that rule were applied to closed-end investment companies. The Fund also will make all required disclosures in accordance with the requirements of Form N-1A concerning CDSCs. Applicants further state that, in the event the Fund imposes CDSCs, the Fund will apply the CDSCs (and any waivers, scheduled variations, or eliminations of the CDSCs) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d-1 under the Act.

#### *Asset-Based Service and/or Distribution Fees*

6. Section 17(d) of the Act and rule 17d-1 under the Act prohibit an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in which such registered company is a joint or a joint and several participant unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d-1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

7. Rule 17d-3 under the Act provides an exemption from section 17(d) and rule 17d-1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b-1 under the Act. Applicants request an order under section 17(d) and rule 17d-1 under the Act to permit the Fund to pay asset-based distribution and/or service fees. Applicants have

agreed to comply with rules 12b-1 and 17d-3 as if those rules applied to closed-end investment companies.

### Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Applicants will comply with the provisions of rules 6c-10, 12b-1, 17d-3, 18f-3 and 22d-1 under the Act, as amended from time to time or replaced, as if those rules applied to closed-end management investment companies, and will comply with the NASD Conduct Rule 2830, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-23288 Filed 9-16-15; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75903; File No. SR-C2-2015-023]

### Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fees Schedule

September 11, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that, on September 1, 2015 C2 Options Exchange, Incorporated (the "Exchange" or "C2") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (<http://www.c2exchange.com/Legal/>), at the Exchange's Office of the Secretary, and

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

at the Commission's Public Reference Room.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange proposes to amend its Fees Schedule. Specifically, the Exchange proposes to increase the Linkage Routing fee from \$0.65 per contract to \$0.70 per contract in addition to the applicable C2 taker fee. The Linkage Routing fee is assessed to all orders routed pursuant to the Options Order Protection and Locked/Crossed Market Plan. The purpose of the proposed change is to help offset the costs associated with routing orders through Linkage and paying the transaction fees for such executions at other exchanges.

#### 2. Statutory Basis

In particular, the Exchange's proposal to increase the Linkage Routing fee from \$0.65 per contract to \$0.70 per contract is reasonable because such increase will help offset the costs associated with routing orders through Linkage and paying the transaction fees for such executions at other exchanges. The Exchange believes the proposed increase is equitable and not unfairly discriminatory because it will apply to all orders routed via Linkage.

### B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the increase to the Linkage Routing Fee will apply equally to all orders routed via linkage and will help offset costs associated with routing orders via linkage. The Exchange does not believe that the proposed change to the Linkage Routing fee will impose any burden on

intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it only applies to trading on the Exchange [sic] and orders sent from the Exchange to other exchanges via Linkage. Should the proposed change make C2 a more attractive trading venue for market participants at other exchanges, such market participants may elect to become market participants at C2.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>3</sup> and paragraph (f) of Rule 19b-4<sup>4</sup> thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-C2-2015-023 on the subject line.

#### Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-C2-2015-023. This file number should be included on the

subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-C2-2015-023 and should be submitted on or before October 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>5</sup>

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-23287 Filed 9-16-15; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75904; File No. SR-BX-2015-056]

### Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 7018

September 11, 2015.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 1, 2015, NASDAQ OMX BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed

<sup>3</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f).

rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### **I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes to amend the fee schedule under Exchange Rule 7018(a) with respect to execution and routing of orders in securities priced at \$1 or more per share and to amend a credit under BX Rule 7018(e).

While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on September 1, 2015.

The text of the proposed rule change is also available on the Exchange's Web site at <http://nasdaqomxbx.cchwallstreet.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

### **II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

#### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

##### **1. Purpose**

The Exchange is proposing to amend the fee schedule under BX Rule 7018(a), relating to charges and credits provided for orders in securities priced and \$1 or more per share that execute on BX, as well as to reduce a credit provided in connection with the Retail Price Improvement ("RPI") program under BX Rule 7018(e).

Under BX Rule 7018(a), the Exchange provides credits to member firms that access certain levels of liquidity on BX per month. The Exchange is proposing to amend several of the credit tiers for orders that access liquidity (excluding orders with midpoint pegging and excluding orders that receive price improvement and execute against an

order with midpoint pegging), as well as modify the criteria for receiving certain of the credits. The Exchange also proposes a few minor changes made for the purposes of clarity and conformity.

Specifically, the Exchange proposes to add a new credit tier of \$0.0016 per share executed, which will be provided for orders that access liquidity, excluding orders with midpoint pegging<sup>3</sup> and orders that receive price improvement and execute against an order with midpoint pegging, entered by a member that accesses liquidity equal to or exceeding 0.15% of total consolidated volume<sup>4</sup> ("Consolidated Volume") during a month. Additionally, the Exchange proposes to amend the credit tier of \$0.0015 per share executed, which is provided for orders that access liquidity, excluding orders with midpoint pegging and orders that receive price improvement and execute against an order with midpoint pegging, entered by a member that accesses liquidity equal to or exceeding 0.10% of Consolidated Volume by reducing the Consolidated Volume threshold to 0.09%.

BX also proposes to eliminate the credit tier of \$0.0012 per share executed, which currently is provided for orders that access liquidity, excluding orders with midpoint pegging and orders that receive price improvement and execute against an order with midpoint pegging, entered by a member that accesses liquidity equal to or exceeding 0.10% [sic] of total Consolidated Volume during a month.

Next, the Exchange proposes to revise the criteria for a member to qualify for the credit tier of \$0.0008 per share executed, which will be provided for orders that access liquidity, excluding orders with midpoint pegging and orders that receive price improvement and execute against an order with midpoint pegging, entered by a member that accesses (rather than adds as is

<sup>3</sup> A Midpoint Peg order has its priced based upon the national best bid and offer, excluding the effect that the Midpoint Peg Order itself has on the inside bid or inside offer. Primary Pegged Orders with an offset amount and Midpoint Pegged Orders will never be displayed. A Midpoint Pegged Order may be executed in sub-pennies if necessary to obtain a midpoint price. A new timestamp is created for the order each time it is automatically adjusted.

<sup>4</sup> Consolidated Volume is defined as the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member's trading activity, expressed as a percentage of or ratio to Consolidated Volume, the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member's trading activity. See Rule 7018(a).

currently stated) liquidity equal to or exceeding 0.05% (rather than 0.02% that is the current level), of total Consolidated Volume during a month.

BX is also proposing to slightly increase the charge for providing liquidity through the NASDAQ OMX BX Equities System ("System") for a displayed order entered by a member that (i) adds liquidity equal to or exceeding 0.25% of total Consolidated Volume during a month; and (ii) adds and accesses liquidity equal to or exceeding 0.50% of total Consolidated Volume during a month from \$0.0014 per share executed to \$0.0016 per share executed.

Currently, a firm may become a Qualified Market Maker ("QMM") by being a member that provides through one or more of its BX System MPIDs more than 0.15% of Consolidated Volume during the month. For a member qualifying under this method, the member must have at least one Qualified MPID, that is, an MPID through which, for at least 200 securities, the QMM quotes at the national best bid and offer ("NBBO") an average of at least 50% of the time during regular market hours (9:30 a.m. through 4:00 p.m.) during the month. The Exchange is proposing to increase the Consolidated Volume requirement from 0.15% to 0.20% during the month and to eliminate the additional requirement that the member must also provide an average daily volume of 1.5M shares or more of non-displayed liquidity during the month.

Lastly, the Exchange is proposing to amend a credit provided under the Retail Price Improvement ("RPI") program in BX Rule 7018(e). The Exchange's RPI program provides incentives to member firms (or a division thereof) approved by the Exchange to participate in the program (a "Retail Member Organization") to submit designated "Retail Orders"<sup>5</sup> for the purpose of seeking price improvement. The Exchange is proposing to decrease the credit of \$0.0002 per share executed to \$0.0000 per share executed that is provided for a Retail Order that receives price improvement (when the accepted price of an order is different than the

<sup>5</sup> A Retail Order is defined in BX Rule 4780(a)(2), in part, as "an agency or riskless principal order that satisfies the criteria of FINRA Rule 5320.03, that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price (except in the case that a market order is changed to a marketable limit order) or side of market and the order does not originate from a trading algorithm or any other computerized methodology."

executed price of an order) and accesses non-RPI order with midpoint pegging.

## 2. Statutory Basis

BX believes that the proposed rule change is consistent with the provisions of section 6 of the Act,<sup>6</sup> in general, and with sections 6(b)(4) and 6(b)(5) of the Act,<sup>7</sup> in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the new and amended credit tiers for orders that access liquidity (excluding orders with midpoint pegging and excluding orders that receive price improvement and execute against an order with midpoint pegging), as well as the modified criteria for receiving certain of the credits based on Consolidated Volume together, as well as related clarifying changes, under BX Rule 7018(a) are reasonable because they provide additional opportunities for market participants to receive credits for participation on BX.

Specifically, the Exchange is proposing a new of [sic] \$0.0016 per share executed credit tier, which requires liquidity accessed of 0.15% or more of Consolidated Volume during the month. The Exchange is also proposing a [sic] eliminate the \$0.0012 per share executed credit tier, which currently requires liquidity accessed of 0.05% or more of Consolidated Volume during the month. Additionally, the Exchange is modifying the existing credit tier of \$0.0008 per share executed by increasing the minimum total Consolidated Volume required from 0.02% to 0.05% and making it applicable to members that access rather than add liquidity. As such, the Exchange is generally providing increased credits for member firms that remove increasing amounts of liquidity from the Exchange. With respect to the accesses Consolidated Volume

requirement to receive the \$0.0008 credit, the Exchange believes this is reasonable because for firms to receive the increased credit they must remove a certain amount of Consolidated Volume, which will improve market quality for all participants.

The Exchange believes that the proposed credits noted above are equitably allocated and are not unfairly discriminatory as they are provided to all member firms that achieve the minimum level of Consolidated Volume required by the tier, with the member firms that remove the greatest level of Consolidated Volume receiving the greatest credit. Additionally, the Exchange believes that this proposed rule change being changed from a member that adds liquidity to being applicable to a member that accesses liquidity is reasonable because the Exchange desires to further incentivize member firms to participate in the Exchange by removing liquidity.

The Exchange believes that elimination of the \$0.0012 per share executed credit tier is reasonable because the Exchange has added a \$0.0016 credit tier per share executed, discussed above, and the Exchange desires to further incentivize member firms to participate in the Exchange by removing liquidity, generally. The Exchange believes that the proposed addition of the \$0.0016 credit tier per share executed and elimination of the \$0.0012 per share executed credit tier, are both an equitable allocation and are not unfairly discriminatory because the \$0.0012 per share executed credit tier is a no longer needed incentive for [sic] market participant and member firms will continue to have the opportunity to qualify for a higher credit based on their participation in BX by removing liquidity.

Additionally, the Exchange believes reducing the Consolidated Volume threshold for the credit tier of \$0.0015 per share executed, which is provided for orders that access liquidity (excluding orders with midpoint pegging and orders that receive price improvement and execute against an order with midpoint pegging) and that is entered by a member that accesses liquidity, from equal or exceeding 0.10% of Consolidated Volume to 0.09%, is reasonable because it will make it easier for members to receive a rebate at that level and encourage market participant activity and will also support price discovery and liquidity provision. The Exchange also believes this proposed rule change is an equitable allocation and is not unfairly discriminatory because it will apply

uniformly to all member firms that so qualify.

The Exchange believes that the proposed change to slightly increase the charge assessed a member for entering a displayed order is reasonable because the exchange must balance the cost of credits provided for orders removing liquidity and the desire to provide QMMs with incentives to provide displayed orders. The Exchange notes that the proposed charge continues to be lower than the default charge assessed for all other displayed orders that do not otherwise qualify for a lower charge, and as such continues to act as an incentive to market participants to provide such liquidity. The Exchange believes that the proposed change is both equitably allocated and is not unfairly discriminatory because the slightly increased charge applies uniformly to all member firms that previously had qualified to receive such a credit.

The Exchange believes that the proposed increase to the monthly Consolidated Volume requirement from 0.15% to 0.20% for a firm to become a QMM is reasonable because member firms are being required to provide through one or more of its BX System MPIDs increased Consolidated Volume to qualify, which will increase liquidity in the market overall. Additionally, for a member qualifying under this method, the member must have at least one Qualified MPID, that is, an MPID through which, for at least 200 securities, the QMM quotes at the NBBO an average of at least 50% of the time during regular market hours (9:30 a.m. through 4:00 p.m.) during the month. BX also believes it is reasonable to eliminate the additional requirement that the member must also provide an average daily volume of 1.5M shares or more of non-displayed liquidity during the month because the Exchange believes removing this criteria will allow QMMs to focus on making better markets.

The Exchange also believes that the proposed increase to the monthly Consolidated Volume requirement from 0.15% to 0.20% for a firm to become a QMM is both equitably allocated and is not unfairly discriminatory because it [sic] the slightly higher Consolidated Volume requirement applies uniformly to firms seeking to qualify as a QMM. The Exchange also believes that the proposed changes to the criteria for a firm to qualify as a QMM expands the opportunity for firms to qualify as a QMM and further perfects the mechanism of a free and open market by making it easier to qualify for this beneficial, market improving program

<sup>6</sup> 15 U.S.C. 78f.

<sup>7</sup> 15 U.S.C. 78f(b)(4) and (5).

and bolster displayed liquidity by eliminating the additional requirement that the member must also provide an average daily volume of 1.5M shares or more of non-displayed liquidity during the month.

BX believes that the proposed change to decrease the credit of \$0.0002 per share executed to \$0.0000 per share executed that is provided for a Retail Order that receives price improvement (when the accepted price of an order is different than the executed price of an order) and accesses non-RPI order with midpoint pegging is reasonable because this incentive is no longer needed to improve the market for retail order flow. Also, the Exchange must continually adjust its incentives to remain competitive with other exchanges. The Exchange also believes the reduced credit is equitably allocated and is not unfairly discriminatory because it applies uniformly to all firms.

Finally, BX notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, BX must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. The changes reflect this environment because although they reflect changes to both credits and charges, with the price increases being minor, while [sic] the amended credits are designed overall to incentivize changes in market participant behavior to the benefit of the market overall.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.<sup>8</sup> BX notes that it operates in a highly competitive market in which market participants can readily favor dozens of different competing exchanges and alternative trading systems if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, BX must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing

practices, BX believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the modification to the fee schedule, as well as modifications to the criteria to become a QMM, do not impose a burden on competition because it is optional and is the subject of competition from other exchanges. The Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. Moreover, because there are numerous competitive alternatives to the use of the Exchange, it is likely that BX will lose market share as a result of the changes if they are unattractive to market participants.

Accordingly, BX does not believe that the proposed rule change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing change has become effective pursuant to section 19(b)(3)(A) of the Act<sup>9</sup> and paragraph (f) of Rule 19b-4<sup>10</sup> thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-BX-2015-056 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2015-056. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2015-056, and should be submitted on or before October 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>11</sup>

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-23289 Filed 9-16-15; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>8</sup> 15 U.S.C. 78f(b)(8).

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 240.19b-4(f).

<sup>11</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75901; File No. SR-NYSEArca-2015-77]

### Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of the Following Under NYSE Arca Equities Rule 8.600: First Trust Heitman Global Prime Real Estate ETF

September 11, 2015.

Pursuant to section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the “Act”)<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that, on August 28, 2015, NYSE Arca, Inc. (the “Exchange” or “NYSE Arca”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under NYSE Arca Equities Rule 8.600 (“Managed Fund Shares”): First Trust Heitman Global Prime Real Estate ETF. The text of the proposed rule change is available on the Exchange’s Web site at [www.nyse.com](http://www.nyse.com), at the principal office of the Exchange, and at the Commission’s Public Reference Room.

#### II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

#### A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange proposes to list and trade the shares (“Shares”) of the following under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares<sup>4</sup> on the Exchange: First Trust Heitman Global Prime Real Estate ETF (“Fund”).<sup>5</sup> The Shares will be offered by First Trust Exchange-Traded Fund IV (the “Trust”), which is organized as a Massachusetts business trust and is registered with the Commission as an open-end management investment company.<sup>6</sup> The investment adviser to the Fund will be First Trust Advisors L.P. (the “Adviser” or “First Trust”). Heitman Real Estate Securities LLC (“Sub-Adviser”) will be the sub-adviser to the Fund. Heitman International Real Estate Securities HK Limited and Heitman International Real Estate Securities GmbH (“Sub-Sub-Advisers”) will be the sub-sub-advisers to the Fund. First Trust Portfolios L.P. (the “Distributor”) will be the principal underwriter and distributor of the

<sup>4</sup> A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a-1) (“1940 Act”) organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

<sup>5</sup> The Commission has previously approved listing and trading on the Exchange of a number of actively managed funds under Rule 8.600. *See, e.g.*, Securities Exchange Act Release Nos. 57801 (May 8, 2008), 73 FR 27878 (May 14, 2008) (SR-NYSEArca-2008-31) (order approving Exchange listing and trading of twelve actively-managed funds of the WisdomTree Trust); 60460 (August 7, 2009), 74 FR 41468 (August 17, 2009) (SR-NYSEArca-2009-55) (order approving listing of Dent Tactical ETF); 62502 (July 15, 2010), 75 FR 42471 (July 21, 2010) (SR-NYSEArca-2010-57) (order approving listing of AdvisorShares WCM/BNY Mellon Focused Growth ADR ETF); 69251 (March 28, 2013), 78 FR 20162 (April 3, 2013) (SR-NYSEArca-2013-14) (order approving listing of Cambria Shareholder Yield ETF).

<sup>6</sup> The Trust is registered under the 1940 Act. On August 27, 2015, the Trust filed with the Commission an amendment to its registration statement on Form N-1A under the Securities Act of 1933 (“1933 Act”) and under the 1940 Act relating to the Fund (File Nos. 333-174332 and 811-22559) (“Registration Statement”). The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 28468 (October 27, 2008) (File No. 812-13477) (“Exemptive Order”).

Fund’s Shares. BNY Mellon Investment Servicing (US) Inc. (the “Administrator” or “BNY”) will serve as administrator, custodian and transfer agent for the Fund.

Commentary .06 to Rule 8.600 provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a “fire wall” between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio. In addition, Commentary .06 further requires that personnel who make decisions on the open-end fund’s portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund’s portfolio.<sup>7</sup> Commentary .06 to Rule 8.600 is similar to Commentary .03(a)(i) and (iii) to NYSE Arca Equities Rule 5.2(j)(3); however, Commentary .06 in connection with the establishment of a “fire wall” between the investment adviser and the broker-dealer reflects the applicable open-end fund’s portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser, the Sub-Adviser and the Sub-Sub-Advisers are not broker-dealers, but the Adviser is affiliated with First Trust Portfolios L.P., a broker-dealer, and the Sub-Adviser and the Sub-Sub-Advisers are affiliated with Heitman Securities LLC and Heitman UK Limited, each a broker-dealer. The Adviser, the Sub-Adviser and the Sub-Sub-Advisers have each implemented fire walls with respect to

<sup>7</sup> An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the “Advisers Act”). As a result, the Adviser, Sub-Adviser and Sub-Sub-Advisers and their related personnel are subject to the provisions of Rule 204A-1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A-1 under the Advisers Act. In addition, Rule 206(4)-7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.



their respective broker-dealer affiliate(s) regarding access to information concerning the composition and/or changes to the portfolio. In the event (a) the Adviser, the Sub-Adviser or either Sub-Sub-Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser, sub-adviser or sub-sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

#### Principal Investments

According to the Registration Statement, under normal market conditions,<sup>8</sup> the Fund will seek to achieve its investment objective by investing at least 80% of its net assets in U.S. and non-U.S. exchange-traded real estate securities, which includes real estate investment trusts (“REITs”), real estate operating companies (“REOCs”)<sup>9</sup> and common stocks or “Depository Receipts” of companies primarily engaged in the real estate industry (collectively, “Real Estate Securities”).<sup>10</sup> The Fund may invest in

<sup>8</sup> The term “under normal market conditions” includes, but is not limited to, the absence of extreme volatility or trading halts in the equity markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

<sup>9</sup> According to the Registration Statement, REITs and REOCs are companies that own and most often actively manage income-generating commercial real estate. Some REITs and REOCs make or invest in loans and other obligations that are secured by real estate collateral. REITs distribute most of their income to investors and therefore receive special tax considerations and are typically a highly liquid method of investing in real estate. REOCs reinvest most income into their operations and therefore do not get the same benefits of lower corporate taxation that are a common characteristic of REITs.

REITs and REOCs are generally categorized as equity, mortgage or hybrid in nature. Equity REITs and REOCs invest in and own properties, and thus are responsible for the equity or value of their real estate assets. Their revenues come principally from their properties’ rents. Mortgage REITs and REOCs deal in investment and ownership of property mortgages. These companies loan money for mortgages to owners of real estate or purchase existing mortgages or mortgage-backed securities. Their revenues are generated primarily by the interest that they earn on the mortgage loans. Hybrid REITs and REOCs combine the investment strategies of equity REITs and REOCs and mortgage REITs and REOCs by investing in both properties and mortgages.

<sup>10</sup> The Fund’s investments in Real Estate Securities and certain non-U.S. companies (as

non-U.S. securities (including securities of certain non-U.S. companies), which include securities issued or guaranteed by companies organized under the laws of countries other than the United States (including emerging markets). The Fund may invest in restricted securities (Rule 144A securities). During the initial invest-up period, the Fund may depart from its principal investment strategies and invest a larger amount or all of its assets in cash equivalents or it may hold cash.

The Fund will seek to provide investors access to a real estate securities portfolio consisting of shares of public companies with professional management teams that own top-tier, prime properties in the world’s dominant cities. The Fund’s portfolio managers will select Real Estate Securities by implementing an investment process that is outlined below.

As a first screen, all securities in the Global Industry Classification Standard (GICS®) real estate industry will be filtered for size and liquidity, based upon free float market capitalization for size and a threshold daily trading volume for liquidity. The purpose of these quantitative screens will be to ensure that the investment strategy can be executed in a buy and hold manner without undue stress.

In the second stage, screening will be conducted using a combination of qualitative and quantitative tools. From a qualitative perspective, portfolio analysts will maintain a close coverage

referred to below under “Non-Principal Investments”) may be in the form of Depository Receipts, which include American Depository Receipts (“ADRs”), Global Depository Receipts (“GDRs”) and European Depository Receipts (“EDRs”). ADRs are receipts typically issued by an American bank or trust company that evidence ownership of underlying securities issued by a foreign corporation. EDRs are receipts issued by a European bank or trust company evidencing ownership of securities issued by a foreign corporation. GDRs are receipts issued throughout the world that evidence a similar arrangement. ADRs, EDRs and GDRs may trade in foreign currencies that differ from the currency the underlying security for each ADR, EDR or GDR principally trades in. Global shares are the actual (ordinary) shares of a non-U.S. company which trade both in the home market and the United States. Generally, ADRs, in registered form, are designed for use in the U.S. securities markets. EDRs, in registered form, are used to access European markets. GDRs, in registered form, are tradable both in the United States and in Europe and are designed for use throughout the world. All Depository Receipts in which the Fund invests will be traded on a U.S. or a non-U.S. exchange. Not more than 10% of the net assets of the Fund in the aggregate invested in equity securities (other than non-exchange-traded investment company securities) shall consist of equity securities whose principal market is not a member of the Intermarket Surveillance Group (“ISG”) or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement. See note 27, *infra*.

universe and will be in regular contact with the management of potential investments, regularly visiting properties and markets to see as many of the properties in person as is reasonably possible. In addition to their own research, the analysts will have access to other property experts and sell-side professionals within their organization who also evaluate their companies. The task of the analysts will be to identify those companies that meet the test of two quantitative filters. The issuers in which the Fund will invest must generally have (1) more than 75% of their gross asset value in prime markets and (2) more than 50% of their assets under management in prime assets.

According to the Registration Statement, executing the quantitative and qualitative screens will produce a universe of companies that meet the size, liquidity, and concentration in prime markets and assets tests. From this universe of prime assets and markets, the portfolio managers’ regional teams will construct a high conviction portfolio that offers the best expected risk/return profile of the names within the prime universe. Consideration for inclusion in the portfolio includes the issuer’s balance sheet, assessment of management’s acumen and the projected long-term growth profile of the company.

#### Non-Principal Investments

According to the Registration Statement, while the Fund, under normal circumstances, will invest at least 80% of its net assets in securities and financial instruments described above, the Fund may invest up to 20% of its net assets in the following securities and financial instruments.

Equity securities, other than Real Estate Securities, in which the Fund will invest may include common and preferred stocks. The Fund may also invest in warrants and rights related to common stocks. The Fund may also invest in preferred equity securities.

The Fund may invest in exchange-traded pooled investment vehicles,<sup>11</sup> open-end or closed-end investment company securities, other exchange-traded funds (“ETFs”)<sup>12</sup> and business

<sup>11</sup> Pooled investment vehicles include Trust Issued Receipts (as described in NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (as described in NYSE Arca Equities Rule 8.201); Currency Trust Shares (as described in NYSE Arca Equities Rule 8.202); Commodity Index Trust Shares (as described in NYSE Arca Equities Rule 8.203); and Trust Units (as described in NYSE Arca Equities Rule 8.500).

<sup>12</sup> The ETFs in which the Fund may invest will be registered under the 1940 Act and include

development companies that invest primarily in securities of the types in which the Fund may invest directly.

The Fund may invest in companies that are considered to be “passive foreign investment companies” (“PFICs”), which are generally certain non-U.S. corporations that receive at least 75% of their annual gross income from passive sources (such as interest, dividends, certain rents and royalties or capital gains) or that hold at least 50% of their assets in investments producing such passive income.

Fixed income investments and cash equivalents held by the Fund may include, the types of investments set forth below:

(1) The Fund may invest in U.S. government securities, including bills, notes and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. government agencies or instrumentalities.

(2) The Fund may invest in certificates of deposit issued against funds deposited in a bank or savings and loan association. Such certificates are for a definite period of time, earn a specified rate of return and are normally negotiable. If such certificates of deposit are non-negotiable, they will be considered illiquid securities and be subject to the Fund’s 15% restriction on investments in illiquid assets. The Fund may only invest in certificates of deposit issued by U.S. banks with at least \$1 billion in assets.

(3) The Fund may invest in bankers’ acceptances, which are short-term credit instruments used to finance commercial transactions.<sup>13</sup>

(4) The Fund may invest in repurchase agreements, which involve purchases of debt securities with counterparties that are deemed by the Adviser to present acceptable credit risks. In such an action, at the time the Fund purchases the security, it simultaneously agrees to resell and redeliver the security to the seller, who

Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Portfolio Depository Receipts (as described in NYSE Arca Equities Rule 8.100); and Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600). Such ETFs all will be listed and traded in the U.S. on registered exchanges. While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged or inverse leveraged (e.g., 2X, -2X, 3X or -3X) ETFs.

<sup>13</sup> Generally, an acceptance is a time draft drawn on a bank by an exporter or an importer to obtain a stated amount of funds to pay for specific merchandise. The draft is then “accepted” by a bank that, in effect, unconditionally guarantees to pay the face value of the instrument on its maturity date. The acceptance may then be held by the accepting bank as an asset or it may be sold in the secondary market at the going rate of interest for a specific maturity.

also simultaneously agrees to buy back the security at a fixed price and time.

(5) The Fund may invest in bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest.

(6) The Fund may invest in commercial paper, which are short-term unsecured promissory notes, including variable rate master demand notes issued by corporations to finance their current operations. Master demand notes are direct lending arrangements between the Fund and a corporation.

(7) The Fund may invest in shares of money market funds, as consistent with its investment objective and policies.

The Fund may invest in non-U.S. fixed income securities (including securities of certain non-U.S. companies), which include securities issued or guaranteed by companies organized under the laws of countries other than the United States (including emerging markets), securities issued or guaranteed by foreign, national, provincial, state, municipal or other governments with taxing authority or by their agencies or instrumentalities and debt obligations of supranational governmental entities such as the World Bank or European Union.<sup>14</sup> Non-U.S. securities may also include U.S. dollar-denominated debt obligations, such as “Yankee Dollar” obligations, of foreign issuers and of supra-national government entities. Yankee Dollar obligations are U.S. dollar-denominated obligations issued in the U.S. capital markets by foreign corporations, banks and governments. Foreign securities also may be traded on foreign securities exchanges.

The Fund may from time to time purchase securities on a “when-issued” or other delayed-delivery basis.

The Fund may invest in forward foreign currency exchange contracts. Forward foreign currency exchange contracts may be used to protect the value of the Fund’s portfolio against uncertainty in the level of future currency exchange rates.<sup>15</sup> The Fund will only enter into transactions in forward foreign currency exchange contracts with counterparties that the Adviser and/or the Sub-Adviser (or a Sub-Sub-Adviser) reasonably believes

<sup>14</sup> Under normal market conditions, the Fund will generally seek to invest in corporate bond issuances that have at least \$100,000,000 par amount outstanding in developed countries and at least \$200,000,000 par amount outstanding in emerging market countries.

<sup>15</sup> The Fund may also enter into foreign currency transactions on a spot (*i.e.*, cash) basis.

are capable of performing under the applicable agreement.<sup>16</sup>

#### Investment Restrictions

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including Rule 144A securities and non-negotiable certificates of deposit deemed illiquid by the Adviser.<sup>17</sup> The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund’s net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.<sup>18</sup>

The Fund intends to qualify annually and to elect to be treated as a regulated

<sup>16</sup> The Fund will seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser and/or the Sub-Adviser (or a Sub-Sub-Adviser) will evaluate the creditworthiness of counterparties on an ongoing basis. In addition to information provided by credit agencies, the Adviser’s and/or Sub-Adviser’s (or Sub-Sub-Adviser’s) analysis will evaluate each approved counterparty using various methods of analysis and may consider the Adviser’s and/or Sub-Adviser’s (or Sub-Sub-Adviser’s) past experience with the counterparty, its known disciplinary history and its share of market participation.

<sup>17</sup> In reaching liquidity decisions, the Adviser may consider the following factors: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace trades (*e.g.*, the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

<sup>18</sup> The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also*, Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding “Restricted Securities”); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N-1A). A fund’s portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a-7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the 1933 Act).

investment company (“RIC”) under the Internal Revenue Code.<sup>19</sup>

The Fund’s investments will be consistent with the Fund’s investment objective and will not be used to enhance leverage. That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund’s investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.*, 2Xs and 3Xs) of the Fund’s broad-based securities market index (as defined in Form N-1A).

#### Creations and Redemptions

According to the Registration Statement, the Fund will issue and redeem Shares on a continuous basis, at net asset value (“NAV”), only in large specified blocks each consisting of 50,000 Shares (each such block of Shares, called a “Creation Unit”). The Creation Units will be issued and redeemed for securities in which the Fund will invest, cash or both securities and cash.

The consideration for purchase of Creation Units of the Fund may consist of (i) cash in lieu of all or a portion of a basket of securities (“Deposit Securities”), and/or (ii) a designated portfolio of securities generally held by the Fund as determined by First Trust per each Creation Unit (“Fund Securities”) and generally an amount of cash (the “Cash Component”). Together, the Deposit Securities and the Cash Component (including the cash in lieu amount) constitute the “Fund Deposit,” which represents the minimum initial and subsequent investment amount for a Creation Unit of the Fund.

BNY, through the National Securities Clearing Corporation (“NSCC”), will make available on each business day, prior to the opening of business of the New York Stock Exchange (“NYSE”) (currently 9:30 a.m., Eastern time (“E.T.”)), the list of the names and the required number of shares of each Deposit Security to be included in the current Fund Deposit (based on information at the end of the previous business day) for the Fund.

In addition to the list of names and numbers of securities constituting the current Deposit Securities of a Fund Deposit, BNY, through the NSCC, also will make available on each business day, the estimated Cash Component, effective through and including the previous business day, per Creation Unit of the Fund.

All orders to create or redeem Creation Units must be received by the transfer agent no later than the closing

time of the regular trading session on the NYSE (ordinarily 4:00 p.m., E.T.) in each case on the date such order is placed in order for creation or redemption of Creation Units to be effected based on the NAV of Shares of the Fund as next determined on such date after receipt of the order in proper form.

Fund Shares may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Fund through the transfer agent and only on a business day. The Fund will not redeem Shares in amounts less than a Creation Unit. With respect to the Fund, BNY, through the NSCC, will make available prior to the opening of business on the NYSE (currently 9:30 a.m., E.T.) on each business day, the identity of the Fund Securities that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form on that day. Fund Securities received on redemption may not be identical to Deposit Securities that are applicable to creations of Creation Units.

Unless cash redemptions are available or specified for the Fund, the redemption proceeds for a Creation Unit generally will consist of Fund Securities—as announced on the business day of the request for redemption received in proper form—plus or minus cash in an amount equal to the difference between the NAV of the Fund Shares being redeemed, as next determined after a receipt of a request in proper form, and the value of the Fund Securities, less the applicable redemption transaction fee as described in the Registration Statement and, if applicable, any operational processing and brokerage costs, transfer fees or stamp taxes.<sup>20</sup>

The Fund may suspend the right of redemption for the Fund only under the following circumstances: (i) When the NYSE is closed (other than weekends and holidays) or trading is restricted; (ii) when trading in the markets normally utilized is restricted, or when an emergency exists as determined by the Commission so that disposal of the Fund’s investments or determination of its net assets is not reasonably practicable; or (iii) during any period when the Commission may permit.

#### Net Asset Value

The Fund’s NAV will be determined as of the close of regular trading on the

NYSE on each day the NYSE is open for trading. If the NYSE closes early on a valuation day, the NAV will be determined as of that time. NAV per Share will be calculated for the Fund by taking the value of the Fund’s total assets, including interest or dividends accrued but not yet collected, less all liabilities, including accrued expenses and dividends declared but unpaid, and dividing such amount by the total number of Shares outstanding. The result, rounded to the nearest cent, will be the NAV per Share. All valuations will be subject to review by the Board of Trustees of the Trust (“Trust Board”) or its delegate.

The Fund’s investments will be valued daily at market value or, in the absence of market value with respect to any investments, at fair value. Market value prices represent last sale or official closing prices from a national securities exchange or foreign exchange (*i.e.*, a regulated market) and will primarily be obtained from third party pricing services (each, a “Pricing Service”). Fair value prices represent any prices not considered market value prices and will either be obtained from a Pricing Service or determined by the pricing committee of the Adviser (the “Pricing Committee”),<sup>21</sup> in accordance with valuation procedures (which may be revised from time to time) adopted by the Trust Board (the “Valuation Procedures”), and in accordance with provisions of the 1940 Act. The information summarized below is based on the Valuation Procedures as currently in effect.

Under normal circumstances, daily calculation of the NAV will utilize the last closing sale price of each security held by the Fund at the close of the market on which such security is principally traded. In determining NAV, portfolio securities for the Fund will be valued as follows:

(1) Common stocks and other equity securities listed on any national or foreign exchange other than The NASDAQ Stock Market (“NASDAQ”) and the London Stock Exchange Alternative Investment Market (“AIM”) will be valued at the last sale price on the business day as of which such value is being determined. Securities listed on NASDAQ or AIM will be valued at the official closing price on the business day as of which such value is being determined. Portfolio securities traded on more than one securities exchange will be valued at the last sale price or

<sup>20</sup> The Adviser represents that, to the extent the Trust effects the creation or redemption of Shares in cash, such transactions will be effected in the same manner for all Authorized Participants.

<sup>21</sup> The Pricing Committee will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the Fund’s portfolio.

<sup>19</sup> 26 U.S.C. 851.

official closing price, as applicable, on the business day as of which such value is being determined at the close of the exchange representing the principal market for such securities.

(2) Securities traded in the over-the-counter (“OTC”) market will be fair valued at the mean of the most recent bid and the asked price, if available, and otherwise at their closing bid price.

(3) Forward foreign currency contracts will be fair valued at the current day’s interpolated foreign exchange rate, as calculated using the current day’s spot rate, and the 30-, 60-, 90- and 180-day forward rates provided by a Pricing Service or by certain independent dealers in such contracts.

(4) Corporate bonds, corporate notes and other debt securities will be fair valued on the basis of valuations provided by dealers who make markets in such securities or by a Pricing Service approved by the Trust Board, which may use the following valuation inputs when available: (i) Benchmark yields; (ii) reported trades; (iii) broker/dealer quotes; (iv) issuer spreads; (v) benchmark securities; (vi) bids and offers; and (vii) reference data including market research publications.

(5) Fixed income and other debt securities having a remaining maturity of 60 days or less when purchased will be fair valued at cost adjusted for amortization of premiums and accretion of discounts (amortized cost), provided the Adviser’s Pricing Committee has determined that the use of amortized cost is an appropriate reflection of fair value given market and issuer specific conditions existing at the time of the determination.

(6) Repurchase agreements will be valued as follows. Overnight repurchase agreements will be fair valued at cost. Term repurchase agreements (*i.e.*, those whose maturity exceeds seven days) will be fair valued by First Trust at the average of the bid quotations obtained daily from at least two recognized dealers.

Certain securities may not be able to be priced by pre-established pricing methods. Such securities may be valued by the Trust Board or its delegate, the Adviser’s Pricing Committee, at fair value. These securities generally include but are not limited to, restricted securities (securities that may not be publicly sold without registration under the 1933 Act) for which a Pricing Service is unable to provide a market price; securities whose trading has been formally suspended; a security whose market or fair value price is not available from a pre-established pricing source; a security with respect to which an event has occurred that is likely to

materially affect the value of the security after the market has closed but before the calculation of Fund’s NAV (as may be the case in foreign markets on which the security is primarily traded) or is likely to make it difficult or impossible to obtain a reliable market quotation; and a security whose price, as provided by the Pricing Service, does not reflect the security’s fair value.

The value of any portfolio security held by the Fund for which market quotations are not readily available will be determined by First Trust in a manner that most fairly reflects fair market value of the security on the valuation date, based on a consideration of all available information.

General factors for determining fair value include, without limitation, the fundamental business data relating to the issuer or borrower; and an evaluation of the forces which influence the market in which these securities are purchased and sold. Specific factors for determining fair value may include, without limitation, type of holding; financial statements of the borrower; cost at date of purchase; size of holding; credit quality and cash flow of issuer, based on the Pricing Committee’s or external analysis; information as to any transactions in or offers for the holding; price and extent of public trading in similar securities (or equity securities) of the issuer/borrower, or comparable companies; coupon payments; quality, value and saleability of collateral securing the loan; business prospects of the issuer/borrower, including any ability to obtain money or resources from a parent or affiliate; the Pricing Committee’s and/or the market’s assessment of the borrower’s management; prospects for the borrower’s industry, and multiples (of earnings and/or cash flow) being paid for similar businesses in that industry; borrower’s competitive position within the industry; borrower’s ability to access additional liquidity through public and/or private markets; and other relevant factors.

#### Availability of Information

The Fund’s Web site ([www.ftportfolios.com](http://www.ftportfolios.com)), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Fund’s Web site will include additional quantitative information updated on a daily basis, including, for the Fund, (1) daily trading volume, the prior business day’s reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (the “Bid/

Ask Price”),<sup>22</sup> and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Core Trading Session (9:30 a.m. to 4:00 p.m. E.T.) on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio as defined in NYSE Arca Equities Rule 8.600(c)(2) that will form the basis for the Fund’s calculation of NAV at the end of the business day.<sup>23</sup>

On a daily basis, the Fund will disclose on the Fund’s Web site the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding); the identity of the security, commodity, index or other asset or instrument underlying the holding, if any; maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund’s portfolio. The Web site information will be publicly available at no charge.

In addition, a basket composition file, which will include the security names and share quantities required to be delivered in exchange for the Fund’s Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the NYSE via the NSCC. The basket will represent one Creation Unit of the Fund.

Information regarding the intra-day value of the Shares of the Fund, which is the Portfolio Indicative Value (“PIV”) as defined in NYSE Arca Equities Rule 8.600 (c)(3), will be widely disseminated every 15 seconds throughout the Exchange’s Core Trading Session by one or more major market data vendors.<sup>24</sup> The PIV should not be viewed as a “real-time” update of the

<sup>22</sup> The Bid/Ask Price of Shares of the Fund will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund’s NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

<sup>23</sup> Under accounting procedures followed by the Fund, trades made on the prior business day (“T”) will be booked and reflected in NAV on the current business day (“T+1”). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

<sup>24</sup> Currently, it is the Exchange’s understanding that several major market data vendors widely disseminate PIVs taken from the Consolidated Tape Association (“CTA”) or other data feeds.

NAV per Share of the Fund because the PIV may not be calculated in the same manner as the NAV, which is computed once a day, generally at the end of the business day. The price of a non-U.S. security that is primarily traded on a non-U.S. exchange shall be updated, using the last sale price, every 15 seconds throughout the trading day, provided, that upon the closing of such non-U.S. exchange, the closing price of the security, after being converted to U.S. dollars, will be used. Furthermore, in calculating the PIV of the Fund's Shares, exchange rates may be used throughout the Core Trading Session that may differ from those used to calculate the NAV per Share of the Fund and consequently may result in differences between the NAV and the PIV.

The Adviser represents that the Trust, First Trust and BNY will not disseminate non-public information concerning the Trust.

Investors can also obtain the Trust's Statement of Additional Information ("SAI"), the Fund's Shareholder Reports, and the Trust's Form N-CSR and Form N-SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N-CSR and Form N-SAR may be viewed on-screen or downloaded from the Commission's Web site at [www.sec.gov](http://www.sec.gov). Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the CTA high-speed line. The intra-day, closing and settlement prices of the portfolio securities are also readily available from the national securities exchanges trading such securities (as applicable), automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters.

#### Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.<sup>25</sup> Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also

may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments comprising the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

#### Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m., E.T. in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, Commentary .03, the minimum price variation ("MPV") for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is \$0.01, with the exception of securities that are priced less than \$1.00 for which the MPV for order entry is \$0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A-3<sup>26</sup> under the Act, as provided by NYSE Arca Equities Rule 5.3. A minimum of 100,000 Shares for the Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

#### Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the Financial Industry Regulatory Authority ("FINRA") on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange

represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.<sup>27</sup>

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.<sup>28</sup>

FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and certain exchange-traded equity securities with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, may obtain trading information regarding trading in the Shares and certain exchange-traded equity securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain exchange-traded equity securities from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Not more than 10% of the net assets of the Fund in the aggregate invested in equity securities (other than non-exchange-traded investment company securities) shall consist of equity securities whose principal market is not a member of the ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement.<sup>29</sup>

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

#### Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit ("ETP") Holders in an Information Bulletin ("Bulletin") of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss

<sup>27</sup> FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

<sup>28</sup> For a list of the current members of ISG, see [www.isgportal.org](http://www.isgportal.org). The Exchange notes that not all components of the Disclosed Portfolio may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

<sup>29</sup> See note 10, *supra*.

<sup>25</sup> See NYSE Arca Equities Rule 7.12.

<sup>26</sup> 17 CFR 240.10A-3.

the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated PIV will not be calculated or publicly disseminated; (4) how information regarding the PIV will be disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Fund will be subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4:00 p.m., E.T. each trading day.

## 2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under section 6(b)(5)<sup>30</sup> that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.600. The Adviser, the Sub-Adviser and the Sub-Sub-Advisers have each implemented fire walls with respect to their respective broker-dealer affiliate(s) regarding access to information concerning the composition and/or changes to the portfolio. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and certain

exchange-traded equity securities with other markets and other entities that are members of the ISG and FINRA, on behalf of the Exchange, may obtain trading information regarding trading in the Shares and certain exchange-traded equity securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain exchange-traded equity securities from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Not more than 10% of the net assets of the Fund in the aggregate invested in equity securities (other than non-exchange-traded investment company securities) shall consist of equity securities whose principal market is not a member of the ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement. The Fund's investments will be consistent with the Fund's investment objectives and will not be used to enhance leverage.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the PIV will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information will be available via the CTA high-speed line. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in a Bulletin of the special characteristics and risks

associated with trading the Shares. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the PIV, the Disclosed Portfolio, and quotation and last sale information for the Shares.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the PIV, the Disclosed Portfolio, and quotation and last sale information for the Shares.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that primarily holds equity securities, which will enhance competition among market participants, to the benefit of investors and the marketplace.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

<sup>30</sup> 15 U.S.C. 78f(b)(5).

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEArca-2015-77 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEArca-2015-77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for

inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR-NYSEArca-2015-77, and should be submitted on or before October 8, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>31</sup>

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-23285 Filed 9-16-15; 8:45 am]

**BILLING CODE 8011-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

[FTA Docket No. FTA-2015-0024]

#### Agency Information Collection Activity Under OMB Review

**AGENCY:** Federal Transit Administration, DOT.

**ACTION:** Notice of request for comments.

**SUMMARY:** The Federal Transit Administration invites public comment about its intention to request the Office of Management and Budget's (OMB) approval to extend the approval of the following information collection:

#### Fixed Guideway Capital Investment Grants—New Starts Section 5309

The information collected is necessary to permit an assessment of program effectiveness and ensure the proper and timely expenditure of federal funds within the scope of the program. The **Federal Register** notice with a 60-day comment period soliciting comments for the Fixed Guideway Capital Investment Grants—New Starts Section 5309 was published on June 24, 2015 (Citation 80 FR 121). No comments were received from that notice.

**DATES:** Comments must be submitted before October 19, 2015. A comment to OMB is most effective, if OMB receives it within 30 days of publication.

**FOR FURTHER INFORMATION CONTACT:** Tia Swain, Office of Administration, Office of Management Planning, (202) 366-0354.

**ADDRESSES:** All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information

and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments are invited on whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

#### SUPPLEMENTARY INFORMATION:

*Title:* Fixed Guideway Capital Investment Grants—New Starts Section 5309 (OMB Number: 2132-0561)

*Abstract:* The Federal Transit Administration (FTA) administers the discretionary Capital Investment Grant (CIG) grant program under 49 U.S.C. Section 5309 that provides funding for major transit capital investments including rapid rail, light rail, commuter rail, bus rapid transit, and ferries. Three types of eligible projects are outlined in law: smaller scaled corridor-based transit capital projects known as "Small Starts"; new fixed guideway transit systems and extensions to existing fixed guideway systems known as "New Starts"; and projects to improve capacity at least 10 percent in existing fixed guideway corridors that are at capacity today or will be in five years, known as "Core Capacity". The CIG program has a longstanding requirement that FTA evaluate proposed projects against a prescribed set of statutory criteria at specific points during the projects' development including when they seek to enter a subsequent phase of the process or a construction grant agreement. In addition, FTA must report on its evaluations and ratings annually to Congress.

The Moving Ahead for Progress Act in the 21st Century (MAP-21) enacted on July 6, 2012, made significant changes to the CIG program, including creation of an entirely new category of eligible projects called Core Capacity. MAP-21 also reduced the number of steps in the CIG process projects must follow to receive funds, created a new congestion relief evaluation criterion FTA must use to evaluate and rate projects, and specified that "warrants" (ways projects can qualify for automatic ratings) should be developed and used to the extent practicable. The requirement for CIG

<sup>31</sup> 17 CFR 200.30-3(a)(12).

project ratings has been in place since 1998. Thus, the requirements for project evaluation and data collection for these proposed projects are not new. In general, the information used by FTA for CIG project evaluation and rating should arise as a part of the normal project planning process.

FTA has been collecting project evaluation information from project sponsors under the existing OMB approval for this program (OMB No. 2132-0561). However, due to the addition of the Core Capacity eligibility, the changes to the steps in the CIG process made by MAP-21, and the proposed implementation of "warrants," it became apparent that some information now required might be beyond the scope of ordinary planning activities.

*Estimated Total Annual Burden:*  
68,840 hours.

**Matthew M. Crouch,**  
*Associate Administrator for Administration.*

[FR Doc. 2015-23293 Filed 9-16-15; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD-2015 0102]

#### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ADRENALINE; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before October 19, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD-2015-0102. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this

docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email [Linda.Williams@dot.gov](mailto:Linda.Williams@dot.gov).

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel ADRENALINE is:

*Intended Commercial Use of Vessel:*  
"Sailing charters for up to 6 passengers"

*Geographic Region:* "Massachusetts"

The complete application is given in DOT docket MARAD-2015-0102 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

#### Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Date: September 8, 2015.

**T. Mitchell Hudson, Jr.,**  
*Secretary, Maritime Administration.*

[FR Doc. 2015-23355 Filed 9-16-15; 8:45 am]

**BILLING CODE 4910-81-P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD-2015 0100]

#### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ALANA MCCREE; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before October 19, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD-2015-0100. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email [Linda.Williams@dot.gov](mailto:Linda.Williams@dot.gov).

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel ALANA MCCREE is:

*Intended Commercial Use Of Vessel:*  
"Private pleasure day and week crewed charters. Passengers only."

*Geographic Region:* "Maryland, Delaware, New Jersey, and Virginia".

The complete application is given in DOT docket MARAD-2015-0100 at <http://www.regulations.gov>. Interested



parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

#### Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: September 8, 2015.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2015–23354 Filed 9–16–15; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD–2015 0104]

#### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel WAVE DANCER; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before October 19, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0104. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email [Linda.Williams@dot.gov](mailto:Linda.Williams@dot.gov).

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel WAVE DANCER is: *Intended Commercial Use of Vessel:* “There are several intended commercial uses of this vessel which are:

1. CHARTERS
  - a. Day Trips—Take passengers out for sightseeing and touring of waterways and notable landmarks. May include half/full day lunch/dinner trips.
  - b. Overnight Trips—Take passengers on passage-making adventures along the Atlantic coast and/or inland waterways from Massachusetts to Florida. Charter may originate or terminate at any point between Massachusetts and Florida.
  - c. Captained Charters—Conduct Captained charters of vessel for overnight outings of one or more days covering various distances along the Atlantic coast and intercoastal waterways.
  - d. Bare Boat Charters—charter boat to qualified individuals (must be American citizens) for use without a licensed captain.

2. SPORT FISHING—trolling for fish while sailing/motoring, bottom fishing and/or drift fishing.

3. INSTRUCTION—Teach sailing, seamanship and navigation skills to students (*i.e.*, passengers) looking to safely operate a pleasure sailing vessel.

4. FUNERALS/BURIALS—Perform privately conducted services at sea to spread cremation ashes on open waters as allowed by governmental guidelines and regulations.

5. MARRIAGES—Perform marriages at sea.”

*Geographic Region:* Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, District of Columbia, North Carolina, South Carolina, Georgia and Florida.

The complete application is given in DOT docket MARAD–2015–0104 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

#### Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: September 8, 2015.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2015–23350 Filed 9–16–15; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD–2015 0101]

#### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel KING OF HEARTS; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime

Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before October 19, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD-2015-0101. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email [Linda.Williams@dot.gov](mailto:Linda.Williams@dot.gov).

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel KING OF HEARTS is:

*Intended Commercial Use Of Vessel:* "Day and Evening cruises of the Intercoastal Waterway in Ft. Lauderdale, FL between Port Everglades and Boca Raton".

*Geographic Region:* "Florida".

The complete application is given in DOT docket MARAD-2015-0101 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state

the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

#### Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: September 8, 2015.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2015-23352 Filed 9-16-15; 8:45 am]

**BILLING CODE 4910-81-P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD-2015 0103]

#### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel THE LONG RUN; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before October 19, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD-2015-0103. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except

federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://www.regulations.gov>.

#### FOR FURTHER INFORMATION CONTACT:

Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-0903, Email [Linda.Williams@dot.gov](mailto:Linda.Williams@dot.gov).

#### SUPPLEMENTARY INFORMATION:

As described by the applicant the intended service of the vessel THE LONG RUN is:

*Intended Commercial Use of Vessel:* "Uninspected Passenger Vessel (Six-pack) fishing charters".

*Geographic Region:* "California".

The complete application is given in DOT docket MARAD-2015-0103 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

#### Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78).

By Order of the Maritime Administrator.

Dated: September 8, 2015.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2015-23351 Filed 9-16-15; 8:45 am]

**BILLING CODE 4910-81-P**

**DEPARTMENT OF TRANSPORTATION****National Highway Traffic Safety Administration**

[Docket No. NHTSA–2014–0025]

**Request for Comments on New Information Collection****ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being submitted to the Office of Management and Budget (OMB) for review and comments.

**DATES:** Written comments should be submitted by October 19, 2015.

**ADDRESSES:** Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention NHTSA Desk Officer.

**FOR FURTHER INFORMATION CONTACT:** For additional information or access to background documents, contact Julie Kang, Ph.D., Vehicle Safety Research, National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Dr. Kang's telephone number is (202) 366–5195.

**SUPPLEMENTARY INFORMATION:** Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). In compliance with these requirements, this notice announces that the following information collection request has been forwarded to OMB. A **Federal Register** notice with a 60-day comment period soliciting comments on the following information collection was published on March 13, 2014 (79 FR 14335).

NHTSA received one comment from the Insurance Institute for Highway Safety (IIHS) on the proposed information collection. In NHTSA's original proposed study, each driver would have experienced a one week baseline period and two one week periods where each driver would use each technology. IIHS stated a within-subject design may result in a carryover effect in which changes in behavior resulting from exposure to the first technology may influence behavioral responses to the second technology in a subsequent week. IIHS's concern is that the reinforcement contingencies drivers learn with the first technology may

carry over to a subsequent phase of study and potentially confound the measurement of the second technology's effect on belt use. Based on IIHS's suggestion, NHTSA has changed the experimental design from a within-subjects design (32 participants, 3 weeks) to a between-subject design (48 participants, 3 weeks). In this between-subject design experiment, each participant will only experience one of the two seat belt interlock technologies. This new design holds reasonable statistical analysis power and clears out the concern of the behavior carry-on effect.

*OMB Control Number:* Not assigned.

*Title:* Recruitment and Debriefing of Human Subjects for Field Test of Vehicle Occupant Protection Technologies.

*Form Numbers:* None.

*Type of Review:* New Information Collection.

*Background:* NHTSA's mission is to save lives, prevent injuries, and reduce economic losses resulting from motor vehicle crashes. Increasing seat belt use is one of the agency's highest priorities. Seat belt use has shown an increasing trend since 1995, accompanied by a steady decline in the percentage of unrestrained passenger vehicle occupant fatalities during daytime. In 2013, the nationwide seat belt use reached 87 percent for drivers and front seat passengers.<sup>1</sup> Despite gains in seat belt usage, data from the 2011 Fatality Analysis Reporting System (FARS) indicates that 52 percent of all passenger vehicle crash fatalities<sup>2</sup> were unbelted occupants.<sup>3</sup> The age group 21 to 24 had the highest percentage of unrestrained occupants killed: 2,172 fatalities, of which 1,385 (64 percent) were unrestrained. The second highest percentage of unrestrained passenger vehicle occupant fatalities was 63 percent among 25- to 34-year-olds.<sup>3</sup> Use of lap/shoulder seat belts reduces the risk of fatal injury to front-seat passenger car occupants by 45 percent and the risk of moderate-to-critical injury by 50 percent. In 2011 alone, seat belts saved an estimated 11,949 lives.<sup>3</sup>

The proposed study will examine seat belt use, users' acceptance of emerging

vehicle technologies designed to increase seat belt use, the likelihood of and potential strategies to circumvent the system, and unintended consequences. The study method consists of a field operational test to collect objective and subjective data about two prototype technologies developed by automakers to increase seat belt use. In response to comments received during the 60-day comment period, NHTSA has changed the experimental design, from a within-subjects design (32 participants, 3-week) to a between-subject design (48 participants, 3-week). This new design holds reasonable statistical analysis power and clears out the concern of the behavior carry-on effect. A total of 48 drivers from two age groups would be recruited to participate in the study, 24 non-seat belt users (12 young drivers; 12 middle-aged drivers), and 24 part-time users (12 young drivers; 12 middle-aged drivers). The study sample would have equal numbers of male and female drivers from each age group. The research team acknowledges that it may be difficult to recruit non-users given the high seat belt use rate in Michigan (more than 90 percent). As a result, the research team will also draw from the University of Michigan Transportation Research Institute's (UMTRI) previous field operational test study participant pool of low seat belt users. This pool of previous participants have indicated that they would be willing to do other studies; therefore, it is expected that this strategy will greatly expedite the recruitment process. The estimated burden hours are shown for a maximum of 391 respondents to respond to the recruitment advertisements. The number of call-ins was calculated based on:

- A 93 percent seat belt use rate in Michigan, so it takes about 343 call-ins to find the 24 non-seat belt users for screening purposes;
- It is estimated at least 50 percent of the part-time seat belt users from previous studies will participate in the current study (pulling from those who have indicated that they would be interested in participating in future studies), so it takes about 48 call-ins to find 24 part-time seat belt users.

Each driver will be presented with one baseline condition and one vehicle occupant protection technology. Each condition will last one week. Therefore, each participant will drive the research vehicles for two weeks. A data acquisition system will record system state (*i.e.*, door, ignition, driver seat belt buckle) and video inside the vehicle cabin. The University of Michigan

<sup>1</sup> Pickrell, T.M., & Liu, C. (2014, January). *Seat Belt Use in 2013—Overall Results*. (Traffic Safety Facts Research Note. Report No. DOT HS 811 875). Washington, DC: National Highway Traffic Safety Administration.

<sup>2</sup> The 2012 and 2013 data on the percent of unrestrained passenger vehicle occupant fatalities during daytime is not yet available.

<sup>3</sup> NHTSA. (2013, June) *Occupant Protection* (Traffic Safety Facts 2011 Data. Report No. DOT HS 811 729). Washington, DC: National Highway Traffic Safety Administration. <http://www-nrd.nhtsa.dot.gov/Pubs/811729.pdf>

Transportation Research Institute, in collaboration with the Virginia Tech Transportation Institute and Montana State University, Western Transportation Institute, will conduct this study under a research contract with NHTSA.

*Description of the Need for the Information and Proposed Use of the Information:* The collection of information consists of: (1) An eligibility questionnaire, (2) a demographic questionnaire; and (3) post-study questionnaires. In the revised study design, minor changes were also made to the three instruments to reflect the study changes. Example changes include deleting the question asking for driver's social security number in the demographic questionnaire, and adding more open-end questions in the post-study questionnaires.

The information to be collected will be used to:

- *Eligibility questionnaire(s)* will be used to obtain self-reported driving history information. Individuals interested in participating in the study will be asked to provide information about their driving history. People who

have been convicted of felony motor convictions will be excluded. Individuals who pass the initial screening will be asked to provide their driver's license number and consent to review their driving records to confirm self-reported driving history information. Drivers' consent and driving license numbers will be used to obtain official driving records from the state of Michigan. Individuals will be excluded from participating in the study if they refuse to grant UMTRI permission to review their public driving records or if they have been convicted of felony motor convictions in the last 2 years. This exclusion criterion is used to reduce the liability risk of providing participants with research vehicles.

- *Demographic questionnaire* will be used to obtain demographic information to confirm that the study group includes participants from various groups (e.g., age; gender; part-time seat belt users or those who sometimes wear their belts; non-users or those who never wear a seat belt; etc. Other demographic information will be collected to describe

the study sample (e.g., annual travel distance).

- *Post-study questionnaire(s)* will be used to get information about drivers' beliefs and attitude towards each occupant protection technology tested, and to identify potential problems associated with each system. These questionnaires will also be used to assess perceived usability of the systems in terms of acceptance and satisfaction, as well as willingness to have this technology in their vehicle. Each driver will complete a post-study questionnaire once, at the end of the second week.

*Respondents:* Michigan drivers with a valid driver license.

*Estimated Number of Respondents:* 50 to 391.

*Estimated Number of Responses:* One to three responses per person, 17 to 85 questions total.

*Estimated Total Annual Burden:* 10 to 45 minutes per respondent (95.2 hours total).

*Estimated Frequency:* One-time for the eligibility; demographic questionnaire; and the post-study questionnaire.

TABLE 1—ESTIMATED BURDEN HOURS

Instrument	Number of respondents <sup>4</sup>	Frequency of responses	Number of questions	Estimated individual burden (minutes)	Total estimated burden hours	Total annualize cost to respondents <sup>5</sup>
Eligibility questionnaire .....	391	1	17	10	65.2	\$1377.60
Demographic questionnaire .....	60	1	23	5	5	105.70
Post-study questionnaire .....	50	1	45	30	25	528.50
<b>Total .....</b>					<b>95.2</b>	<b>2011.80</b>

<sup>4</sup> The number of respondents in this table includes drop-out rates.

<sup>5</sup> Estimated based on the mean hourly rate for Michigan (all occupations) is \$21.14 as reported in the May 2011 Occupational Employment and Wage Estimates, Bureau of Labor Statistics. [http://www.bls.gov/oes/oes\\_dl.htm](http://www.bls.gov/oes/oes_dl.htm)

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended; 5 CFR part 1320; and 49 CFR 1.95.

Issued in Washington, DC.  
**Nathaniel Beuse,**  
*Associate Administrator for Vehicle Safety Research.*  
 [FR Doc. 2015-23294 Filed 9-16-15; 8:45 am]  
**BILLING CODE 4910-59-P**

**DEPARTMENT OF TRANSPORTATION**

**Surface Transportation Board**

[Docket No. AB 290 (Sub-No. 378X)]

**Norfolk Southern Railway Company—  
 Abandonment Exemption—in  
 Nottoway County, VA**

Norfolk Southern Railway Company (NSR) has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon approximately 0.70 miles of

railroad line (the Line). The Line extends between mileposts N 133.4 (near Atwood Street) and N 134.1 (near Highway 460 and Burkes Tavern Road), in Nottoway County, Va., and traverses United States Postal Service Zip Code 23922.

NSR has certified that: (1) No local traffic has moved over the Line for at least two years; (2) there is no overhead traffic on the Line that would have to be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c)

(environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption may become effective on October 17, 2015, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,<sup>1</sup> formal expressions of intent to file an

<sup>1</sup> The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

OFA under 49 CFR 1152.27(c)(2),<sup>2</sup> and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by September 28, 2015. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by October 7, 2015, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423-0001.

A copy of any petition filed with the Board should be sent to NSR's representative: William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

NSR has filed a combined environmental and historic report that address the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by September 22, 2015. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423-0001) or by calling OEA at (202) 245-0305. Assistance for the hearing

<sup>2</sup> Each OFA must be accompanied by the filing fee, which is currently set at \$1,600. See 49 CFR 1002.2(f)(25).

impaired is available through the Federal Information Relay Service at (800) 877-8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by NSR's filing of a notice of consummation by September 17, 2016, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at "[www.stb.dot.gov](http://www.stb.dot.gov)."

Decided: September 14, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

**Brendetta S. Jones,**  
*Clearance Clerk.*

[FR Doc. 2015-23345 Filed 9-16-15; 8:45 am]

**BILLING CODE 4915-01-P**



# FEDERAL REGISTER

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Part II

## Department of Health and Human Services

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Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, *et al.*

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

**21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211**

[Docket No. FDA-2011-N-0920]

**Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending our regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food in two fundamental ways. First, we are modernizing the long-standing current good manufacturing practice requirements. Second, we are adding requirements for domestic and foreign facilities that are subject to our regulation for Registration of Food Facilities to establish and implement hazard analysis and risk-based preventive controls for human food. We also are revising certain definitions in our regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided for “farms” and, in so doing, to clarify which domestic and foreign facilities are subject to the requirements for hazard analysis and risk-based preventive controls for human food. We are taking this action as part of our announced initiative to revisit the current good manufacturing practice requirements since they were last revised in 1986 and to implement new statutory provisions in the FDA Food Safety Modernization Act. The rule is intended to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system.

**DATES:** This rule is effective November 16, 2015, except for the amendment to part 110 in instruction 13, which is effective September 17, 2018 and paragraph (2) of the definition of “qualified auditor” in § 117.3, and §§ 117.5(k)(2), 117.8, 117.405(a)(2), 117.405(c), 117.410(d)(2)(ii), 117.430(d), 117.435(d), 117.475(c)(2) and 117.475(c)(13). FDA will publish a document in the **Federal Register** announcing the effective dates of paragraph (2) of the definition of “qualified auditor” in § 117.3, and §§ 117.5(k)(2), 117.8, 117.405(a)(2), 117.405(c), 117.410(d)(2)(ii), 117.430(d),

117.435(d), 117.475(c)(2), and 117.475(c)(13). See section LVI for the compliance dates.

**FOR FURTHER INFORMATION CONTACT:**

Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

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## Executive Summary

### Purpose and Coverage of the Rule

This rule is part of FDA’s implementation of the FDA Food Safety Modernization Act (FSMA), which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule creates certain new requirements for the production of human food by registered food facilities, and revises previous requirements, in three key ways.

First, this rule creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. In general, these requirements apply to establishments that are required to register with FDA as a food “facility.” This portion of the rule requires registered food facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards, unless an exemption applies. Facilities must also monitor their controls, conduct verification activities to ensure the controls are effective, take appropriate corrective actions, and maintain records documenting these actions.

Second, this rule modernizes FDA’s long-standing current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food. We have updated, revised, and otherwise

clarified certain requirements within the CGMP regulations, which were last updated in 1986.

Third, this rule clarifies the scope of the exemption for “farms” in FDA’s current food facility registration regulations and makes corresponding revisions to FDA’s current regulations for the establishment, maintenance, and availability of records. These revisions affect who is subject to the existing regulations for registration and recordkeeping, as well as the new requirements for hazard analysis and risk-based preventive controls requirements established here.

This final rule is the result of significant stakeholder engagement, beginning before the proposed rule. In response to extensive stakeholder input on the proposed rule, we revised key provisions in a supplemental notice of proposed rulemaking. After the supplemental notice of proposed rulemaking, we conducted even more outreach to the stakeholder community to ensure that the risk-based, preventive requirements in this final rule are practical and protective of public health.

### Summary of the Major Provisions of the Rule

The final rule implements the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the rule establishes requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions and corrections;
- Verification;
- Supply-chain program;
- Recall plan; and
- Associated records.

We have added flexibility and clarity to these provisions in response to comments. Although there are similarities between these requirements of FSMA and the requirements of food safety systems known as Hazard Analysis and Critical Control Point (HACCP) systems, not every provision in FSMA is identical to the provisions of HACCP systems, and we have revised much of our terminology to distinguish FSMA’s requirements for hazard analysis and risk-based preventive controls from HACCP requirements. A facility subject to the rule must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether

there are any hazards requiring preventive controls. The first step of a hazard analysis is hazard identification, which must consider known or reasonably foreseeable hazards, including biological, chemical, and physical hazards. The hazard analysis must consider hazards that may be present in the food because they occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain. We continue to believe that hazards that may be intentionally introduced for economic gain will need preventive controls in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. Economically motivated adulteration that affects product integrity or quality, for example, but not food safety, is out of the scope of this rule.

A facility subject to the rule must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated. The rule establishes preventive control management components (monitoring, corrective actions and corrections, and verification) as appropriate to ensure the effectiveness of the preventive controls. One way we have clarified the risk-based flexibility of these requirements is by clearly stating in the final rule that a facility must take into account the nature of the preventive control and the facility's food safety system when considering which activities are appropriate for that facility.

We have also added flexibility and made risk-based modifications for specific preventive control management components. For example, the final rule allows flexibility for the specific records required to document monitoring of refrigeration controls during storage of a food that requires time/temperature control for safety. These records can be either affirmative records demonstrating temperature is controlled or "exception records" demonstrating loss of temperature control. As another example, the rule includes tailored, less burdensome requirements for corrections. A correction is defined in this rule as an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce). The final rule

clarifies that corrections must be taken in a timely manner and must be recorded when appropriate, but they do not, for example, need to be included in a written plan or accompanied by a reanalysis of the written food safety plan.

As a third example, the final rule provides flexibility for which verification activities must occur. In general, a facility is required to conduct verification activities, as appropriate to the nature of the preventive control and its role in the facility's food safety system, including validation, verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, and reanalysis. Validation is not required for all controls. For example, the rule specifies that validation is not required for certain types of preventive controls (*i.e.*, food allergen controls, sanitation controls, supply-chain controls, and the recall plan) and provides flexibility for the facility to not validate other preventive controls with a written justification based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. Product testing and environmental monitoring are listed as possible verification activities, but, like other preventive control management components in general, they are only required as appropriate to the food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system. In many cases, neither product testing nor environmental monitoring will be appropriate. For example, there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold produce raw agricultural commodities that are rarely consumed raw, such as potatoes.

A facility must reanalyze the food safety plan as a whole at least once every three years. The final rule provides the flexibility for a facility to only reanalyze the applicable portion of the food safety plan under certain other circumstances, such as when a facility becomes aware of new information about potential hazards associated with a food.

The final rule also adds flexibility to the preventive controls requirements and recognizes the reality of modern distribution chains by not requiring a manufacturing/processing facility to implement a preventive control in certain circumstances when the hazard requiring a preventive control will be controlled by another entity in the distribution chain. For example, if a facility's customer (or another entity in

the distribution chain) will control the hazard, then that facility can rely on its customer to provide written assurance that the identified hazard will be controlled by an entity in the distribution chain, with flexibility for how the customer provides that written assurance depending on whether the customer, or an entity subsequent to the customer, will control the hazard. We have identified four specific circumstances in which a manufacturing/processing facility can rely on another entity in the distribution chain to control a hazard, with practical solutions explained further in section XXVII. We also have provided flexibility for a facility to establish, document, and implement an alternative system that ensures adequate control, at a later distribution step, of the hazards in the food product distributed by a manufacturing/processing facility such that the facility would not need to implement a preventive control.

We revised the proposed provisions for a supplier program to add flexibility, recognizing that the receiving facility and the supplier may be separated by several entities in a supply chain. We are allowing entities such as distributors, brokers, and aggregators to determine, conduct, and document appropriate supplier verification activities as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. However, because the approval of suppliers is ultimately the responsibility of the receiving facility, the rule specifies that only a receiving facility can approve suppliers. To improve clarity and readability we redesignated the proposed provisions into eight distinct sections of regulatory text in a newly established subpart G (Supply-Chain Program).

Each facility subject to the rule must have a recall plan for a food with a hazard requiring a preventive control.

Many activities required by the final rule must be conducted (or overseen) by a preventive controls qualified individual, a new term we are coining here. A preventive controls qualified individual is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system.

The rule establishes several exemptions (including modified requirements in some cases) from the requirements for hazard analysis and risk-based preventive controls. All of

these exemptions are expressly authorized by FSMA. A facility that manufactures, processes, packs, or holds food and that is required to register with FDA would be required to comply with the requirements for hazard analysis and risk-based preventive controls unless it is covered by an exemption, as shown in the following table.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Who or what is exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
<p>“Qualified Facility” as defined by FSMA:</p> <ul style="list-style-type: none"> <li>• Business with average annual sales of &lt;\$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or.</li> <li>• Very small business, which the rule defines as a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).</li> </ul> <p>• Low-risk, on-farm activities performed by small business (&lt;500 full-time equivalent employees).</p> <p>-or-</p> <p>• Low-risk, on-farm activities performed by a very small business (dollar threshold of \$1,000,000, as described previously).</p> <p>Activities that are subject to the seafood HACCP requirements of part 123 (21 CFR part 123).</p> <p>Activities that are subject to the juice HACCP requirements of part 120 (21 CFR part 120).</p> <p>Activities that are subject to the “low-acid canned food” requirements of part 113 (21 CFR part 113).</p> <p>The manufacturing, processing, packaging, or holding of a dietary supplement that is subject to the CGMP requirements of part 111 (21 CFR part 111).</p> <p>Activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).</p> <p>Alcoholic beverages at a facility that is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States.</p> <p>Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.</p> <p>A facility solely engaged in the storage of packaged food that is not exposed to the environment.</p>	<p>Modified requirements apply—i.e., a qualified facility is required to:</p> <ul style="list-style-type: none"> <li>• Notify FDA about its status; and</li> <li>• Either: <ul style="list-style-type: none"> <li>○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or</li> <li>○ Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.</li> </ul> </li> <li>• The notification is in the form of an attestation, and must be submitted every two years, during the same timeframe as the facility is required to update its facility registration.</li> </ul> <p>Small and very small on-farm businesses conducting only the specified low-risk activities are exempt from the requirements for hazard analysis and risk-based preventive controls.</p> <p>We define the low-risk, on-farm activities that qualify for the exemption, including the specific foods to which they relate (such as making jams, jellies, and preserves from acid fruits, and making milled grain products such as cornmeal).</p> <p>The facility must be in compliance with part 123.</p> <p>The facility must be in compliance with part 120.</p> <ul style="list-style-type: none"> <li>• The exemption applies only with respect to microbiological hazards regulated under part 113.</li> <li>• The facility must be in compliance with part 113.</li> <li>• The facility must be in compliance with part 111.</li> <li>• The facility must be in compliance with requirements for serious adverse event reporting for dietary supplements.</li> </ul> <p>These activities will be established in FDA’s forthcoming rule for produce safety.</p> <p>The exemption also applies to food other than alcoholic beverages at such a facility, provided that the food is in prepackaged form and constitutes not more than 5 percent of the overall sales of the facility.</p> <p>A facility that stores raw agricultural commodities that are fruits and vegetables is not exempt.</p> <p>Modified requirements apply for the storage of unexposed packaged food that must be refrigerated for safety.</p>

The rule includes procedures for withdrawing a qualified facility exemption, in the event of an active investigation of a foodborne illness outbreak that is directly linked to the facility, or if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on relevant conditions or conduct associated with the qualified facility. The final rule provides procedures for a facility to appeal an order to withdraw a qualified facility exemption, for a facility to request an informal hearing, for the conduct of an informal hearing, for an appeal, for revoking an order to withdraw a qualified facility exemption, and for reinstating an exemption that was withdrawn.

The rule finalizes recordkeeping provisions associated with the new provisions for hazard analysis and risk-based preventive controls. These records allow facilities to show, and FDA to determine, compliance with the new requirements. To meet these requirements, a facility may use existing records as appropriate.

In addition to finalizing new requirements for hazard analysis and risk-based preventive controls as required by FSMA, the rule does two more key things. First, it modernizes the existing CGMPs. Second, it revises the “farm” definition.

The rule makes several revisions to the CGMPs to update and clarify them. For example, the final CGMPs do not include nonbinding provisions, because

it is no longer FDA’s practice to include guidance in the regulatory text. The rule finalizes some of the previously nonbinding provisions in the CGMPs as binding requirements, including a requirement for education and training, but deletes other nonbinding provisions. We have revised some key terms for consistency and clarity. And we have clarified FDA’s long-standing position that the CGMPs address allergen cross-contact by making that explicit in the regulatory text. Finally, the rule revises a long-standing exemption from the CGMP requirements regarding specific activities conducted on raw agricultural commodities to reflect the contemporary regulatory framework associated with the “farm” definition. In addition, elsewhere in this issue of the **Federal**

**Register**, in a final rule that establishes requirements for hazard analysis and risk-based preventive controls for food for animals, FDA is establishing an additional revision to the human food CGMPs to address comments about the practice of human food manufacturers sending by-products to local farmers or animal food manufacturers for use as animal food. Because we proposed these requirements as part of the rulemaking for the animal preventive controls rule, we are finalizing these provisions in the final animal preventive controls rule rather than in this rule.

Finally, the rule clarifies the “farm” definition that is central to the determination of whether certain entities must register as a food facility and, thus, become subject to the new requirements for hazard analysis and risk-based preventive controls. The final “farm” definition reflects current farming practices, differentiates between two types of farm operations (*i.e.*, a “primary production farm” and a “secondary activities farm”), and allows for a consistent—although not identical—regulatory approach across similar operations, to the extent possible. In general, a “primary production farm” is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of

crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. A farm packs and holds raw agricultural commodities and may conduct certain manufacturing/processing activities (*i.e.*, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling). The term farm also now includes a “secondary activities farm,” which is an operation, not located on a primary production farm, devoted to the key farming operations of harvesting, packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grow, harvest, and/or raise the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm.

**Costs and Benefits**

This final regulation requires domestic and foreign facilities to adopt a food safety plan, perform a hazard

analysis, and to institute preventive controls for the mitigation of those hazards. It also includes requirements for facilities to institute risk-based environmental monitoring, product testing, and a supply-chain program as appropriate to the food, the facility, and the nature of the preventive controls, as well as a requirement to institute controls to help prevent hazards associated with economically motivated adulteration. The total annualized domestic costs are estimated to be approximately \$381 million per year, estimated with a 3 percent discount rate, and \$382 million per year, estimated at 7 percent when discounted over 10 years. We estimate that processed foods covered by this rulemaking are responsible for approximately 903,000 foodborne illnesses each year, at a total cost to the American public of approximately \$2.2 billion. Our break-even analysis shows that for the rule to be cost effective, it would have to prevent \$382 million worth of foodborne illness; approximately 17 percent of the total annual illnesses, or approximately 157,000 illnesses when using a discount rate of 7 percent. For the rule to be cost effective using a discount rate of 3 percent, it would have to prevent \$381 million worth of foodborne illness (about 17 percent or 156,000 illnesses).

**COSTS AND HEALTH BENEFITS**  
[\$ millions]

PCHF Provision	One-time cost first yr compliance period	One-time cost second yr compliance period (small businesses <500 FTE's)	One-time cost third yr compliance period (very small businesses <\$1 million)	Annual cost (annually recurring costs)	Total annualized cost at 7%	Total Annualized cost at 3%
Learn about Rule	\$6	\$96	\$21	\$0	\$16	\$14
Total Costs Sub-parts A & D .....	17	148	88	15	43	41
Total Costs Sub-parts C & G .....	9	183	0	340	323	326
Total Domestic Costs .....	32	427	109	355	382	381
Total Foreign Costs .....	68	915	234	760	820	817
<b>Total Costs .....</b>	<b>100</b>	<b>1,342</b>	<b>344</b>	<b>1,115</b>	<b>1,202</b>	<b>1,198</b>
Total Health Benefits .....	Not Quantified. Break-even occurs when 157,000 illnesses are prevented per year (based on domestic costs discounted at 7 percent).					

**TABLE OF ABBREVIATIONS AND ACRONYMS**

Abbreviation/acronym	What it means
Bioterrorism Act .....	Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188).
CFSAN .....	Center for Food Safety and Applied Nutrition.
CGMP .....	Current Good Manufacturing Practice.
Codex .....	Codex Alimentarius Commission.

TABLE OF ABBREVIATIONS AND ACRONYMS—Continued

Abbreviation/acronym	What it means
Codex Validation Guidelines	Codex Guidelines for the Validation of Food Safety Control Measures.
CSA	Community Supported Agriculture.
CPG	Compliance Policy Guide.
EO	Executive Order.
EPA	U.S. Environmental Protection Agency.
EU	European Union.
FDA	U.S Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture.
FSIS Validation Guidelines	FSIS' Compliance Guidelines on HACCP Systems Validation.
FSMA	FDA Food Safety Modernization Act.
FSPCA	Food Safety Preventive Controls Alliance.
GFSI	Global Food Safety Initiative.
HACCP	Hazard Analysis and Critical Control Point.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
Infant formula rule	Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula, June 10, 2014 (79 FR 33057).
ISO	International Organization for Standardization.
LACF	Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (commonly called "Low-Acid Canned Foods").
N/A	Not Applicable.
NCIMS	National Conference on Interstate Milk Shipments.
NIFA	National Institute of Food and Agriculture.
NOP	National Organic Program.
OMB	Office of Management and Budget.
PHS Act	Public Health Service Act.
PMO	Pasteurized Milk Ordinance.
PMO facilities	Facilities that comply with the PMO and are regulated under the NCIMS system.
PFP	Partnership for Food Protection.
PRA	Paperwork Reduction Act.
PSA	Produce Safety Alliance.
RAC	Raw agricultural commodity.
RFR	Reportable Food Registry.
Section 103(c)(1)(C) draft RA	Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.
Section 103(c)(1)(C) RA	Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (Final).
SBA	Small Business Administration.
SECG	Small Entity Compliance Guide.
TCS food	Time/Temperature Control for Safety Food.
USDA	U.S. Department of Agriculture.

**I. Background**

*A. FDA Food Safety Modernization Act*

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily

on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal,

and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls rule.	78 FR 3646, January 16, 2013
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule	78 FR 3504, January 16, 2013
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls rule.	78 FR 64736, October 29, 2013
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule	78 FR 45730, July 29, 2013
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification rule.	78 FR 45782, July 29, 2013

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA—Continued

Title	Abbreviation	Publication
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule.	78 FR 78014, December 24, 2013
Sanitary Transportation of Human and Animal Food .....	2014 proposed sanitary transportation rule.	79 FR 7006, February 5, 2014

We also issued a supplemental notice of proposed rulemaking for the rules listed in table 2 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 2—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice ...	79 FR 58574, September 29, 2014

As FDA finalizes these seven foundational rulemakings, we are putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Ref. 1) (Ref. 2). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step

forward for food safety that will protect consumers into the future.

*B. Stages in the Rulemaking for the Human Preventive Controls Rule*

With regard to this rulemaking, we published proposed provisions in the 2013 proposed human preventive controls rule and we published new and re-proposed provisions in the 2014 supplemental human preventive controls notice. In the 2014 supplemental human preventive controls notice, we reopened the comment period only with respect to specific proposed provisions. In addition, we emphasized that the re-proposed provisions we included in the regulatory text were based on a preliminary review of the comments.

In this document, we use the broad term “proposed human preventive controls rule” to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed human preventive controls rule and the new and re-proposed provisions we published in the 2014 supplemental human preventive controls notice. We use the narrow terms “2013 proposed human preventive controls rule” and “2014 supplemental human preventive controls notice” to refer to specific text published in the **Federal Register** of January 16, 2013 (78 FR 3646) and September 29, 2014 (79 FR 58524), respectively. We use the terms “final human preventive controls rule” and “this rule” to refer to the regulations we are establishing as a result of this rulemaking.

We issued a notice correcting several typographical and stylistic errors in the 2013 proposed human preventive controls rule and a mistake in the date of a reference (78 FR 17142, March 20, 2013). In that correction notice, we republished the Appendix in its entirety (78 FR 17142 at 17143 through 17155; the corrected Appendix) because all the references to the Appendix as published in the 2013 proposed human preventive controls rule (78 FR 3646 at 3812 through 3824) had been numbered incorrectly. We also extended the comment periods for the 2013 proposed human preventive controls rule, its information collection provisions, and a related risk assessment (see section I.D) in response to several requests that we do so.

*C. Summary of the Major Provisions of Proposed Human Preventive Controls Rule*

As part of our announced initiative (Ref. 3) to revisit the CGMP requirements since they were last revised in 1986, we proposed to amend our regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food (currently established in part 110 (21 CFR part 110)) to: (1) Modernize it; (2) adjust and clarify what activities fall within the long-standing exemption from the CGMP requirements for establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities (RACs) based on experience and changes in related areas

of the law since issuance of the CGMP regulation; (3) delete some non-binding provisions of current part 110; and (4) re-establish the provisions of current part 110 in new part 117 (21 CFR part 117). We also requested comment on: (1) Additional proposed revisions or clarifications to our CGMP regulations, including whether to further implement opportunities for CGMP modernization, such as on how best to revise the current provisions for training; and (2) whether to revise some non-binding provisions to establish new requirements in proposed part 117, or to simply retain them as useful provisions of a comprehensive CGMP.

As part of our implementation of new statutory provisions in FSMA, we also proposed to add, in newly established part 117, requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. As directed by FSMA (see section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), these new provisions would apply to domestic and foreign facilities that are required to register under section 415 of the FD&C Act and our regulation for Registration of Food Facilities (21 CFR part 1, subpart H; the section 415 registration regulations). As directed by FSMA (see sections 418(l) and (m) of the FD&C Act), we proposed to establish modified requirements for certain facilities. We requested comment on all aspects of the proposed requirements, including an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supply-chain program, and hazards that may be intentionally introduced for purposes of economic gain.

As directed by section 103 of FSMA, we proposed to clarify the scope of the exemption from the section 415 registration regulations for “farms” by revising the “farm” definition and by adding or modifying the definitions for certain activities (*i.e.*, for “harvesting,” “holding,” “manufacturing/processing,” and “packing” activities) that govern, in part, whether a business that is devoted to the growing of crops, the raising of animals, or both is within the “farm” definition. We also proposed to add or revise these definitions in our current regulation (implementing section 414 of the FD&C Act) for Establishment and Maintenance of Records for Foods (21 CFR part 1, subpart J; the section 414 recordkeeping regulations), which also have an exemption for “farms.”

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive

controls, and related requirements in new part 117 as shown in table 3:

TABLE 3—PROPOSED SUBPARTS IN NEW PART 117

Sub-part	Title
A .....	General Provisions.
B .....	Current Good Manufacturing Practice.
C .....	Hazard Analysis and Risk-Based Preventive Controls.
D .....	Modified Requirements.
E .....	Withdrawal of an Exemption Applicable to a Qualified Facility.
F .....	Requirements Applying to Records That Must Be Established and Maintained.

*D. Draft Risk Assessment*

We issued for public comment a “Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” (the section 103(c)(1)(C) draft RA) (78 FR 3824, January 16, 2013). The purpose of the section 103(c)(1)(C) draft RA was to provide a science-based risk analysis of those activity/food combinations that would be considered low risk when conducted in a facility co-located on a farm. We used the tentative conclusions of the section 103(c)(1)(C) draft RA to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities from the requirements for hazard analysis and risk-based preventive controls. We are including the final risk assessment (the section 103(c)(1)(C) RA) in the docket established for this document (Ref. 4).

*E. Definition of “Retail Food Establishment”*

An establishment that meets the definition of “retail food establishment” is exempt from the requirements of the section 415 registration regulations and, thus, from FSMA’s requirements for hazard analysis and risk-based preventive controls. Section 102(c) of FSMA requires that we revise the definition of “retail food establishment” in § 1.227 to clarify its intent. We are addressing the requirements of section 102(c) of FSMA in a separate rulemaking and issued a separate proposed rule to amend the definition of “retail food establishment” in the section 415 registration regulations and the section 414 recordkeeping regulations (80 FR 19160, April 9, 2015). We intend to issue a final rule to amend the definition of “retail food

establishment” in the section 415 registration regulations in the near future.

*F. Public Comments*

We received more than 8,000 public submissions on the 2013 proposed human preventive controls rule, and more than 1,300 public submissions on the 2014 preventive controls supplemental notice, each containing one or more comments. We received submissions from diverse members of the public, including food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress; Federal, State, local, and tribal Government Agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments address virtually every provision of the proposed human preventive controls rule. In the remainder of this document, we describe these comments, respond to them, and explain any revisions we made to the proposed human preventive controls rule.

Some comments address issues that are outside the scope of this rule. For example, some comments express concern over pesticides being used on local crops being harmful to the honeybee population. Other comments address the requirements of the proposed produce safety rule, such as standards for water quality. Other comments express concern about the use of bioengineered food ingredients, and ask that foods containing such ingredients be labeled so that consumers can identify such foods and choose whether to consume them. Other comments assert that the rules should address social issues. We do not discuss such comments in this document.

**II. Legal Authority**

The proposed rule contained an explanation of its legal basis under authorities in the FDA Food Safety Modernization Act, the FD&C Act, and the Public Health Service Act. After considering comments received in response to the 2013 proposed human preventive controls rule and 2014 supplemental human preventive controls notice, FDA made changes in the final rule. The legal authorities relied on for the final rule are the same as in the proposed rule unless otherwise described in the sections that follow.



### A. Changes to Current 21 CFR Part 1, Subparts H, I, and J

Sections 103(c)(2)(A) and (B) of FSMA require that the Secretary adopt final rules for purposes of section 415 of the FD&C Act (Registration of Food Facilities) with respect to “activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership” and “activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.” In section IV, we discuss our revision of the section 415 registration regulations (21 CFR part 1, subpart H) to clarify the types of activities that are included as part of the definition of the term “facility” under section 415 of the FD&C Act and the scope of the exemption for “farms” provided by section 415 of the FD&C Act. The final rule also makes corresponding changes in part 1, subpart I (Prior Notice of Imported Food) and in part 1, subpart J (Establishment, Maintenance, and Availability of Records). FDA’s legal authority to modify these regulations is derived from section 103(c) of FSMA and sections 414, 415, 381(m) and 371(a) of the FD&C Act (21 U.S.C. 350c, 350d, 801(m), and 701(a)).

### B. Changes to Current 21 CFR Part 110

The changes to the current CGMP regulation finalized in this document clarify the existing requirements of the regulation and update existing requirements to reflect changes in the food industry and in scientific understanding of food safety since issuance of the current regulation. FDA’s legal authority to require Current Good Manufacturing Practices derives from sections 402(a)(3), (a)(4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3), 342(a)(4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The revisions we are making to the current CGMP regulation are necessary to prevent food from containing filthy,

putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

In addition to the FD&C Act, FDA’s legal authority for the changes to current CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States \* \* \* or from one State \* \* \* into any other State” (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary.) The revisions we are making to the current CGMP regulation are necessary to prevent the spread of communicable disease.

### C. Hazard Analysis and Risk-Based Preventive Controls

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations “to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. . . .” Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms “small business” and “very small business,” taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Further, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit “[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].”

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or

agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to “prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act]. . . .” In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities. These include hazard analysis (section 418(b)), preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)).

Section 103(c)(2)(C) of FSMA requires that the Secretary adopt a final rule with respect to the requirements under sections 418 and 421 of the FD&C Act from which the Secretary may issue exemptions or modifications of the requirements for certain types of facilities. Sections 418(j)–(m) of the FD&C Act and sections 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to seafood and juice HACCP, and low-acid canned food (section 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (section 418(k)); qualified facilities (section 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (section 418(m)); facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses (section 103(c)(1)(D) of FSMA), and dietary supplements (section 103(g) of FSMA). In sections XI, XII, XXXVIII, and XXXIX, we discuss provisions that implement these exemptions and modified requirements.

In the 2014 supplemental human preventive controls notice, we included potential requirements for a supplier program, environmental monitoring, and product testing. We are including provisions for such activities in the final

rule. Section 418(o)(3) of the FD&C Act provides supplier verification activities and an environmental monitoring program as examples of preventive controls. Section 418(f)(4) of the FD&C Act provides for the use of environmental and product testing programs as part of required verification that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

In certain circumstances, the final rule does not require a manufacturing/processing facility to implement a preventive control for a hazard requiring a preventive control. Instead, the facility is permitted to rely on a subsequent entity in the distribution chain to significantly minimize or prevent the hazard. In such a circumstance, a facility must disclose in documents accompanying the food, that the food is “not processed to control [identified hazard].” This requirement is supported by sections 418 and 701(a) of the FD&C Act (21 U.S.C. 350g and 371(a)). The requirement that facilities apply preventive controls to significantly minimize or prevent hazards is fundamental to the public health benefits of the rule. To accommodate the realities of modern food production, the rule allows a facility to rely on a subsequent entity in the distribution chain rather than requiring that facility to apply the control. A food may pass through multiple entities in the distribution chain before it reaches consumers. Further, ordinarily it is not apparent from visual examination of the food whether a hazard requiring a preventive control has been addressed. Consequently, without labeling, a facility might not know that a facility upstream in the supply chain has not applied a preventive control and is relying on a downstream entity to do so. Therefore, the agency concludes that information that food has not been processed to control an identified hazard is necessary for a facility to fulfil its obligation under section 418 when a facility is relying on a subsequent entity to control the hazard. The agency also concludes that such labeling is necessary for the efficient enforcement of the Act because the labelling is critical for FDA to hold facilities responsible for their obligations under this regulatory scheme. Further, when the hazard can cause a communicable disease, FDA concludes that the requirement is necessary to prevent the spread of communicable disease from one state into another state and relies on sections 311, 361, and 368 of the PHS Act.

FDA concludes that the provisions in subpart C and related requirements in subparts A, D, F, and G should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 (section 418(o)(2) of the FD&C Act) and does not exclude a facility from the requirements because food from such a facility is not in interstate commerce. Further, the prohibited act provision associated with section 418 (section 301(uu) of the FD&C Act) does not require interstate commerce for a violation.

FDA also is issuing the provisions in subpart C and related requirements in Subparts A, D, F, and G, under sections 402(a)(3), 402(a)(4), 403(w), and 701(a) of the FD&C Act to the extent such requirements are necessary to prevent food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food; and to the extent necessary to prevent food from being misbranded under section 403(w). FDA also is finalizing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent those provisions are necessary to prevent the interstate spread of communicable disease.

#### *D. Comments on Legal Authority*

(Comment 1) One comment asserts that FDA does not have authority to regulate intrastate commercial activities. Another comment asserts that FDA does not have authority to regulate farms that are selling wholly intrastate.

(Response 1) With regard to farms, this rule does not apply. With respect to farms that engage in activities outside the farm definition (*i.e.*, farm mixed-type facilities), this rule applies to the non-farm portion of the operation.

FDA disagrees with the comments regarding application of this rule to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 (section 418(o)(2) of the FD&C Act) and does not exclude a facility because food from such a facility is not in interstate commerce. Section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)) provides that “the operation of a facility that

manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418” is a prohibited act. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C. 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 418 and 301(uu) of the FD&C Act as not limiting the application of the rule only to those facilities with a direct connection to interstate commerce.

FDA is mindful that its interpretation of FSMA and the FD&C Act should not cast doubt on their constitutionality. (See *Solid Waste Agency of Northern Cook County v. U.S.*, 531 U.S. 159 (2001)). FDA has considered the relevant provisions of FSMA and the FD&C Act, FDA’s responsibilities in implementing those laws, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Congress’ power to legislate under the commerce clause is very broad. However, such power is not without limits, see *United States v. Lopez*, 514 U.S. 549, 567 (1995); *U.S. v. Morrison*, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in *Lopez*, *supra*, the Supreme Court acknowledged the continuing vitality of *Wickard v. Filburn*, 317 U.S. 111 (1942), noting that “although *Filburn*’s own contribution to the demand for wheat may have been trivial by itself, that was not ‘enough to remove him from the scope of Federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.’” (514 U.S. at 556.) See also *Gonzales v. Raich*, 545 U.S. 1, 17–25 (2005). This principle applies to the application of sections 418 and 301(uu) of the FD&C Act, as added by section 104 of FSMA. Accordingly, given the collective impact on commerce of facilities that manufacture, process, pack, or hold food that is sold in intrastate commerce, FDA concludes that such facilities should be subject to the rule. FDA notes that to the extent these facilities are very small, they are subject to modified requirements under § 117.201. This outcome regarding intrastate commerce is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that in any action to enforce the act’s requirements respecting foods, drugs, devices, and cosmetics, any necessary connection

with interstate commerce is presumed. Likewise, this outcome is consistent with FSMA's risk-based, preventive approach to food safety because the risk presented by unsafe food can be significant, whether or not the food moves from one state to another.

### III. General Comments on the Proposed Rule

(Comment 2) Several comments ask us to develop guidance to accompany the rule, particularly with respect to the new requirements for hazard analysis and risk-based preventive controls. For example, comments ask us to provide guidance on topics such as hazard analysis, environmental monitoring, and validation. Some of these comments ask that drafts of the guidance first be made available for public comment.

Other comments emphasize the importance of education and outreach and ask us to provide support for ongoing education and outreach, including an active role in providing needed instructional examples and lessons learned from current investigations and foodborne outbreaks. Some comments ask us to convene a scientific workgroup that includes experts in food and laboratory science, public health, proficiency testing, quality control, and other areas on at least an annual basis to assess what pathogens should be addressed in a food safety plan.

Some comments ask that funding and information on funding for training be provided. Other comments assert that we must make available adequate resources to support outreach and technical assistance delivered by State regulatory agencies, as well as Cooperative Extension programs and non-governmental organizations that work directly with farmers and facilities.

(Response 2) We are developing several guidance documents, including general guidance on hazard analysis and preventive controls, as well as guidance on specific aspects such as environmental monitoring and food allergen control (Ref. 5). We also intend to develop guidance specific to a variety of food types based in part on technical information we obtained through a grant for this purpose, as well as on other topics, such as validation. We will develop and issue this guidance in accordance with our good guidance practices regulation, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when appropriate (§ 10.115(g)) (21 CFR

10.115(g)). The public may submit comments on any guidance document at any time (§ 10.115(g)(5)).

We agree with comments that stress the importance of education and outreach. A central element of our strategy to gain industry compliance is to help make available to facilities subject to this rule the education and technical assistance they need to understand and implement the requirements (Ref. 6). Within the Agency we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 6). This will allow us to respond in a timely and consistent way to industry questions on preventive controls technical and compliance issues (Ref. 6).

We also are working in collaboration with the Food Safety Preventive Controls Alliance (FSPCA) to develop training materials and establish training and technical assistance programs (Ref. 5) and (Ref. 7). The Alliance includes members from FDA, State food protection agencies, the food industry, and academia. It is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health, a nationally-recognized leader in food safety. In addition to developing a standardized preventive controls training curriculum, the FSPCA is developing selected sections of model food safety plans for several food types that will provide needed instructional examples. Although we have provided funding to the FSPCA to develop a standardized preventive controls training curriculum, we are unable to fund training for individual groups who might need particular training materials.

We also are partnering with the National Institute of Food and Agriculture (NIFA) of the U.S. Department of Agriculture (USDA) to administer the FSMA-mandated National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, a grant program to provide technical assistance for FSMA compliance to owners and operators of small and medium-size farms and small food processors (Ref. 8). Such efforts will help ensure widespread voluntary compliance by encouraging greater understanding and adoption of established food safety standards, guidance, and protocols.

At this time, we intend to rely on scientific publications and epidemiological findings to assess the potential that new pathogens, or more virulent pathogenic strains, have

emerged, and do not intend to convene annual workgroups to assess that data and information.

(Comment 3) Several comments ask us to classify specific on-farm activities as harvesting, packing, holding, or manufacturing/processing so that an operation that conducts these activities on a farm can determine whether conducting that specific activity is within, or outside, the "farm" definition. These comments emphasize that a farm operation needs to know when a specific activity that it conducts would be outside the "farm" definition for the purposes of the requirements to register as a food facility and, thus, require that the farm operation both register as a food facility and comply with the new requirements for hazard analysis and risk-based preventive controls. Some of these comments focus on activities that we have previously classified in more than one way (*e.g.*, "washing," which we have previously classified as both "harvesting" and "manufacturing/processing," depending on when the activity occurs) (See table 1 in the Appendix to the 2014 supplemental human preventive controls rule, 79 FR 58524 at 58571–58572.) Other comments ask us to periodically review our lists of harvesting, packing, holding, and manufacturing/processing activities to ensure that they reflect current practices. Some comments ask us to make a table of activities prominently available on our Internet site for easy access whenever the public seeks out information regarding the forthcoming produce safety rule and the human preventive controls rule.

(Response 3) We have added several examples of "harvesting," "packing," "holding," and "manufacturing/processing" to the regulatory text (see §§ 1.227, 1.328, and 117.3 and Response 27, Response 28, Response 29, Response 31, Response 37, Response 38 and Response 39). However, it is not practical to include every possible activity conducted by farm operations in the regulatory text. Attempting to include a more extensive set of examples in the regulatory text has the potential to signal—incorrectly—that any activity not specified in the regulatory text cannot be considered to be within the definition of that activity. In addition, we have not previously discussed our approach to classifying some of the activities mentioned in the comments, and we believe that we should provide an opportunity for public comment on a more extensive list of activities classified as "harvesting," "packing," "holding," or "manufacturing/processing."

To address these comments, in the near future we intend to issue a draft guidance with our current thinking on the classification of activities as “harvesting,” “packing,” “holding,” or “manufacturing/processing.” In accordance with our regulation on good guidance practices (§ 10.115(g)(1)), we will review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate; publish a notice in the **Federal Register** announcing that the guidance document is available; and post the guidance document on the Internet and make it available in hard copy. Under our good guidance practices regulation (§ 10.115(g) and (h)), the public can comment on any guidance document at any time, and we will revise guidance documents in response to public comments when appropriate.

In addition, our previously issued “Guidance for Industry: Questions and Answers Regarding Food Facility Registration” (Ref. 9) is in its sixth edition, and we intend to update it in the near future to reflect the changes to the definitions of “farm,” “harvesting,” “packing,” “holding,” and “manufacturing/processing” that we are establishing in this rulemaking.

(Comment 4) Some comments ask us to prepare a table or flow chart of activities that make an operation a farm, a retail food establishment, or a facility because food businesses will need to be able to easily determine their regulatory classification to comply with the applicable regulations. Other comments ask us to amend the definition of “manufacturing/processing” to ensure that community supported agriculture (CSA) programs will not become subject to the requirements for hazard analysis and risk-based preventive controls. Other comments ask us to clarify how the revised definitions we are establishing in the section 415 registration regulations will affect entities classified as research and development entities, pilot plants, test kitchens, shared use storage facilities, co-packers, sales offices, corporate offices, private residences, and registered foreign facilities that only send samples to the United States. Some comments ask us to clarify how the revised definitions we are establishing in the section 415 registration regulations will affect a determination of whether an entity or program (such as a farmers’ market, roadside stand, CSA program, commissary kitchen, community and incubator kitchens) is a retail food establishment that is not required to register as a food facility in the human preventive controls rule

rather than through a separate rulemaking. One comment notes that its farm has a store and a café that use products from the farm, and it is not clear if the store and café will be under regulations while nearby restaurants and grocery stores are not. Some comments ask us to define farmers’ markets, CSA programs, roadside stands, and other direct-to-consumer programs as retail food establishments not subject to registration as part of the human preventive controls rulemaking rather than through a separate rulemaking.

(Response 4) Section 102(c) of FSMA requires that we revise the definition of “retail food establishment” in § 1.227 to clarify that, in determining the primary function of an establishment or a retail food establishment under the section 415 registration regulations, the sale of food products directly to consumers by such establishments includes the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers’ market where such stand or market is located other than where the food was manufactured or processed; the sale and distribution of such food through a CSA program; and the sale and distribution of such food at any other such direct sales platform as determined by the Secretary of HHS. As discussed in section I.E, we have begun the process of amending the definition of “retail food establishment” in a separate rulemaking conducted under section 102(c) of FSMA, and are continuing that separate rulemaking by issuing a separate final rule. We intend to issue a final rule to amend the definition of “retail food establishment” in the section 415 registration regulations in the near future. We also intend to update our previously issued “Guidance for Industry: Questions and Answers Regarding Food Facility Registration” (Ref. 9) to reflect any changes to a determination of whether an entity is a retail food establishment as a result of that rulemaking. In the meantime, commenters may find our existing guidance helpful in addressing their questions.

(Comment 5) Some comments ask us to explain how we will enforce the rule, particularly with respect to coordination with State and local authorities and with other Federal agencies. For example, some comments ask whether FDA or the States will pay for inspections, whereas other comments ask us to coordinate inspection of imports with USDA’s Food Safety and Inspection Service (FSIS) or ask us to combine our inspections with those of USDA where possible (such as when USDA conducts inspections for

adherence to organic standards). Some comments express concern about the time gap between the effective date of this rule and the time it will take to incorporate applicable provisions into State law.

(Response 5) We are working through the Partnership for Food Protection (PFP) (a group of dedicated professionals from Federal, State, local, tribal, and territorial governments with roles in protecting the food supply and public health) to develop and implement a national Integrated Food Safety System consistent with FSMA’s emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA). For an example of our current thinking on establishing partnerships for achieving compliance, see the “best practices” document made available by PFP (Ref. 10). This “best practices” document provides information to FDA field and State programs on a variety of issues, including how to coordinate compliance activities. Our document entitled “Operational Strategy for Implementing FSMA” also recognizes the importance of developing operational partnerships with States and other government counterparts to optimize the effectiveness, efficiency, and consistency of FSMA implementation domestically (Ref. 11).

We are implementing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance (Ref. 12). This new paradigm involves a major reorientation and retraining, for which we are seeking funding, of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of State, local, and tribal inspectors (Ref. 12).

(Comment 6) Some comments ask us to specify that the human preventive controls rule does not apply to activities subject to the animal preventive controls rule.

(Response 6) The human preventive controls rule does not apply to activities subject to the animal preventive controls rule. The title of the rule (*i.e.*, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food) narrows its applicability to human food. Moreover, regulations directed to food for animals are established in subchapter E of 21 CFR (*i.e.*, Animal Drugs, Feeds, and Related Products, parts 500–599), whereas regulations directed to human food are established

in subchapter B of 21 CFR (*i.e.*, Food For Human Consumption, parts 100–199).

(Comment 7) Some comments ask us to look to existing industry information technology solutions where possible to lower the burden on industry for implementation. These comments also ask us to adopt a centralized information technology solution with robust functionality to facilitate tracking stakeholders' compliance with the rule.

(Response 7) The rule allows for use of any available information technology (*e.g.*, in the creation and retention of records) that will allow industry to comply with the rule, and we encourage the use of information technology to streamline compliance. The long-standing CGMP requirements allow for the use of automated systems (see § 117.40(d)). We are developing new electronic systems to track compliance. However, our internal procedures for tracking compliance are outside the scope of this rule.

(Comment 8) Some comments ask us to re-evaluate the proposed human preventive controls rule, compare it with existing programs, and identify a mechanism for integrating compliance verification with existing industry and governmental programs. These comments note that many handlers/processors use and understand voluntary food safety management systems such as HACCP and HACCP-based certification programs (*e.g.*, certification to Global Food Safety Initiative (GFSI) benchmark schemes) and ask us why we proposed to create a separate inspection framework for FSMA, without integrating that inspection framework with existing programs.

(Response 8) We decline this request. As previously discussed, we are establishing this rule as required by section 103 of FSMA (78 FR 3646 at 3657–3659 and 3668–3669). However, where compliance with this rule mirrors compliance with existing regulatory requirements, there is no need to duplicate existing records, which may be supplemented as necessary to include all of the required information. (See also Response 5 regarding implementation of a national Integrated Food Safety System.)

(Comment 9) Some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other.

(Response 9) We have aligned the provisions of the various rules to the extent practicable. For example, we use the same definitions of “farm” and the same terms used in the definition of “farm” (*i.e.*, harvesting, packing, holding, and manufacturing/processing)

in this rule, the animal preventive controls rule, and the proposed produce safety rule. However, the statutory direction is not the same for all the rules, and this difference in statutory direction does lead to some differences between the rules. For example, section 418(l) of the FD&C Act (which relates to this rule) provides for modified requirements for facilities that are very small businesses in addition to facilities that satisfy criteria for sales to qualified end-users, but section 419(f) of the FD&C Act (which relates to the proposed produce safety rule) only provides for modified requirements for direct farm marketing.

Likewise, we have worked to align the provisions of this rule with the provisions of the FSVP rule. Again, however, there are statutory differences that lead to some differences between the rules. For example, section 805 of the FD&C Act (21 U.S.C. 348a) applies to an importer whereas section 418 of the FD&C Act applies to a facility that is required to register under section 415 of the FD&C Act.

(Comment 10) Some comments ask us to clarify how the requirements for hazard analysis and risk-based preventive controls will apply to an establishment that supplies raw materials and other ingredients to a registered facility.

(Response 10) The requirements for hazard analysis and risk-based preventive controls apply to facilities that are required to register under section 415 of the FD&C Act. If an establishment that supplies raw materials and other ingredients to a registered facility is itself a facility that is required to register under section 415 of the FD&C Act, that establishment is subject to the requirements for hazard analysis and risk-based preventive controls. If that establishment is not itself a facility that is required to register under section 415 of the FD&C Act, that establishment is not subject to the requirements for hazard analysis and risk-based preventive controls. However, such facilities may be subject to verification activities of manufacturers/processors that are required to verify controls implemented by their suppliers.

(Comment 11) Some comments express concern about the potential for unfair enforcement of the rule relating to business size. Some comments assert that we should strictly enforce the rule for big industry, but be lenient towards small farms.

(Response 11) We intend to enforce the rule in a fair and reasonable manner. We note that farms are not covered by this rule, and the rule contains special

provisions applicable to a farm mixed-type facility that is a small or very small business. Specifically, a small or very small business that is a farm mixed-type facility is exempt from the requirements for hazard analysis and risk-based preventive controls if the only activities that it conducts are the low-risk activity/food combinations listed in § 117.5(g) and (h). A very small business that is a farm mixed-type facility, but does not satisfy the criteria for the exemptions for only conducting low-risk activity/food combinations, is eligible for modified requirements as a qualified facility, and we will enforce the modified requirements, rather than the full requirements for hazard analysis and risk-based preventive controls, for such very small businesses.

(Comment 12) Some comments express concern that we will enforce the rule more strictly for domestic facilities than for foreign facilities—*e.g.*, because we lack the funds and manpower to enforce the rule for foreign facilities. Other comments assert that it is unprecedented for importing countries to regulate the production processes in exporting countries and that no scientific evidence supports such regulation. These comments express concern that this regulatory requirement will greatly increase trading costs and might constitute a barrier to trade for exporting countries.

(Response 12) We intend to enforce this rule in a consistent manner to ensure that imported and domestically produced foods are in full compliance with the requirements of this rule. We note that the forthcoming FSVP rule will require importers to help ensure that food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under this rule. The implementation of these supplier verification programs by U.S. importers will thus provide assurances that imported food is in compliance with this regulation.

We disagree that we are seeking to “regulate the production processes in exporting countries” inappropriately. This rule provides for a flexible set of principles and a framework for hazard analysis and risk-based preventive controls to be applied to a given production process in order to ensure the production of safe food destined for the United States. Mandating that a finished food is manufactured under general methods applicable to all foods (*e.g.*, good manufacturing practices) is a widely accepted regulatory practice and

fundamentally different than mandating that food be produced in a certain way. We note that many countries have adopted food safety regulations that mandate certain principles and conditions be applied to food manufacturing. These include mandatory HACCP programs for seafood and other foods. For example, in a guidance document on food safety import requirements, the European Commission stated: “The EU rules on food hygiene confirm that all food businesses in third countries after primary production must put in place, implement and maintain a procedure based on the HACCP principles.” The mandate that preventive controls be applied to control hazards in the production of foods in this rule is similar to the European Union (EU) rules. Because the requirements being implemented by FDA under this regulation are flexible and not prescriptive, we do not agree that this regulation will significantly increase costs or impede trade.

We also disagree that there is no scientific evidence supporting this rule. In the 2013 proposed preventive controls rule, we provided an extensive background discussing the scientific evidence and international food safety standards upon which this rule is based (78 FR 3646 at 3659 through 3667, January 16, 2013). That discussion reviews a number of well documented food safety risks and how they can be controlled by modern food safety systems including the Codex HACCP principles contained in the HACCP Annex of the Codex General Principles of Food Hygiene (78 FR 3646 at 3667, January 16, 2013). In that discussion we stated: “The proposed rule would require that a food safety system similar to HACCP be implemented in food facilities and would harmonize our requirements with the recommendations and requirements of internationally recognized food safety experts/authorities, such as experts/authorities in [Codex Alimentarius], [Food Safety Authority Australia New Zealand], [Canadian Food Inspection Agency], and the European Union.” (78 FR 3646 at 3663, January 16, 2013) In addition, the Appendix to the 2013 proposed preventive controls rule provided additional scientific information on activities such as product testing and environmental monitoring to support their role in ensuring safe food and how these align with international standards such as those of Codex Alimentarius (78 FR 3646 at 3818–3820); republished in its entirety with corrected reference

numbers on March 20, 2013, 78 FR 17142 at 17149–17151).

(Comment 13) Some comments assert that the rule should be more concise, and that the average person without a team of experts should be able to understand the rule and manage the application of the rule.

(Response 13) We agree the rule needs to be understandable. We have incorporated plain language techniques—*e.g.*, by using active voice in the new requirements for hazard analysis and risk-based preventive controls. We also have established additional definitions that enable us to improve readability (*e.g.*, “qualified facility exemption,” “raw agricultural commodity,” “unexposed packaged food,” and “you.”) The comprehensive nature of the new requirements for hazard analysis and risk-based preventive controls reflects the extensive statutory provisions they implement and the broad range of activities and foods covered. We have used examples in the regulatory text, where relevant, and provided examples throughout the preamble to assist with understanding the requirements. Likewise, the long-standing CGMP requirements need to be comprehensive, because they are broadly directed to all stages of the production of food. We will be producing guidance documents that will be helpful in understanding the rule (see Response 2).

We will issue a Small Entity Compliance Guide (SECG) in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121). A Small Entity Compliance Guide is a guidance that explains the actions a small or very small business must take to comply with a rule.

(Comment 14) Some comments ask whether we will translate the rule into foreign languages, such as Japanese.

(Response 14) We do not intend to translate the rule. As discussed in Response 13, to help small and very small businesses comply with a rule we issue a SECG. We are considering whether to translate the SECG and outreach and technical assistance materials into additional languages.

(Comment 15) Some comments assert that the rule incorrectly assumes that all bacteria are harmful.

(Response 15) We have long recognized that some bacteria have a role in food production, such as the lactic-acid producing bacteria that our regulations explicitly acknowledge as being added to yogurt (see, *e.g.*, the standards of identity for yogurt, low fat yogurt, and nonfat yogurt, in 21 CFR 131.200, 131.203, and 131.206,

respectively). The rule defines the terms “microorganism” and “pathogen,” and the definition of “microorganism” explains that the term “undesirable microorganism” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. The CGMP provisions directed to either preventing the growth of undesirable microorganisms or preventing contamination with undesirable microorganisms are long-standing, and these comments do not provide any examples of how we have interpreted the CGMP requirements in the past in a way that does not recognize that some bacteria have a role in food production or that creates practical problems for the future. With regard to biological hazards, the new requirements for hazard analysis and risk-based preventive controls focus on pathogens.

(Comment 16) Some comments assert that the rule will disproportionately affect New England farmers because they are small and production costs are higher compared to elsewhere in the country and that the cost of the rule will have negative consequences on New England’s food supply. Other comments assert that the rule will force small farmers out of business, forcing us to rely on foreign suppliers who are under very little FDA oversight, and that FDA oversight should be reduced so that the public can continue supporting small, local farmers. Other comments express concern that excessive rules will discourage farmers from supplying the Farm to School market.

(Response 16) We believe that the “farm” definition that we are establishing in this rule greatly reduces the impact on farms of all size, because several operations that would have been required to register as a food facility under the section 415 registration regulations as established in 2003 (68 FR 58894, October 10, 2003) will no longer be required to do so. (See the discussion of the changes to the “farm” definition in section IV.B) In addition, a farm mixed-type facility that is a small or very small business, and that only conducts low-risk activity/food combinations for manufacturing, processing, packing, and holding foods that are not RACs, is exempt from the new requirements for hazard analysis and risk-based preventive controls. A farm mixed-type facility that does not satisfy these criteria for exemption, but is a very small business, is a qualified facility that is subject to modified requirements. All of these factors will reduce the burden on small farms.

(Comment 17) Some comments express concern about contamination of produce and other food in open containers by sulfuric hydrogen being discharged from lead acid batteries that are used to operate forklifts.

(Response 17) The long-standing CGMP provisions require that the food establishment must appropriately use equipment to avoid the adulteration of food with such contaminants (see § 117.40(a)(2)).

(Comment 18) Some comments assert that we do not address comments submitted by individuals.

(Response 18) We address comments on the provisions of the rule regardless of who submits the comments. However, we group similar comments together, and do not discuss the specific text of each submitted comment letter when the point being made by one comment letter can be included in a general discussion of several comment letters that express similar points of view.

(Comment 19) Some comments assert that we need specific standards and quantifiable guidelines for compressed air.

(Response 19) We agree that specific standards and quantifiable guidelines for material such as compressed air could be useful to food establishments that use such material in the production of food. However, we disagree that such standards and guidelines need to be included in the rule. The rule is intended to establish procedures for the safe manufacturing, processing, packing, and holding of food, and for hazard analysis and risk-based preventive controls in the production of food, rather than to set standards for specific levels of contaminants in specific raw materials and other ingredients. If a facility believes that its use of compressed air should be addressed in its food safety plan, then it should do so.

(Comment 20) Some comments ask us to address model laboratory standards and accreditation to ensure that laboratories are using sound and reliable test methods for detecting and identifying pathogens.

(Response 20) We decline this request. A separate section of FSMA addresses “Laboratory Accreditation For Analyses Of Foods” (see section 202 of FSMA). This rule focuses on section 103 of FSMA (section 418 of the FD&C Act).

#### **IV. Comments on Proposed Revisions to the Definitions in the Section 415 Registration Regulations (21 CFR Part 1, Subpart H) and the Section 414 Recordkeeping Regulations (21 CFR Part 1, Subpart J)**

##### *A. Definitions That Impact a Determination of Whether an Establishment Is a “Farm”*

We previously described section 103(c) of FSMA (78 FR 3646 at 3674). In brief, section 103(c) of FSMA directs us to conduct rulemaking to clarify the on-farm manufacturing, processing, packing, and holding activities that would trigger a requirement for a farm to register as a food facility and, thus, be subject to section 418 of the FD&C Act. We discussed the current legal and regulatory framework for farms under sections 415 and 418 of the FD&C Act, and explained how the status of a food as a RAC or a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act. We then articulated a comprehensive set of organizing principles that formed the basis for proposed revisions to the section 415 registration regulations. Because these definitions also are established in the section 414 recordkeeping regulations, these organizing principles also formed the basis for proposed revisions to definitions in the section 414 recordkeeping regulations.

Our previous description (78 FR 3646 at 3675–3676) of the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations focused on the framework that governs whether an establishment that grows and harvests crops or raises animals satisfies the definition of “farm,” because the facility registration requirements of section 415 of the FD&C Act do not apply to “farms.” Under that framework, a key factor in whether an establishment falls within the definition of “farm,” even with respect to crops it grows and harvests itself, is whether the activities conducted by the establishment fall within definitions of “harvesting,” “packing” or “holding” (which are within the “farm” definition). Another key factor is whether activities conducted by the establishment fall within the definition of manufacturing/processing (which have been outside the “farm” definition).

We previously described comments regarding proposed revisions to the definitions of “farm,” “harvesting,” “packing” and “holding,” as well as comments regarding the triggers for an

activity to be considered manufacturing/processing (79 FR 58524 at 58530–58538). In the 2014 supplemental human preventive controls notice, we proposed additional revisions to the definitions of “farm,” “harvesting,” “packing,” and “holding” to address these comments.

Even after the revisions we proposed in the 2014 supplemental human preventive controls notice, some comments assert that the overall “farm” definition still presents an unrealistic and incomplete understanding of how most farms in the United States are structured with regard to their physical location(s) and business models. Most of the comments suggest alternative or additional regulatory text (see, e.g., Comment 22, Comment 23, Comment 24, Comment 25, Comment 27, Comment 37, Comment 39, and Comment 50) or ask us to clarify how we will interpret the provisions (see, e.g., Comment 26, Comment 28, Comment 29, Comment 40, Comment 41, Comment 42, Comment 43, Comment 44, Comment 47, and Comment 48).

As discussed in section I.A, there are several FSMA-required regulations that provide the framework for industry’s implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food (see the seven foundational rules listed in table 1). Two of the proposed rules listed in table 1 (i.e., the 2013 proposed animal preventive controls rule and the 2013 proposed intentional adulteration rule) proposed to include a cross-reference to the “farm” definition in § 1.227, and a third proposed rule (i.e., the 2013 proposed produce safety rule) proposed to establish the same “farm” definition as would be in § 1.227. A fourth proposed rule (i.e., the 2013 proposed FSVP rule) did not propose to establish the “farm” definition (or a cross-reference to the “farm” definition in § 1.227), but under its proposed definition of “foreign supplier” some foreign suppliers would be farms—i.e., establishments that harvest food that is exported to the United States. As a result, we received comments relevant to the “farm” definition for all of these rules. The majority of the comments submitted to these other rulemakings addressed issues that were the same as, or similar to, the issues raised in the comments submitted to this rulemaking. One comment submitted to the proposed rulemaking for the forthcoming FSVP rule requested clarification regarding harvesting companies, and we are also providing

that clarification in this rulemaking. See Response 32.

We proposed to redesignate all definitions in § 1.227 in the section 415 registration regulations (*i.e.*, current § 1.227) to eliminate paragraph designations (such as (a) and (b)). We received no comments that disagreed with our proposed redesignations and are finalizing them as proposed.

We proposed several technical amendments and conforming changes to the section 415 registration regulations and to the section 414 recordkeeping regulations. No comments opposed the proposed technical amendments and conforming changes, except for

comments noting that our proposed technical amendment to § 1.361 was unnecessary because we had already made this change in a different rulemaking (see 77 FR 10662, February 23, 2012). We are finalizing these technical amendments and conforming changes without change.

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed definitions as shown in table 4, with editorial and conforming changes as shown in table

52. We also are establishing a new provision to allow off-farm establishments that package, pack, and hold RACs that are produce as will be defined in the produce safety rule to comply with the CGMPs in part 117, subpart B by complying with the applicable requirements for packing and holding that will be established in the final produce safety rule (see § 117.8 and Response 25). Because the new provision refers to provisions in a future produce safety rule, we will publish a document in the **Federal Register** announcing the effective date of § 117.8 once we finalize the produce safety rule.

TABLE 4—REVISIONS TO THE PROPOSED DEFINITIONS IN THE SECTION 415 REGISTRATION REGULATIONS AND THE SECTION 414 RECORDKEEPING REGULATIONS

Definition	Revision
Farm .....	<ul style="list-style-type: none"> <li>• A farm is an “operation” rather than an “establishment.”</li> </ul>
Primary production farm .....	<ul style="list-style-type: none"> <li>• There are two types of farms: (1) Primary production farm; and (2) secondary activities farm.</li> <li>• A primary production farm is “under one management” rather than “under one ownership.”</li> <li>• Although a primary production farm continues to be “in one general physical location,” we have clarified that “one general physical location” is “not necessarily contiguous.”</li> <li>• A primary production farm is an operation devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. Although some primary production farms both grow and harvest crops, other primary production farms grow crops but do not harvest them, and other primary production farms harvest crops but do not grow them.</li> <li>• Treatment to manipulate the ripening of RACs, and packaging and labeling the treated RACs, without additional manufacturing/processing, is within the “farm” definition.</li> <li>• We added an example of drying/dehydrating RACs to create a distinct commodity that would fall within the “farm” definition (<i>i.e.</i>, drying/dehydrating grapes to produce raisins), as well as an example of additional manufacturing/processing that would cause an operation that dries/dehydrates RACs to create a distinct commodity to fall outside the “farm” definition (<i>i.e.</i>, slicing).</li> <li>• We added an example of additional manufacturing/processing that can cause an operation that packages and labels RACs to fall outside the “farm” definition (<i>i.e.</i>, irradiation).</li> </ul>
Secondary activities farm .....	<ul style="list-style-type: none"> <li>• A “secondary activities farm” is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.</li> <li>• A secondary activities farm may also conduct those additional activities allowed on a primary production farm.</li> </ul>
Harvesting .....	<ul style="list-style-type: none"> <li>• We added additional examples of harvesting activities.</li> </ul>
Holding .....	<ul style="list-style-type: none"> <li>• We added additional examples of holding activities.</li> </ul>
Manufacturing/Processing .....	<ul style="list-style-type: none"> <li>• We added additional examples of manufacturing/processing activities.</li> </ul>

*B. Proposed Revisions to the Definition of Farm*

We proposed to revise the “farm” definition to: (1) Provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACs; (2) include, within the “farm” definition, a description of packing activities that include packaging RACs grown or raised on a farm without additional manufacturing/processing; and (3) provide for drying/dehydrating RACs to create a distinct commodity (such as the on-farm drying of grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing, to remain within the farm definition. We also

requested comment on whether we should retain, remove, or modify the phrase “in one general physical location” in the “farm” definition.

(Comment 21) Most of the comments support our proposed revision to provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACs. However, some comments oppose this proposed revision. Some comments ask us to require that a farm that packs, packs and sells, commingles lots, and holds produce grown on a farm under different ownership comply with the requirements of this rule for hazard analysis and risk-based preventive controls for six reasons: (1) Commingling. Contamination from one farm could find its way to another farm,

leading to potential contamination of products from both farms, making it difficult to pinpoint the source of contamination in the event of a recall. (2) Recall Plan. It is critical for everyone in the produce supply chain to be “recall ready,” especially those packing, commingling lots, and selling produce grown on another farm under different ownership. (3) Traceability. It is important that produce be traceable from the specific farm where it was grown to the end-user, and from the end-user back to the farm where it was grown. (4) Exemptions. A covered farmer packing, packing and selling, commingling lots, or holding others’ produce might be doing so from a farm that is exempt from the produce safety rule. (5) Supplier program. Under the



human preventive controls rule a farmer would be required to have a valid supplier program. (We note that a farmer might be a supplier to a facility that is subject to the human preventive controls rule, and could be subject to the facility's supplier program, but would not itself be required to "have a valid supplier program.") With this requirement, receiving facilities could purchase in confidence knowing that if the farm did pack others' produce it was produced in accordance with the rules required by FSMA. (6) Conflict with the National Organic Program (NOP). Under the NOP, a grower that purchases produce from another farm under different ownership, packs produce from another farm, or mixes produce is no longer considered a crop producer and must seek certification as a handler—an operation that has additional requirements to approve suppliers, segregate product, and maintain records necessary to demonstrate compliance. Comments assert that this NOP requirement is logical and is a practice that FDA should take into consideration.

Other comments assert that allowing a farm to pack produce from another farm must account for the problem created by our proposal to exempt farm vehicles transporting RACs from the sanitary transportation rule. These comments argue that unless we revise that rule to prevent possible contamination during transport, we should develop guidance for farms packing produce that is transported from another farm, particularly where the commodity is high risk.

(Response 21) The final "farm" definition continues to provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACs. We have acknowledged that doing so would have consequences such as those described in these comments, as well as other consequences (see 79 FR 58524 at 58532). Although comments pointed out consequences that we had already considered, they did not point to any other consequences. Therefore, we affirm our tentative conclusion that impacts such as these, while not always optimal, are necessary to establish a sensible framework of risk-based regulations that both implement FSMA and reflect common farm activities. We intend to issue the final produce safety rule in the near future and respond to comments related to traceability of produce, including whether to include a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its

name, complete business address, and description of the produce in any individual shipment, as well as respond to comments on whether it would be appropriate to also require the farm that receives the shipment maintain such record of information and, if so, for what specified period of time.

In the 2014 proposed sanitary transportation rule, we explained our reasons for tentatively concluding that the sanitary transportation practices that would be required by that proposed rule are not necessary to prevent RACs from becoming adulterated during transportation by farms (79 FR 7006 at 7016, February 5, 2014). For example, we explained that we are not aware of instances in which insanitary conditions (e.g., improper temperature control, improper equipment construction, inadequate equipment cleaning) with regard to transportation operations conducted by farms involving the transportation of RACs have contributed to foodborne illness, regardless of whether the farms are conducting transportation operations for their own RACs or for others' RACs. We will consider comments we receive on our proposal to exempt farm vehicles transporting RACs from the sanitary transportation rule when we issue a final sanitary transportation rule. We will consider necessary guidance in light of the final sanitary transportation rule, but we note that good transportation practices are already included in our 1998 guidance for industry entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (Ref. 13).

(Comment 22) Some comments assert that farms are neither facilities nor establishments. These comments ask us to revise the "farm" definition to use a term more suited to the nature of farming.

(Response 22) We consider a farm to be a type of "establishment" but have nonetheless revised the "farm" definition to refer to an "operation" rather than an "establishment" as requested by these comments.

(Comment 23) Many comments address the role of "ownership" in the "farm" definition. Some of these comments emphasize that farming operations are complex, with complex business structures, and are often not held under sole ownership. Some comments describe the role of multiple business models (such as cooperatives, on-farm packinghouses under ownership by multiple growers, food aggregators, and food hubs) in modern farming and ask us to revise the "farm" definition to provide for such business models. Other comments emphasize

ownership of the land on which crops are grown or animals are raised, noting that some farms are operated by "tenant" farmers who do not own the land used in the farm's operations. Some comments ask us to replace the concept of ownership with the concept of a responsible party, such as a "farm operator" and to define a farm operator as "the person or entity that has operational control over the farm and benefits in whole or in part from the farm's normal operation. A farm operator may be an owner, a tenant, a partner, or an employee."

Some comments ask us to remove the phrase "under one ownership" to allow sugar makers who share equipment and sugarhouses to qualify as a farm. Other comments ask us to clarify how renting or leasing storage rooms or facilities would affect the definition of a farm.

(Response 23) We have revised the "farm" definition by replacing the phrase "under one ownership" with the phrase "under one management." Although the original phrase "under one ownership" was not referring to a single owner, we agree that the "farm" definition should reflect modern business models (such as cooperatives, on-farm packinghouses under ownership by multiple growers, food aggregators, and food hubs) and use language that the modern farming community understands. We decline the request to define and introduce a new term, such as "farm operator." The term "management" has a common meaning that captures the request of these comments and is suitable for the purposes of the farm definition.

(Management. The person or persons controlling and directing the affairs of a business, institution, etc.) (Ref. 14).

Under either the previous or the revised "farm" definition, leasing land to grow or store crops or raise animals does not impact whether an operation is within the "farm" definition. Under the previous definition, "ownership" focused on ownership of the business entity conducting farm operations, not ownership of the land. Leasing land is a business practice common to a variety of business types, not just farms. Likewise, leasing buildings to store RACs does not impact whether an operation is within the "farm" definition. See also Response 24 regarding comments on "one general physical location."

To the extent that sugar makers who share equipment and sugarhouses only conduct activities that are within the "farm" definition, the revision from "under one ownership" to "under one management" should clarify that those operations would be within the "farm"

definition. However, when sugar makers conduct operations outside the “farm” definition, they are facilities that are required to register under the section 415 registration regulations, not “farms” that are exempt from that registration requirement. A sugar maker that is a small or very small farm mixed-type facility that only conducts the low-risk activity/food combinations listed in the exemptions in § 117.5(g) and (h) (such as making syrup and sugar (e.g., making maple syrup from maple sap)) is exempt from the requirements of this rule. However, a farm mixed-type facility that is not a small or very small business as those terms are defined in this rule, or that conducts activities in addition to the low-risk activity/food combinations listed in the exemptions in § 117.5(g) and (h), is subject to the requirements for hazard analysis and risk-based preventive controls. Consistent with the discussion in Response 228, a farm mixed-type facility that must comply with the requirements for hazard analysis and risk-based preventive controls and makes sugar from sugarcane or sugar beets can consider the findings of the section 103(c)(1)(C) RA (i.e., that this is a low-risk activity/food combination) in determining whether there are any hazards requiring a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components. For additional information about the section 103(c)(1)(C) RA and the exemptions for on-farm low-risk activity/food combinations for farm mixed-type facilities that are small or very small businesses, see sections VI and XI.G.

(Comment 24) Many comments address the role of “one general physical location” in the “farm” definition and ask us to revise the “farm” definition to acknowledge that farms may be composed of multiple parcels, buildings, or structures that may or may not be contiguous. Some comments point out that there are many farming operations that may fall under the same management and ownership, but are separated by either a strip of land, body of water, or another structure, particularly with respect to sites designated for packing and holding operations. Some comments assert that as long as an economic unit is operating a farm it should be irrelevant where the land is located, and state that this interpretation is consistent with a USDA

definition of a “farm operator.” Some comments note that sugar makers rely on sap from existing stands of trees that are often not concentrated in a single area or even nearby the sugarhouse where the maple products are made. Some comments suggest that the term “reasonable distance” could be used to better define “general physical location.” Some comments ask us to issue guidance that will clarify and further designate the boundaries of “one general physical location.”

Some comments note that the “farm” definition we proposed in the 2014 supplemental human preventive controls notice correctly considers a farm operation to remain within the “farm” definition even if it packs and holds produce from another farm. However, these comments state that it is confusing that if the same two farms pack and hold produce together at an off-farm location, using the exact same practices, that packing location is considered a “facility” even though there is no difference in risk. Other comments state that both in-line and off-line egg production facilities should be considered farms. According to these comments, off-line egg production facilities receive eggs laid by hens at nearby farms, whereas in-line egg production facilities receive eggs laid by hens in henhouses adjacent to the plant and located on the same property.

Some comments ask us to retain “one general physical location” in the “farm” definition because the word “farm,” and USDA’s definition of “farm,” are “place-based.” Other comments assert that if we delete the phrase “in one general physical location” then a fully integrated operation could be a single farm even though it was made up of numerous distinct farms possibly in several different states. Other comments ask us to retain “one general physical location” in the “farm” definition because different locations may have different food safety risks, different water sources, different personnel, and even different types of crops. Some comments assert that considering each unique and individually State-permitted dairy farm to be an individual “farm” regardless of common ownership or geographic proximity will prevent conflict and interference with the permitting and inspection activities of the Grade “A” program while maintaining food safety. Other comments state that regardless of whether we retain “one general physical location” in the “farm” definition, we must interpret the term “farm” to cover a very limited geographic area and that separate locations that are not in close

proximity to each other should not be considered the same “farm.”

(Response 24) We have revised the “farm” definition to specify that a farm is “in one general (but not necessarily contiguous) physical location.” We have concluded that adding “not necessarily contiguous” makes it clear that farming operations that are under one management but have some physical separation (e.g., with respect to the location of packing operations) can remain within the “farm” definition and that both in-line and off-line egg production facilities would be considered “farms.”

We agree that separate locations that are not in close proximity to each other should not be considered the same “farm.” As the comments point out, there already is a framework of State inspections for farms such as dairy farms, and we will need to work with our State regulatory partners to identify farms covered by the produce safety rule. However, even without the new phrase “not necessarily contiguous,” some situations would be complex. We intend to address these types of situations with our State food safety partners. (See Response 5.)

We do not see that adding “not necessarily contiguous” creates a “farm” definition that is not “place-based,” as was asserted by some comments, because the definition continues to specify “in one general physical location.” We also do not see that adding “not necessarily contiguous” presents any food safety concerns, as asserted by comments noting that different locations may have different food safety risks, different water sources, different personnel, and different types of crops. For example, a farm that will be covered by the forthcoming produce safety rule will be subject to standards for all of its water sources, all of its personnel, and all food subject to that rule. Likewise, we also do not believe that adding “not necessarily contiguous” affects a determination of whether a fully integrated operation could be a single farm.

(Comment 25) Some comments ask us to consider revising the regulatory text to ensure that similar activities would be treated the same way under either the produce safety rule or the human preventive controls rule and be held to the same risk-based requirements. These comments point out some of the differences between the requirements that would be established under the proposed human preventive controls rule and the requirements that would be established under the proposed produce safety rule. For example, comments state that the proposed human

preventive controls rule, but not the proposed produce safety rule, would require off-farm packinghouses and off-farm cooling and storage facilities to have a written hazard analysis; written preventive controls; written procedures for monitoring and corrective actions; validation of process controls; a written recall plan; environmental monitoring and product testing requirements; and a written supplier program. As another example, comments state that off-farm packing and holding operations would be required to comply with the human preventive controls rule one year earlier than we proposed that similar sized on-farm packing and holding operations would be required to comply with the forthcoming produce safety rule.

Some comments recommend options to achieve the goal of regulating on-farm and off-farm packinghouses the same way. These options include adding an exclusion to the “farm” definition in the produce safety rule; adding provisions to the human preventive controls rule to enable off-farm packinghouses to meet their obligation by complying with specified, applicable subparts of the produce safety rule; shortening the “farm” definition to simply state “Farm means an establishment under one ownership devoted to the growing and/or harvesting of crops, the raising of animals (including seafood), or any or all of these activities;” addressing off-farm establishments engaged solely in “low-risk” farming and harvesting activities by adding low-risk activities such as hulling, shelling, and drying of tree nuts; expanding the scope of the produce safety rule to include registered facilities; and allowing modified requirements in the human preventive controls rule to allow off-farm packinghouses to be subject to requirements (and exemptions) of the produce safety rule within the framework of the human preventive controls rule.

Some comments emphasize that farm activities are farm activities, regardless of where they happen. Some comments assert that establishments that are engaged solely in traditional harvesting, holding, or packing activities associated with a RAC that will be covered by the produce safety rule should be subject to the produce safety rule, rather than the human preventive controls rule, regardless of physical location, ownership, or legal ties to an operation devoted to the growing and harvesting of produce. Some comments assert that an off-farm operation that packs and holds RACs could be regulated in an identical fashion to an on-farm operation that packs and holds RACs without changing the section 415

requirement for registration by making them subject to the requirements of the produce safety rule for compliance purposes. Some comments ask us to provide an exemption from, or waiver for, the requirements of the human preventive controls rule if a business entity provides documentation that the entity is following the standards of the produce safety rule even though it is not on a farm. Other comments ask us to clarify that a farm can pack or hold RACs that have already undergone packing or holding activities by another farm.

Some comments ask to revise the “farm” definition to include establishments solely engaged in “packing” and “holding” activities performed on RACs, regardless of whether the establishment grows crops. Other comments emphasize that any revisions to the “farm” definition must allow genuine farm operators to carry out harvesting, packing, and holding without opening loopholes for packing and processing businesses. Some comments ask us to revise the “farm” definition to provide for a multi-ownership operation provided that all of the partial owners are themselves farmers.

Some comments ask us to provide that off-farm packing and holding operations that do not change the status of a RAC into a processed food should be able to comply with either the produce safety rule or with the CGMPs in subpart B of the human preventive controls rule. According to these comments, we could simply apply the same logic that we applied when providing that the packing and holding of RACs that have been dried/dehydrated to create a distinct commodity that is a processed food (*i.e.*, no longer a RAC) may achieve compliance with the CGMP requirements by complying either with subpart B of the human preventive controls rule or by complying with the applicable requirements for packing and holding produce RACs in the produce safety rule (see § 117.5(k)(2)).

(Response 25) We have revised the “farm” definition to provide for two types of farms: (1) A primary production farm and (2) a secondary activities farm (see § 117.3). We use the term “primary production farm” to refer to the “farm” definition as proposed, with the revisions described in this final rule. We use the term “secondary activities farm” to mean an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or

raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm. With the added definition of “secondary activities farm,” off-farm packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) can be within the “farm” definition. We are making these changes to reflect the current reality of what it means to be a farm. The changes will allow farms that use certain business models to harvest, pack, and/or hold produce to be able to comply with the produce safety rule for all of their operations. We believe that this flexibility allows for the requirements of the produce safety rule to apply to a wider array of activities than our original proposal without opening the “farm” definition to operations that have no connection to the growing of crops or the raising of animals—the core activities of a farm. By specifying that the farms that grow or raise the majority of the RACs harvested, packed, and/or held by the operation must own, or jointly own, a majority interest in the secondary activities farm, the revised “farm” definition does, as requested by comments, allow “farms” to carry out harvesting, packing, and holding activities in the same way as the produce safety rule.

We are, as requested by some comments, establishing a new provision to allow off-farm establishments that package, pack, and hold RACs that are produce as will be defined in the produce safety rule to comply with the CGMPs in part 117, subpart B by complying with the applicable requirements for packing and holding that will be established in the final produce safety rule (see § 117.8). Because the new provision refers to provisions in a future produce safety rule, we will publish a document in the **Federal Register** announcing the effective date of that provision once we finalize the produce safety rule.

However, the revised “farm” definition does not, as requested by some comments, establish the exact same regulatory framework for operations, such as certain packinghouses and hulling/shelling operations, that are within the “farm” definition as for operations that conduct similar activities but are outside the “farm” definition by allowing off-farm operations to be subject to the produce

safety rule rather than the requirements for hazard analysis and risk-based preventive controls. We disagree that the statutory framework provides flexibility for entities such as packinghouses and hulling/shelling operations that do not have a connection to a farm to be subject to the requirements of the produce safety rule for compliance purposes. (See the discussion at 79 FR 58524 at 58536.) We continue to believe that an off-farm packinghouse that is subject to this rule will be able to draw from the provisions of the produce safety rule in developing its food safety plan and establishing preventive control management components that are appropriate in light of the nature of the preventive controls and their role in the facility's food safety system. For example, as previously discussed (79 FR 58524 at 58536) we expect that the food safety plan for an off-farm packinghouse would focus on a few key preventive controls, including some that would have counterparts in the proposed produce safety rule, such as maintaining and monitoring the temperature of water used during packing (which would have counterparts under proposed § 112.46(c) in the proposed produce safety rule). We also expect that an off-farm packinghouse would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food-packaging material, and other food-contact surfaces. On-farm packinghouses would be subject to similar, but not identical, requirements (see *e.g.*, proposed § 112.111(b) for cleanliness of food-contact surfaces and proposed § 112.113 for protection against contamination).

We acknowledge that some of the provisions of the human preventive controls rule have no explicit counterparts in the proposed produce safety rule (*e.g.*, the requirements for product testing and environmental monitoring as verification activities). As discussed in Response 525, we do not expect either product testing or environmental monitoring to be common in facilities that process, pack, or hold produce RACs.

Finally, in response to comments that ask for a clarification that a farm can pack or hold RACs that have already undergone packing or holding activities by another farm, we presume that the commenter was asking about a case where the farm that did the previous packing and holding activities was not the farm on which the RACs were grown

and harvested. The definition of "farm" allows packing and holding of one's own RACs and other's RACs, even if they have been previously packed or held by another farm that was not the farm on which the RACs were grown and harvested.

(Comment 26) Some comments ask us to clarify whether the "and" between provisions that allow a farm to dry/dehydrate RACs to create a distinct commodity, and provisions that allow a farm to package and label RACs, means that an operation must do both of these activities to remain within the farm definition. These comments state that they do not think this is the intended (or logical) outcome, which is to provide that farms can do either or both activities and still be within the farm definition and ask us to consider editorial changes (such as replacing "and" with "or," or adding a new paragraph that would encompass both activities).

(Response 26) The rule does not require a farm to do both activities (*i.e.*, drying/dehydrating RACs to create a distinct commodity, and packaging and labeling RACs) to remain within the farm definition.

(Comment 27) Some comments ask us to add artificial ripening of RACs as an activity that is within the farm definition. Some comments assert that artificial ripening of RACs is not manufacturing/processing because artificial ripening does not transform a RAC into a processed food.

(Response 27) We have revised the "farm" definition to specify that treatment to manipulate the ripening of RACs (such as by treating produce with ethylene gas), and packaging and labeling the treated RACs, without additional manufacturing/processing, are within the "farm" definition. We agree that a treatment such as artificial ripening does not transform a RAC into a processed food but disagree that such a treatment is not manufacturing/processing. To make that clearer, we have added "treating to manipulate ripening" to the list of examples of manufacturing/processing in the definition of that term. As discussed during the rulemaking to establish the section 415 registration regulations, artificial ripening constitutes manufacturing/processing because it involves treating, modifying, or manipulating food (68 FR 58894 at 58912, October 10, 2003). See also our previous statements about artificial ripening in this rulemaking (78 FR 3646 at 3683 and 79 FR 58524 at 58572).

As previously discussed, the activities that transform a RAC into a processed food (and are sometimes therefore

referred to as "processing" in the context of a food's status as a RAC or processed food) are not coextensive with the activities described in our definition of "manufacturing/processing" (78 FR 3646 at 3679). When we first established the section 415 registration regulations, a key criterion in determining whether a business entity was a "farm" or a "facility" was whether the operation conducted activities classified as "manufacturing/processing." Indeed, in the 2013 proposed preventive controls rule we continued to rely on that key criterion in proposing revisions to the "farm" definition. However, as already discussed, some changes to the "farm" definition are necessary to establish a sensible framework of risk-based regulations that both implement FSMA and reflect common farm activities (see Response 21). One of these changes is to specify those manufacturing/processing activities that are within the "farm" definition, rather than attempt to reclassify an activity that arguably is manufacturing/processing as harvesting, packing, or holding in order to provide for the activity to remain within the "farm" definition.

(Comment 28) Some comments disagree that we should provide for drying/dehydrating RACs to create a distinct commodity to be within the "farm" definition because this activity is a manufacturing/processing activity and should be subject to the requirements for hazard analysis and risk-based preventive controls. Other comments agree that we should provide for this activity but assert that "drying/dehydrating RACs to create a distinct commodity" is confusing to the average reader and ask us to add examples of what this means. Some comments ask us to clarify whether this activity applies to specific situations, such as drying/baling of hops (because hops are a low-risk product and beer brewing should eliminate any pathogens on the hops), drying plums to create prunes, and concentrating maple sap into maple syrup, cream, and candy. Some comments assert that maple syrup should be considered a RAC because the process of producing maple syrup mirrors the regulatory text "drying/dehydrating RACs to create a distinct commodity," because maple syrup can only be produced through the concentration of maple sap and the process of that concentration is akin to the harvesting of other raw products. Other comments assert that the processing of sap is more appropriately viewed as a harvesting activity (rather than food manufacturing).

Other comments ask us to clarify the specific methods of drying/dehydrating that we would consider to be within the “farm” definition—*e.g.*, whether drying/dehydrating is constrained to in situ, with no heat or mechanical air circulation, because the example we discussed in the 2014 supplemental preventive controls notice was “natural condition raisins.” These comments ask us to specify the allowable methods of drying to avoid confusion, and assert that there is no food safety reason to exclude use of heat or air, especially if sun and light are to be permitted. Other comments ask us to clarify what we mean by “without additional manufacturing/processing.”

(Response 28) We are retaining drying/dehydrating RACs to create a distinct commodity as an activity that is within the “farm” definition even though it is manufacturing/processing. As previously discussed, the processes (described in comments to the 2013 proposed human preventive controls rule) for drying grapes to “natural condition raisins” are akin to other harvesting activities traditionally conducted by farms on RACs grown and harvested on farms, because they are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food (79 FR 58524 at 58533). As also previously discussed, the information provided by the comments to the 2013 proposed human preventive controls rule included information that “natural condition raisins” are produced with either sun-drying or artificial dehydration (79 FR 58524 at 58533). We did not intend to limit the processes for drying/dehydrating RACs to sun-drying, and the regulatory text includes no such limitation. We decline the request to specify specific methods of drying/dehydrating that would remain within the “farm” definition because doing so could imply that the list of methods was exhaustive and preclude use of new technology in the future.

However, we are adding “boiling” and “evaporating” to the list of activities that we classify as manufacturing/processing to preclude interpretations, such as those expressed in some of these comments, that the processes to produce products such as maple syrup, maple cream, and maple candy are “drying/dehydrating.” In the 2013 proposed human preventive controls rule we included “Boiling/evaporation of maple sap to make maple syrup” as a low-risk manufacturing/processing activity/food combination in the exemption for small and very small businesses that only conduct specified

on-farm low-risk activity/food combinations (proposed § 117.5(h)), and we have retained—and broadened—that activity/food combination as an on-farm, low-risk manufacturing/processing activity/food combination in the final human preventive controls rule (see § 117.5(h), which includes making sugar and syrup from fruits and vegetables (*e.g.*, dates), grains (*e.g.*, rice, sorghum), other grain products (*e.g.*, malted grains such as barley), saps (*e.g.*, agave, birch, maple, palm), sugar beets, and sugarcane). Processes such as “boiling,” “concentrating,” and “evaporating” are not “drying/dehydrating” as the term “drying/dehydrating” is used in this rule, and maple syrup is a processed food, not a RAC. See also the discussion in Response 23 regarding how a farm mixed-type facility that makes sugar from sugarcane or sugar beets can consider the findings of the section 103(c)(1)(C) RA (*i.e.*, that this is a low-risk activity/food combination) in determining whether there are any hazards requiring a preventive control. A farm mixed-type facility that makes maple products from maple sap could follow the same approach.

We have added “slicing” to the regulatory text as an example of additional manufacturing/processing that would be outside the “farm” definition. We also have added “drying/dehydrating grapes to produce raisins” to the regulatory text as an example of what we mean by “drying/dehydrating RACs to create a distinct commodity.” Drying plums to produce prunes is another example of drying/dehydrating RACs to create a distinct commodity. Drying/baling hops is within the “farm” definition, but as a “holding” activity because drying/baling hops does not create a distinct commodity. As discussed in Response 39, we have revised the definition of “holding” to add drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa) as an example of a holding activity.

(Comment 29) Some comments agree that the activities of packaging and labeling RACs should remain within the “farm” definition but ask us to reclassify these activities so that they are not considered manufacturing/processing because they do not transform a RAC into a processed food or change the nature of the RAC. These comments ask us to add examples to regulatory text to explain what we mean by “packaging and labeling without additional manufacturing/processing.” As an example, these comments ask whether a farm that packs produce

grown by another farm, and washes the produce before packing it, would be conducting “additional manufacturing/processing.”

Other comments ask us to clarify whether packaged RACs are processed food because “packaging” is defined as a manufacturing/processing operation. These comments also ask us to clarify whether a farm would be precluded from holding RACs packaged in retail form because the packaged RACs are processed food.

(Response 29) See Response 27. We decline the request to reclassify packaging and labeling so that they would not be considered manufacturing/processing. Although we classify packaging and labeling as manufacturing/processing, packaging and labeling RACs do not transform the RACs into processed food, and we classify “packaged RACs” as RACs.

We classify washing RACs as a harvesting or packing activity when done on RACs before or during packing or packaging, regardless of whether a farm is packing or packaging its own RACs or others’ RACs. As requested by the comments, we have added an example of additional manufacturing/processing that would not be within the “farm” definition—*i.e.*, irradiating—to both the “farm definition” and to the definition of “manufacturing/processing.” This example is different from the example we used in the preamble of the 2014 supplemental human preventive controls notice to describe a limitation on activities within the “farm definition”—*i.e.*, “modified atmosphere packaging” (see 79 FR 58524 at 58532). We have decided to not restrict the specific types of packaging procedures that are within the “farm” definition because doing so could be confusing. Moreover, the specific safety concern that can be associated with modified atmosphere packaging (*i.e.*, the production of *Clostridium botulinum* toxin), would be addressed by a proposed provision in the forthcoming produce safety rule, if that provision is finalized (see proposed § 112.115; 78 FR 3504 at 3589 and 3638). To clarify that “modified atmosphere packaging” is a type of “packaging,” we have revised the definition of “manufacturing/processing” to specify “packaging (including modified atmosphere packaging)” as an example of a manufacturing/processing activity.

(Comment 30) Some comments assert that non-produce botanicals require treatments that do not create a new commodity and ask us to recognize these treatments as farm activities rather than manufacturing/processing activities. As examples, these comments

assert that activities such as cutting, slicing, drying, freezing, wet or dry heat treating to kill plant tissues, and aging or fermenting are all activities that are traditionally performed by farms on non-produce botanicals for the purpose of removing non-produce botanical RACs from the place where they were grown and preparing them for use as food. These comments also assert that we have been inconsistent in our activity classifications because we both state that “heat treatment” is a food processing activity and state that activities traditionally performed by farmers to prepare crops for use are farm activities. These comments express concern that farmers won’t use heat treatments to control pests, based on a misunderstanding of what constitutes “food processing.”

(Response 30) We note that these comments used the term “non-produce botanicals,” which is not a term we have used or defined, and it is not clear to us what the commenters intended this term to represent. In this document, we are not addressing the question of whether certain “botanicals” are or are not “produce.” The term “produce” was proposed to be defined in the forthcoming produce safety rule, and we intend to define it in that rule.

However, we can address in this rule these commenters’ questions about activity classification. Some of these activities are within the “farm” definition. For example, drying/dehydrating a RAC without creating a distinct commodity is part of “holding” and drying/dehydrating a RAC that creates a distinct commodity, without additional manufacturing/processing, is manufacturing/processing that is included within the “farm” definition. (See Response 28.) Cutting (or otherwise separating) the edible portion of the RAC from the crop plant and removing or trimming part of the RAC (*e.g.*, foliage, husks, roots or stems) are harvesting activities. (See Response 37.) We have revised the definition of “holding” to include the example of “fumigating food during storage.” (See Response 39.) We decided to include this example of a holding activity based on previous discussions of how we classify fumigating as a type of pest control (*see, e.g.*, 78 FR 3646 at 3682 and 79 FR 28524 at 28571). Although we have not previously classified heat treatment for purposes of pest control, we agree that we should classify heat treatment for purposes of pest control the same way that we have classified fumigating for purposes of pest control—*i.e.*, as a holding activity. Regarding classification of the other

activities listed in these comments, see Response 3.

(Comment 31) Some comments assert that the “farm” definition is too limited and ask us to include standard farm activities such as culling, conveying, sorting, waxing, labeling, storing, packaging and shipping of raw, whole produce. These comments assert that these normal activities do not change the shape or structure of RACs, or alter the hazards, and should be covered under the produce safety rule rather than the human preventive controls rule.

(Response 31) All of the activities described by these comments could be within the “farm” definition (*see* 79 FR 58524 at 58571–58572), either because they are specified in the “farm” definition itself or because they are examples of activities within the definition of “packing” or holding.” Packaging and labeling RACs, without additional manufacturing/processing, are specified in the regulatory text of the “farm” definition. Sorting and culling are included in the regulatory text of the definition of “packing.” Storing is simply another term for “holding.” We had already included “weighing and conveying” as an example of a low-risk packing or holding activity in the exemption applicable to on-farm low-risk activity/food combinations (§ 117.5(g)). To give more prominence to this packing activity, we have added it to the definition of “packing” as well.

(Comment 32) One comment, submitted to Docket No. FDA–2011–N–0143 for the FSVP rulemaking, notes that RACs often are harvested by a contract harvest company (Ref. 16). This comment asks us to clarify what is meant by “establishment that harvests a food” in the definition of “foreign supplier” and whether, in such circumstances, the supplier of the RAC would be the contract harvest company or the establishment that owns the crop and sells it to an importer.

(Response 32) The 2014 supplemental human preventive controls notice had similar phrasing (“establishment that harvests the food”) in the definition of “supplier.” In the final rule the definition of “supplier” has changed in relevant part to include the “establishment that grows the food,” consistent with changes to the farm definition and as described in the following paragraphs.

There are several different business models in which RACs are harvested by a contract harvester (Ref. 17). In one business model, a grower contracts with a harvester to perform harvesting on behalf of the grower. In another business model, a third-party handler enters into

separate contracts with the grower and the harvester. In another business model, a grower sells its crop to an entity that contracts with a separate harvester to harvest the RACs and then packs the RACs. There are variations on these business models, such as when a grower sells its crop to an entity that both harvests and packs the RACs, without a contract with a separate harvester.

Growing and harvesting operations are not under the same management in some of these business models. As discussed in Comment 23, comments emphasize that farming operations can have complex business structures, and ask us to revise the “farm” definition to provide for these business models. To explicitly include these business models in the “farm” definition, we have revised the “farm” definition to mean an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. With this revision, an operation can be within the “farm” definition if it grows crops but does not harvest them or if it harvests crops but does not grow them.

The “farm” definition established in the section 415 registration regulations in 2003 (68 FR 58894), and the proposed revisions to the “farm” definition in the 2013 proposed human preventive controls rule and the 2014 supplemental human preventive controls notice, all describe a “farm” as an entity “devoted to the growing *and* harvesting of crops” (emphasis added). In light of the revision to the “farm” definition and as discussed more fully in section IX.C.35, we have revised the “supplier” definition to include the establishment that “grows the food” rather than the establishment that “harvests the food.” With this change in the “supplier” definition, the supplier is the farm that grows the food regardless of the business model for harvesting the food.

(Comment 33) Some comments ask us to modify the “farm” definition to exclude feed mills that provide feed to more than 5 other farms. These comments assert that egg farms are most likely to be company owned and the median number of farms owned by a company is under 8 and cite USDA as the source of this information. These comments assert that setting the limit at 5 would not automatically exempt feed mills operated by these large egg laying businesses from the animal preventive controls rule.

(Response 33) We decline this request. The statutory exemption from

the section 415 registration regulations (and, thus, from the requirements for hazard analysis and risk-based preventive controls) for “farms” is based on the activities that an operation conducts rather than on the size of the operation.

(Comment 34) Some comments assert that the hulling or dehydration of walnuts should not be considered processing and, thus, that an establishment that conducts hulling or dehydration activities on tree nuts such as walnuts should not be considered a facility subject to the requirements for hazard analysis and risk-based preventive controls. These comments also assert that all growers who hull and dry should operate under the same rules, regardless of whether or not they own their own crop. Some comments assert that the hulling and shelling operations in the nut industry are part of the harvesting operation in which the outer shells are removed. These comments state that regardless of whether activities are conducted on the farm in which they are grown or at an off-farm facility that provides hulling and shelling services, the food is a RAC, the activity is low-risk and does not transform the RAC into a processed food, and the product is delivered to a processing facility and is not distributed in commerce. The comments argue that for all these reasons and because hulling and shelling activities are not subject to subpart B, it is not appropriate to subject facilities that conduct such activities to subpart C. Comments request that hulling, shelling, and drying of tree nuts be considered “on farm” for the purposes of this rule. Other comments ask us to specify that the production of “natural dried raisins,” dried plums, and dried hops are within the “farm” definition.

(Response 34) Hulling of tree nuts (such as walnuts, almonds, and pistachios) is a harvesting activity that is within the “farm” definition when conducted on a farm or the farm part of a farm mixed-type facility. Drying/dehydrating RACs without creating a distinct commodity (such as drying walnuts and hops) is a holding activity that also is within the “farm” definition when conducted on a farm or farm mixed-type facility. As discussed in Response 25, we have revised the “farm” definition to provide that an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition (as a “secondary activities farm”), provided that the primary production farm(s) that grows, harvests, and/or raises the majority of

the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.

Drying/dehydrating RACs (such as grapes and plums) to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing is within the “farm” definition when conducted on a farm or farm mixed-type facility. (See Response 28.) However, additional manufacturing/processing activities (such as removing pits from dried plums) are outside the “farm” definition, and a farm or farm mixed-type facility that conducts such activities becomes a facility that is required to register and is subject to the requirements for hazard analysis and risk-based preventive controls for those activities outside the farm definition. The exception is when a farm is a small or very small business eligible for the exemptions in § 117.5(g) and (h) for a farm mixed-type facility that only conducts low-risk activity/food combinations. Such a small or very small business must still register as a food facility, but will be exempt from the requirements for hazard analysis and risk-based preventive controls. (See also the discussion in the 2014 supplemental human preventive controls notice (79 FR 58524 at 58533–58534 and table 1 in the Appendix to the 2014 supplemental human preventive controls notice (79 FR 58524 at 58571–58572)).

(Comment 35) Some comments assert that we have referred to raw milk as being “inherently dangerous” and should not consider any activities that result in the preparation of an inherently unsafe product for sale to consumers to be within the “farm” definition (*i.e.*, production of raw milk for direct human consumption should not be considered “harvesting” or “packing”). These comments ask us to re-consider the definition of “farm” as it applies to the production of raw milk for human consumption. Specifically, these comments ask us to consider such activities to be outside the traditional business of a dairy farm and to subject businesses that conduct such activities to FSMA’s requirements for hazard analysis and risk-based preventive controls requirements as a means of advancing public health.

(Response 35) We decline this request. Producing milk is a traditional activity of a dairy farm, regardless of whether the milk produced by that dairy farm is pasteurized and introduced into interstate commerce in accordance with § 1240.61 (Mandatory pasteurization for all milk and milk products in final

package form intended for direct human consumption) or sold unpasteurized to consumers within a State consistent with applicable State laws and regulations. Distributing raw milk in interstate commerce would be unlawful, but would not form the basis for a decision that the business is “not a farm.”

(Comment 36) Some comments express concern that farmers who grow seed that is sold as animal feed must register as a food facility. These comments ask why sales of grain for animal feed are included in a rule that is focused on the safety of human food and ask us to exempt this category of farms and their sales of grain for animal feed from the registration rule.

(Response 36) Establishments that satisfy the “farm” definition, including farms that grow seed that is sold as animal food, are not required to register as a food facility. These comments may mistakenly believe that we intended any food establishment that is required to register as a food facility to comply with the regulations we are establishing in part 117 regarding human food, regardless of whether the facility produces food for consumption by humans or food for consumption by animals. This is not the case. We simply proposed to revise definitions in the section 415 registration regulations relevant to the definition of “facility” in the same notice in which we proposed to modernize the current CGMPs for food and establish requirements for hazard analysis and risk-based preventive controls for human food, because section 103 of FSMA addresses the definitions in the section 415 registration regulations, as well as the requirements for hazard analysis and risk-based preventive controls. If a facility sells grain for use as animal food, and is not exempt from the section 415 registration regulations, that facility would be subject to the animal preventive controls rule, not the human preventive controls rule that is the subject of this document.

### C. Proposed New Definition of Harvesting

We proposed to define “Harvesting,” as a new definition in §§ 1.227 and 1.328, to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed on RACs on a farm, and that harvesting does not include activities that transform a RAC into a processed

food. The proposed definition included examples of activities that would be harvesting. As noted in table 52 of this document, we have reorganized the listed examples of harvesting to present them in alphabetical order. We also have modified the proposal that harvesting be limited to activities performed on RACs on a farm to provide that harvesting can also be performed on processed foods created by drying/dehydrating a RAC without additional manufacturing/processing, because processed foods created by drying/dehydrating RACs are within the “farm” definition. See Response 28 and 79 FR 58524 at 58533 regarding drying/dehydrating RACs to create a distinct commodity.

(Comment 37) Some comments ask us to provide more examples of harvesting activities, in the regulatory text and in guidance. Examples of the requested activities include braiding; bunching; cutting the edible portion of the crop from the plant; hydro-cooling; maintaining hydration of product; refrigerating; removing foliage; removing free water from (*e.g.*, spinning); removing or trimming roots; trimming the tops of bunches of allium crops such as leeks, chives, or garlic and root crops such as carrots, beets, turnips, parsnips, etc. to prepare them for sale; and trimming the lower stems of harvested herb crops such as parsley, basil, or cilantro, or the lower stems of leafy greens. Other comments ask us to specify that harvesting also encompasses seed conditioning (*i.e.*, cleaning the seed, including removal of leaves, stems, and husks to prepare for marketing), ripening (artificial or natural) of fruit, and waxing or coating of RACs.

(Response 37) We have added or modified several examples of harvesting in the regulatory text (*i.e.*, cutting (or otherwise separating) the edible portion of the RAC from the crop plant, removing or trimming part of the RAC (*e.g.*, foliage, husks, roots or stems), field coring, and hulling). In table 1 in the Appendix to the 2014 supplemental human preventive controls notice (79 FR 58524 at 58571–58572), we provided a more extensive list of examples of harvesting activities, including examples that are not in the regulatory text. Although we have classified some of these activities in more than one way (see 79 FR 58524 at 58571–58572), in general these activities would fall within the “farm” definition when conducted on RACs that are not otherwise processed. For example, coating RACs with wax/oil/resin for the purpose of storage or transport can be a packing (not harvesting) activity, but

waxing also has long been considered a manufacturing/processing activity during the production of processed food (because it involves making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food) (see 78 FR 3646 at 3679). Artificial ripening of fruit is manufacturing/processing (not harvesting), but is now within the “farm” definition (see § 117.3 and Response 27). Regarding classification of the other activities listed in these comments, see Response 3.

(Comment 38) Some comments assert that fermenting cocoa beans and coffee beans should be classified as “harvesting” rather than “holding.”

(Response 38) We agree that the process of fermenting cocoa beans and coffee beans begins as a “harvesting” activity, when the pods are harvested and the beans are removed; it continues as “holding,” while the harvested beans ferment. Thus, fermenting cocoa beans and coffee beans has elements of both “harvesting” and “holding,” which are both within the “farm” definition. It is not necessary to place the process of fermenting cocoa beans and coffee beans squarely in one activity or the other for the regulatory purpose of determining whether an operation is within the “farm” definition. See also Response 41.

#### *D. Proposed Revision to the Definition of Holding*

We proposed to revise the definition of “Holding” in §§ 1.227 and 1.328 to add that holding also includes activities performed incidental to storage of a food, but does not include activities that transform a RAC into a processed food. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(Comment 39) Some comments ask us to provide more examples of holding activities, in the regulatory text and in guidance. Examples of the requested activities include fumigating RACs; application of chemicals (including fungicides, sanitizers, and anti-oxidants); application of ripening agents; using wax as a carrier of fungicides or anti-oxidants applied before storage; and waxing or coating of RACs, including “coating” grain RACs with diatomaceous earth to control insects. According to these comments, these activities are incidental to storage and do not transform RACs into processed food.

(Response 39) We have added or modified several examples of holding in the regulatory text (*i.e.*, fumigating food during storage, and drying/dehydrating RACs when the drying/dehydrating

does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). In table 1 in the Appendix to the 2014 supplemental human preventive controls notice (79 FR 58524 at 58571–58572), we provided a more extensive list of examples of holding activities, including examples that are not in the regulatory text. We have previously classified some of these activities in more than one way (see 79 FR 58524 at 58571–58572) depending on when the activity occurs. For example, sorting, culling, and grading RACs can be either a holding activity or a packing activity. Drying/dehydrating RACs is holding when the drying/dehydrating does not create a distinct commodity, but is manufacturing/processing when the drying/dehydrating creates a distinct commodity (see Response 28). Regarding classification of the other activities listed in these comments, see Response 3.

(Comment 40) Some comments ask us to clarify that mixing or blending intact RACs is considered “holding” regardless of whether the RACs are the same or different.

(Response 40) We use the term “blending” when referring to RACs such as grain and when the RACs are the same. For example, we consider the activity of “blending” different lots of the same grain to meet a customer’s quality specifications to be a practical necessity for product distribution and, thus, to be within the definition of “holding” (see 79 FR 58524 at 58537). However, we use the term “mixing” when the RACs are different. For example, we consider the activity of “mixing” corn and oats in the production of animal food to be manufacturing/processing, because mixing two different foods is “making food from one or more ingredients” (which is our definition of “manufacturing/processing”), and the animal food produced by mixing corn and oats is a processed food.

We classify “mixing” intact RACs that does not create a processed food as incidental to, and therefore part of, “packing” or “holding” as applicable.

(Comment 41) Some comments ask us to clarify whether the expanded definition of holding that we proposed in the 2014 supplemental human preventive controls notice would mean that a warehouse that both stores cocoa beans and fumigates the cocoa beans to prevent pest infestation would be exempt from the requirements for hazard analysis and risk-based preventive controls for a facility solely engaged in the storage of RACs (other than fruits and vegetables) for further distribution or processing (§ 117.5(j)).



(Response 41) Fumigating RACs such as cocoa beans to prevent pest infestation would be within the definition of “holding.” Therefore, such fumigation would not prevent a facility that stores RACs (other than fruits and vegetables) from being eligible for the exemption in § 117.5(j), provided that the facility does not conduct other activities not classified as “holding.” However, a threshold question for any facility solely engaged in the storage of RACs is whether the stored RACs are fruits or vegetables. We classify cocoa beans within the category of “fruits and vegetables” (78 FR 3646 at 3690) and, thus, a facility that stores cocoa beans is not eligible for the exemption in § 117.5(j).

(Comment 42) Some comments ask us to clarify whether there is a timeframe associated with holding and to better distinguish between “holding” and “storage.”

(Response 42) There is no timeframe (maximum or minimum) associated with holding. The definition of holding states “Holding means storage of food” and, thus, there is no distinction between “holding” and “storing.”

(Comment 43) Some comments ask us to clarify how the definition of holding relates to practices, such as fumigation, on almond hull stockpiles held on a farm, a farm mixed-type facility, or off-farm.

(Response 43) Practices that are incidental to storage of food, such as fumigation of almond hull stockpiles, are holding, regardless of whether they are conducted on-farm, on a farm mixed-type facility, or off-farm.

(Comment 44) Some comments ask us to clarify that value added activities (such as repacking and blast freezing) conducted in facilities such as warehouses would be considered holding when product is not exposed to the environment.

(Response 44) We consider the activities described in these comments to be activities performed as a practical necessity for the distribution of the food and, thus, to be within the definition of holding.

(Comment 45) Some express concern that the definition of holding would prevent a facility that samples food (such as sugar) for grading or quality control purposes from qualifying for the exemption for facilities engaged solely in holding unexposed packaged food because they would temporarily expose otherwise unexposed packaged food to the environment. These comments ask us to make clear that the requirements for hazard analysis and risk-based preventive controls only apply to the sampling activities and that engaging in

sampling activities does not remove a warehouse’s exemption altogether.

(Response 45) We consider that sampling food in the manner described by this comment is a practical necessity for the distribution of the food within the definition of “holding,” and that the exemption still applies to a facility that conducts such sampling. Importantly, the sampling must be in done in accordance with CGMPs such that the exposure does not result in contamination of the food.

#### *E. Proposed Revision to the Definition of Manufacturing/Processing*

We proposed to revise the definition of “Manufacturing/Processing” in §§ 1.227 and 1.328 by adding to the existing definition a criterion applicable to farms and farm mixed-type facilities. As noted in table 52, we have reorganized the listed examples of manufacturing/processing to present them in alphabetical order.

(Comment 46) Some comments express concern that some activities included in the definition of “manufacturing/processing” overlap with activities (such as trimming, washing, and cooling) included in the definition of “harvesting.”

(Response 46) We acknowledge that there is some overlap in the activities that the regulatory text lists as examples of both “manufacturing/processing” and “harvesting,” because some activities can occur during more than one operation (see also the discussion at 79 FR 58524 at 58538 and table 1 in the Appendix to the 2014 supplemental human preventive controls notice (79 FR 58524 at 58571–58572)). For example, “cutting” the core of the lettuce from the crop plant can occur on-farm in the field where the lettuce is harvested, and “cutting” the core of the lettuce from the rest of the harvested lettuce also can occur in a fresh-cut processing facility. An important consequence of the multiple revisions we have made to the “farm” definition in this rulemaking is that there are fewer situations in which classification of a particular activity is the only trigger for an operation to be subject to the section 415 registration regulations. For example, the revised “farm” definition no longer classifies the packing and holding of others’ RACs to be a manufacturing/processing activity that triggers the registration requirement. As another example, the revised “farm” definition specifies three manufacturing/processing activities that are within the “farm” definition. We conclude that the overlap in the examples of activities listed in the definitions of “harvesting” and

“manufacturing/processing” does not create problems with determining the status of an operation as a “farm” or a “facility” and we are retaining examples in both definitions because doing so reflects current practices on farms and in manufacturing/processing facilities.

(Comment 47) Some comments ask us to clarify that the traditional activities of a packing shed—cleaning and packing intact fruits and vegetables—do not constitute “manufacturing/processing” that would trigger the requirement to register as a facility.

(Response 47) Packing activities are within the definition of “packing,” and holding activities are within the definition of “holding,” regardless of whether the packing or holding activities take place on-farm or off-farm. In other words, neither packing produce nor holding produce would be classified as manufacturing/processing merely because the business entity conducting the activity is a facility that is subject to the section 415 registration regulations. As discussed in Response 25, we have revised the “farm” definition to provide that an operation devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition (as a “secondary activities farm”), provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. With this revision, some off-farm packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) can be within the “farm” definition, provided that the primary production farm(s) that grows, harvests, or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the packing operation.

(Comment 48) Some comments ask us to make clear, in our response to comments in the final rule, that any adjustments we make to the definition of manufacturing/processing in no way change the definitions of “raw agricultural commodity,” “processing,” and “processed food,” which were mutually agreed to by EPA and FDA (Ref. 15) to address regulatory responsibilities for antimicrobials applied to food, process water contacting food, or hard food-contact surfaces.

(Response 48) The revisions we made to the “farm” definition, and to the classification of activities relevant to the

“farm” definition, do not change the statutory definitions of “raw agricultural commodity,” and “processed food,” or impact our interpretation of the definition of “processing,” with respect to regulatory jurisdiction for antimicrobials applied to food, process water contacting food, or hard food-contact surfaces.

#### F. Proposed New Definition of Mixed-Type Facility

We proposed to define “Mixed-type facility,” as a new definition in §§ 1.227 and 1.328, to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. We specified in the regulatory text that an example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. As a conforming change associated with the revisions to the “farm” definition, we have revised the example of a “farm mixed-type facility” to specify that it is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

(Comment 49) Some comments assert that there is no scientific basis for the definition of mixed-type facility.

(Response 49) The proposed definition is not a science-based definition. It is a descriptive term that we are using to refer to certain food establishments. We used this same term during the rulemaking to establish the section 415 registration regulations (see response to comment 46, 68 FR 58894 at 58906, October 10, 2003).

(Comment 50) Some comments ask us to revise the definition to add more details about activities that are inside the farm definition and activities that are outside the farm definition.

(Response 50) We decline the request of these comments. Adding such details would detract from the focus of the definition—*i.e.*, that it refers to a facility that conducts both activities that are inside the farm definition and activities that are outside the farm definition. We have included additional examples of “harvesting,” “packing,” and “holding” activities in the regulatory text of the definitions for those terms (see §§ 1.227, 1.328 and 117.3 and Response 31, Response 37 and Response 39). (See also Response 3.)

(Comment 51) Some comments ask us to revise the definition to exclude those establishments that only conduct low-

risk activities specified in the exemptions for on-farm, low-risk activity/food combinations (§ 117.5(g) and (h)).

(Response 51) We decline this request. Whether a particular establishment that falls within the definition of “mixed-type facility” is subject to the requirements for hazard analysis and risk-based preventive controls is governed by the exemptions established in this rule.

#### G. Proposed Revision to the Definition of Packing

We proposed to revise the definition of “Packing” in §§ 1.227 and 1.328 by adding that packing includes activities performed incidental to packing a food, but does not include activities that transform a RAC into a processed food. We have revised the definition to clarify that packing includes “re-packing.”

(Comment 52) Some comments ask us to include minimal “manufacturing/processing” of RACs in the definition of packing when the minimal “manufacturing/processing” does not transform the RAC into a processed food. The comments describe waxing of fresh fruit (such as apples) and vegetables as examples of activities that do not transform a RAC into a processed food.

(Response 52) As already discussed, the activities that transform a RAC into a processed food (and are sometimes therefore referred to as “processing” in the context of a food’s status as a RAC or processed food) are not coextensive with the activities described in our definition of “manufacturing/processing.” (See Response 27.) Although waxing has long been considered a manufacturing/processing activity during the production of processed food (because it involves making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food), we classify coating RACs with wax/oil/resin for the purpose of storage or transport as a packing activity. (See Response 37.)

(Comment 53) Some comments ask us to clarify the distinction between “packing” and “packaging” because the terms are different but seem to be used interchangeably. These comments express concern that “placing food into containers” on farms that have traditionally done so will be classified as “manufacturing/processing” and trigger the requirement to register as a food facility and ask us to reclassify “packaging” within the definition of “packing.” Other comments ask us to remove the words “other than packaging of food” from the definition of

“packing.” Some comments state that when a RAC is packed in the field and/or is placed into a clamshell container, as a practical matter it is considered to have been “packed,” not “packaged.”

(Response 53) We acknowledge that farms traditionally refer to field packing, including placing RACs into clamshell containers that will serve as a consumer package, as “packing,” not “packaging.” Indeed, in the 2013 human preventive controls rule we proposed to revise the definition of “packing” to specify that, for farms and farm mixed-type facilities, “packing” includes “packaging.”

However, in the 2014 supplemental human preventive controls notice we proposed a simpler approach to accommodate requests such as those in these comments, by simply specifying in the “farm” definition that packaging and labeling RACs, without additional manufacturing/processing, is within the “farm” definition. We conclude that the distinctions between the terms “packing” and “packaging” do not create problems with determining the status of an operation as a “farm” or a “facility.” Further, we note that we have given these terms identical meanings across multiple FDA regulations that are applicable to facilities.

(Comment 54) Some comments refer to discussions at a “listening session” regarding harvesting several varieties of lettuce, washing them, and combining heads or bunches of the different varieties in one bag that is sealed with a knot or twist tie. During these discussions, this type of activity was classified as being within the “farm” definition. These comments ask how this activity can be classified as being within the “farm” definition when mixing and washing are listed as manufacturing/processing activities that trigger registration as a food facility and whether there is a discrepancy between what the rule requires and what they heard at the listening session. Other comments express the view that mixing RACs that have not been transformed into processed food (such as bagging mixed greens or different types of whole produce, such as potatoes, beets, and carrots) should not put a farm in the category of a mixed-type facility.

(Response 54) Removing several varieties of lettuce from the place in which they were grown, washing them on the farm, and combining heads or bunches of the different varieties in one bag that is sealed with a knot or twist tie on the farm are all activities within the “farm” definition. We classify “washing” and “mixing” in more than one way depending on when the activity occurs, and the “farm” definition now specifies that

“packaging” RACs (without additional manufacturing/processing, such as slicing) is a farm activity, even though it is a type of “manufacturing/processing.” We have recognized “washing” as a harvesting activity since we first issued the section 415 registration regulations (68 FR 58894 at 58961, October 10, 2003), even though we also classify “washing” RACs as “manufacturing/processing” when done in a food processing facility (such as a fresh-cut processing facility). We classify “mixing” intact RACs that does not create a processed food as incidental to, and therefore part of, “packing” or “holding” as applicable. Mixing heads or bunches of lettuce as described in the example does not create a processed food, because he mixing has not created a distinct commodity, but only a set of mixed RACs. On the other hand, mixing that creates a processed food is not “packing” or “holding.” The definitions of both “packing” and “holding” are limited so that they do not include activities that transform a RAC into processed food. Some kinds of mixing of RACs do create a distinct commodity (for example, mixing corn and oats to make animal food). In such cases, the mixing is manufacturing/processing and is not within the farm definition. Likewise, although we classify placing RACs in a plastic bag with a twist tie as “packaging” rather than “packing” when the plastic bag is the container that the consumer receives, we have provided for “packaging” RACs as an activity within the “farm” definition.

**V. Comments on the Organizing Principles for How the Status of a Food as a Raw Agricultural Commodity or as a Processed Food Affects the Requirements Applicable to a Farm Under Sections 415 and 418 of the FD&C Act**

In the 2014 supplemental human preventive controls notice, we discussed comments on the organizing principles that formed the basis for proposed revisions to the section 415 registration regulations and the section 414 recordkeeping regulations (79 FR 58524 at 58538). We also explained how our proposed revisions to the “farm” definition would require us to reconsider those organizing principles (79 FR 58524 at 58538).

(Comment 55) Some comments assert that we should revise the organizing principles to reflect the realities and range of activities that farms conduct to prepare their crops for market and to make the organizing principles consistent with FSMA’s risk-based mandate. These comments ask us to revise the organizing principles as follows: (1) The basic purpose of farms is to produce RACs and deliver them for sale to end-users or other buyers; (2) activities that involve RACs and that farms perform for the purposes of selling their own RACs, including growing them, harvesting them, preparing them for consumption in their raw and unprocessed state, and packing, sorting, grading, packaging, labeling, holding, transporting, marketing, and delivering them, should all be within the definition of “farm;” (3) even though farms traditionally also do a wide variety of activities that may be considered processing, for the purpose of these organizing principles, activities should be classified based on whether

the activity transforms a RAC into a processed food (as defined by these rules); (4) manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

(Response 55) We have revised the “farm” definition to refer to farms as “operations” rather than “facilities” or “establishments”; reflect modern business models (such as cooperatives, on-farm packinghouses under ownership by multiple growers, food aggregators, and some types of food hubs (e.g., those that consolidate and distribute RACs but do not conduct activities that transform the RACs into a processed food)); specify that a farm is in one general (but not necessarily contiguous) physical location; and provide that an operation devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition as a secondary activities farm, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm (e.g., an off-farm produce packinghouse owned by farmers or a farmer-owned tree nut hulling and drying operation). (See Response 22, Response 23, Response 24, and Response 25.) All of these changes to the “farm” definition do, as requested by these and other comments, reflect the realities and range of activities that farms conduct. See table 5 for organizing principles regarding classification of activities on-farm and off-farm in light of the changes to the “farm” definition.

TABLE 5—ORGANIZING PRINCIPLES REGARDING CLASSIFICATION OF ACTIVITIES ON-FARM AND OFF-FARM

No.	Organizing principle
1	The basic purpose of farms is to produce RACs, and RACs are the essential products of farms.
2	A farm is in one general (but not necessarily contiguous) location.
3	Farm operations include business models such as cooperatives, on-farm packinghouses under ownership by multiple growers, food aggregators, and some types of food hubs.
4	Activities that involve RACs and that farms traditionally do for the purposes of growing RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding, and transporting them, are all within the “farm” definition.
5	Activities are classified based in part whether the activity transforms a RAC into a processed food.
6	A limited number of traditional operations that farms do for the purpose of preparing RACs for use as a food RAC, but that are classified as “manufacturing/processing,” are within the “farm” definition. These are: (1) Drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; (2) treatment to manipulate the ripening of RACs, and packaging and labeling the treated RACs, without additional manufacturing/processing; and (3) packaging and labeling RACs, when these activities do not involve additional manufacturing/processing.
7	Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm is within the farm definition.

## VI. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

### A. Section 103(c)(1)(C) of FSMA

We previously described provisions of FSMA that direct us to conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the “farm” definition and, thus, subject to the requirements for hazard analysis and risk-based preventive controls (see section 103(c)(1)(C) of FSMA and 78 FR 3646 at 3674 and 3689–3691). Consistent with this statutory direction, we developed the section 103(c)(1)(C) draft RA and made it available for public comment (Ref. 18 and 78 FR 3824). We are including the final risk assessment (the section 103(c)(1)(C) RA) in the docket established for this document (Ref. 4).

We previously described provisions of FSMA that direct us to consider the results of the science-based risk analysis and exempt facilities that are small or very small businesses from the requirements for hazard analysis and risk-based preventive controls (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of on-farm activities that we determine to be low risk involving specific foods that we determine to be low risk (see section 103(c)(1)(D) of FSMA and 78 FR 3646 at 3675, 3691, and 3705–3707). Later in this document (see section XI.G), we discuss the provisions we are establishing in § 117.5(g) and (h), based on the results of the section 103(c)(1)(C) RA, to exempt farm mixed-type facilities that are small or very small businesses from requirements for hazard analysis and risk-based preventive controls if the only activities that the business conducts that are subject to those requirements are low-risk activity/food combinations.

We also previously described provisions of FSMA that direct us to: (1) Identify high risk-facilities and allocate resources to inspect facilities according to the known safety risks of the facilities (as determined by several factors) and immediately increase the frequency of inspection of all facilities (see the discussion of section 421 of the FD&C Act at 78 FR 3646 at 3654–3655); and (2) consider a possible exemption from or modification of requirements of section 421 of the FD&C Act as we deem appropriate (see the discussion of section 103(c)(1)(D) of FSMA at 78 FR 3646 at 3658). We tentatively concluded that we should not exempt or modify the frequency requirements under section 421 based solely upon whether

a facility only engages in low-risk activity/food combinations and is a small or very small business and requested comment on this tentative conclusion.

### B. Comments on Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition

(Comment 56) Some comments address the qualitative nature of the section 103(c)(1)(C) draft RA and assert that it is based on professional judgment rather than data. These comments ask us to update the section 103(c)(1)(C) draft RA when more data become available. Some comments assert that we should not rely on data from the Food Processing Sector Study (Ref. 19), but instead collect data from large-scale surveys of actual farm mixed-type facilities and their activities. Other comments ask us to dedicate resources and enter into agreements with agencies/organizations to collect, analyze, and interpret data. Some comments ask us to consult with subject matter experts to ensure that the final risk assessment reflects sufficient geographic diversity.

(Response 56) We have acknowledged the limitations of the section 103(c)(1)(C) draft RA (Ref. 18; see section I.F in that document). Rather than limit public input to subject matter experts, we requested comment from all interested persons, and received a number of comments alerting us to activity/food combinations conducted on farms and farm mixed-type facilities, including comments from diverse geographic areas. We also received comments about activity/food combinations focused on botanicals that might be used in the production of dietary ingredients. We disagree that we need to conduct large scale surveys, or enter into agreements with agencies/organizations, to collect additional information in light of the previous opportunity for broad public input regarding the activity/food combinations conducted on farms and farm mixed-type facilities. (See also Response 139 regarding the Food Processing Sector Study.)

(Comment 57) Some comments state that it is not clear how certain high- or moderate-risk practices (e.g., washing), which are necessary to move product from the field, will affect exemptions. These comments recommend that future risk assessments examine the impact of these practices by commodity and volume of intact fruits and vegetables marketed through small and very small farm mixed-type facilities. Other comments ask us to re-examine our data sources in assessing commodity-specific

risks, and assert that it is likely that many will be found to be low risk. Other comments suggest that the Centers for Disease Control and Prevention (CDC) expand its data analysis effort (Ref. 20) to separate out commodities to assess attribution of foodborne illnesses for additional commodities.

(Response 57) Because of changes we made to the farm definition, practices such as washing that are necessary to move product from the field are within the farm definition and are not addressed in the section 103(c)(1)(C) RA. We disagree that we should re-examine our data sources in assessing commodity-specific risks. As we discussed in the section 103(c)(1)(C) draft RA, we focused on considering the risk of activity/food combinations rather than separately considering the risk of specific food categories because doing so would better enable us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act. The comments did not identify additional data sources to use in assessing commodity-specific risks. However, we did revise the section 103(c)(1)(C) draft RA by taking into consideration: (1) Comments submitted to Docket FDA–2012–N–1258 on the section 103(c)(1)(C) Draft RA; (2) comments submitted to Docket FDA–2011–N–0920 on the proposed rule relevant to activities conducted on foods on farms; and (3) a revised Food Processing Sector Study on domestic establishments co-located on farms (Ref. 21). This led us to include additional activity/food combinations in our evaluation, and many were found to be low risk. With respect to CDC expanding its data analysis effort, the CDC publication cited by the comments (Ref. 20) is the most up-to-date publication available, and more finely grained data for additional commodities are not currently available.

(Comment 58) Some comments assert that we should revise the section 103(c)(1)(C) draft RA and then make it available for additional public comment before finalizing the rule.

(Response 58) As we previously noted (78 FR 3824 at 3826, January 16, 2013), we subjected the section 103(c)(1)(C) draft RA to peer review in accordance with the requirements of the Final Information Quality Bulletin for Peer Review (issued by the Office of Management and Budget to implement the Information Quality Act (Pub. L. 106–554)) before we made it available for broader public comment during a

time period that exceeded 10 months. The additional iterative process recommended by these comments is not necessary and would go beyond the processes we routinely apply for public input on a risk assessment.

*C. Comments Regarding an Exemption for Small and Very Small Farm Mixed-Type Facilities Under Section 421 of the FD&C Act*

1. Request for Comment on Data Submission Requirements

We requested comment on whether we should establish data submission requirements that would allow us to identify types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act. We provided examples of such data elements, including identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees, and food category/activity type. We also requested comment on any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

Comments did not support these data submission requirements. We are not establishing any data submission requirements that would allow us to identify types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act.

2. Request for Comment on an Exemption From the Requirements of Section 421 of the FD&C Act

We received no comments that disagreed with our tentative conclusion that we should not exempt or modify the inspection frequency requirements under section 421 based solely upon whether a facility only engages in low-risk activity/food combinations and is a small or very small business. We are not establishing any exemption from, or modification to, the inspection frequency requirements under section 421 for facilities that only engage in low-risk activity/food combinations and are a small or very small business.

**VII. Comments on Proposed General Revisions to Current Part 110 (Final Part 117)**

We proposed some general revisions to the CGMP requirements in part 110, including revising the title; redesignating the provisions in part 117; revising some terms for consistency within the rule; referring to the “owner, operator, or agent in charge” rather than to “plant management” or “operator”; revising provisions directed to preventing contamination of food and food-contact substances so that they also are consistently directed to preventing contamination of food-packaging materials; revising several provisions to explicitly address allergen cross-contact, as well as contamination; referring to “raw materials and ingredients” rather than “raw materials and other ingredients”; deleting some non-binding provisions; and making some editorial revisions (78 FR 3646 at 3692 to 3693).

Some comments support one or more of these proposed general revisions

without change. For example, some comments agree that there is no meaningful distinction between “manufacturing/processing,” “packing,” and “holding” as defined in the proposed revisions to §§ 1.227 and 1.328 and those terms as they have been used in the long-standing CGMP requirements. These comments also agree that consistent use of these terms throughout proposed part 117, in reference to activities taking place in food facilities, establishments, or plants, would make the regulations more clear and have no substantive effect on the current requirements. Other comments support the proposed replacement of the term “facility” or “facilities” in the CGMP requirements with the term “establishment” or “plant” whenever the term “facility” or “facilities” could be confused with the firms that are subject to the proposed requirements for hazard analysis and risk-based preventive controls. Other comments agree that it is appropriate to replace the word “shall” with the term “must.” Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 59, Comment 63, and Comment 65).

We received no comments that disagreed with our proposed redesignations and are finalizing them as proposed. In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed provisions as shown in table 6.

TABLE 6—OUTCOME OF THE PROPOSED GENERAL REVISIONS TO PART 110

Proposed revision	Outcome
Establish the title of part 117 .....	We have revised the title to read “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.”
Consistency of terms: Activities subject to part 117.	We are establishing in part 117 the same definitions for the terms “manufacturing/processing,” “packing,” and “holding” as we are establishing in the section 415 registration regulations and the section 414 recordkeeping regulations.
Consistency of terms: Facility .....	We have made the following changes to the proposed rule: 1. We have revised the definition of “plant” to focus it on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food. 2. We have revised applicable provisions to use “establishment” rather than “plant” when focusing on a business entity rather than on buildings or other structures. 3. We have made conforming changes throughout the rule.
Consistency of terms: Owner, operator, or agent in charge.	We are: (1) Defining the term “you” to mean, for purposes of part 117, the owner, operator, or agent in charge of a facility and (2) limiting use of the term “you” to provisions directed to “facilities” (i.e., provisions in subparts C, D, E, and G).
Consistency of terms: Food-packaging materials.	We received no comments that disagreed with our proposal that provisions of current part 110 directed to preventing contamination of food and food-contact substances consistently be directed to preventing contamination of food-packaging materials as well and are finalizing the applicable provisions as proposed.
Additions regarding allergen cross-contact.	The CGMPs that we are establishing in subpart B explicitly address allergen cross-contact.

TABLE 6—OUTCOME OF THE PROPOSED GENERAL REVISIONS TO PART 110—Continued

Proposed revision	Outcome
Revisions for consistency with the definition of “food”.	We have retained the current phrase “raw materials and other ingredients” (rather than the proposed phrase “raw materials and ingredients”) throughout the rule to make it clear that raw materials are ingredients.
Revisions to delete some non-binding provisions.	We are deleting those nonbinding provisions of current part 110 that we proposed to delete. (For a list of these deleted provisions, see table 8 in the 2013 proposed human preventive controls rule, 78 FR 3646 at 3714).
Revisions to re-establish some non-binding provisions of part 110 as binding provisions in part 117.	With one exception, we are, as proposed, re-establishing certain non-binding provisions of part 110 in part 117 as binding provisions. See table 11 in the 2013 proposed human preventive controls rule (78 FR 3646 at 3728). The exception is one provision of § 110.80(b)(1) regarding inspecting containers of raw materials on receipt, which we are deleting rather than re-establishing it as a requirement.
Editorial changes .....	We are finalizing the proposed editorial changes regarding “Federal Food, Drug, and Cosmetic Act,” “includes, but is not limited to,” “must,” “adulteration,” and “when” as proposed, except that we are retaining the term “such as” in place of the proposed term “including” in two provisions.

A. Title of Part 117

We proposed to re-establish the provisions of current part 110 in new part 117 and to establish the title of part 117 as “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” (78 FR 3646 at 3691). (Note that in the 2013 proposed human preventive controls rule, we described this as revising the title of “current subpart B.” We should have described this as revising the title of current part 110.)

(Comment 59) Some comments ask us to revise the title to read “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.”

(Response 59) We have revised the title of the rule as requested.

B. Proposed Revisions for Consistency of Terms

1. Activities Subject to Proposed Part 117

We noted that we had previously described activities that may be considered “manufacturing, processing, packing, or holding” by establishing definitions for these terms in the section 415 registration regulations and the section 414 recordkeeping regulations (78 FR 3646 at 3692). We proposed to revise these existing definitions (see sections IV.D, IV.E, and IV.G) and to incorporate the revised definitions in part 117. We tentatively concluded that there is no meaningful distinction between these terms as we would define them in the revised definitions and these terms as they had been used in the CGMPs. We also tentatively concluded that consistent use of these terms throughout part 117, in reference to activities taking place in food facilities, establishments, or plants, would make the regulations more clear and have no substantive effect on the current requirements (78 FR 3646 at 3692). In the 2014 preventive controls

supplemental notice, we proposed revisions to the definitions of “holding” and “packing” after considering comments submitted to the 2013 proposed human preventive controls rule.

(Comment 60) Some comments ask us to clarify how we were “revising” the definitions of the terms manufacturing, processing, packing, and holding because these terms had not been defined in the CGMPs in part 110.

(Response 60) The comments are correct that these terms had not been defined in the CGMPs in part 110. We proposed to “revise” these definitions in the section 415 registration regulations and the section 414 recordkeeping regulations and then establish in part 117 those revised definitions.

(Comment 61) Some comments from the produce industry state that it is difficult to assess whether there is a meaningful distinction between “packing” and “holding” as would be defined in the proposed human preventive controls rule and as had been used in the CGMPs in part 110 because most harvesting and post-harvest handling activities of RACs had been excluded from the CGMP requirements under § 110.19.

(Response 61) We assume that these comments are concerned about distinguishing “packing” from “holding” because some exemptions (e.g., the exemption in § 117.5(k) from the CGMP requirements for holding RACs and the exemption in § 117.5(j) from the requirements for hazard analysis and risk-based preventive controls) apply to “holding” RACs. As previously discussed, we have previously classified several on-farm activities in more than one way (79 FR 58524 at 58538 and 58571) depending on when the activity occurs. For example, sorting, culling, and grading RACs can occur during both packing and holding activities. However, we

disagree that the full regulatory text of the definitions for “packing” and “holding” are not adequate to provide a meaningful distinction between the two terms. “Packing” means, in part, “placing food into a container” whereas holding means, in part “storage of food.” “Placing food into a container” is in no way similar to “storage of food.”

(Comment 62) Some comments disagree with our tentative conclusion that there is no meaningful distinction between “manufacturing/processing,” “packing,” and “holding” as we would define them in the revised definitions and these terms as they had been used in the CGMPs. These comments ask us to define these terms differently in the human preventive controls rule. These comments state that although they do not object to the consistent use of these terms throughout part 117 in reference to activities taking place in food facilities, establishments, or plants, they believe there are significant distinctions in these terms that need to be considered when finalizing the requirements of part 117.

(Response 62) These comments provide neither specific suggestions for how we should define these terms for the purpose of the human preventive controls rule nor specific reasons for their assertion that there are significant distinctions in these terms that need to be considered when finalizing the requirements of part 117. Without more specific information, we assume that the changes we have made to the definitions of “farm,” “holding,” and “packing” adequately address these comments.

2. The Term “Facility”

We proposed to replace the term “facility” or “facilities” in current part 110 with the term “establishment” or “plant” in proposed part 117 whenever the term “facility” or “facilities” could be confused with the firms that are subject to the proposed requirements for hazard analysis and risk-based

preventive controls required by section 418 of the FD&C Act (78 FR 3646 at 3692). However, we tentatively concluded that it would not be necessary to replace the use of the term “facilities” in current requirements directed to specific functional parts of a plant or establishment, such as “toilet facilities” and “hand-washing facilities,” because the use of the term “facilities” in these contexts would not create confusion.

(Comment 63) Some comments state that it would not be helpful to use “plant” interchangeably with “establishment” when referring to a business that is not required to register. These comments ask us to consistently use one of these terms and to define a term that would mean “a business that is not required to register” to help distinguish such businesses from “facilities.”

(Response 63) We agree that it is appropriate to consistently use one term when referring to a business entity. However, we disagree that it is necessary to establish a definition for a business entity that is not required to register. A business that meets the definition of “facility” is required to register; a business that is not required to register is simply a business that does not meet the definition of “facility.”

To address these comments, we have revised provisions of the rule in three ways. First, we have revised the definition of “plant” to focus it on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food, rather than on the “building or establishment.” Second, we have revised applicable provisions of part 117 to use “establishment” rather than “plant” when focusing on a business entity rather than on buildings or other structures. Third, we have revised provisions that use the terms “plant,” “establishment,” or both to conform to the definition of “plant” and the described usage of “establishment.” For example, § 117.10 establishes requirements for “the management of the establishment” rather than “plant management,” because “establishment” is the term focusing on the business entity. As another example, § 117.20(a)(1) establishes requirements for properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the “plant” rather than within the immediate vicinity of the “plant buildings or structures,” because the defined term “plant” focuses on the buildings and structures, and it is not necessary to repeat “buildings and

structures” when the term “plant” is used.

### 3. Owner, Operator, or Agent in Charge

In the 2013 proposed human preventive controls rule, we requested comment on whether there is any meaningful difference between the persons identified in current part 110 and the “owner, operator, or agent in charge” identified in section 418 of the FD&C Act. We also requested comment on whether it would be appropriate to refer to the “owner, operator, or agent in charge” of a plant, establishment, or facility throughout proposed part 117 and, if so, whether the requirements would be clear if we revised the proposed rule to use pronouns (such as “you” and “your”) within proposed part 117 (78 FR 3646 at 3693). In the 2014 supplemental human preventive controls notice, we described comments on these issues and we tentatively concluded that we could simplify the regulations directed to the “owner, operator, or agent in charge of a facility” in provisions in subparts C, D, and E by using pronouns, without creating confusion, if we (1) define the term “you” to mean, for purposes of part 117, the owner, operator, or agent in charge of a facility and (2) limit use of the term “you” to provisions in proposed subparts C, D, and E (79 FR 58524 at 58556).

We received no comments that disagreed with the proposed definition of “you” and are finalizing that proposed definition without change.

### 4. Food-Packaging Materials

We proposed that provisions of current part 110 directed to preventing contamination of food and food-contact surfaces consistently be directed to preventing contamination of food-packaging materials as well (78 FR 3646 at 3693). We received no comments that disagreed with this proposal and are finalizing provisions directed to preventing contamination of food-packaging materials as proposed. For additional discussion regarding the term “food-packaging materials,” see Comment 107.

#### *C. Proposed Additions Regarding Allergen Cross-Contact*

We proposed to revise several CGMP provisions to explicitly address cross-contact (see 78 FR 3646 at 3693 and table 10 of the 2013 proposed human preventive controls rule, 78 FR 3646 at 3718–3719). In the 2014 supplemental human preventive controls notice, we proposed to define and use the term “allergen cross-contact” rather than “cross-contact,” and we are finalizing

the definition of the term “allergen cross-contact” in this rule (see § 117.3). As discussed in sections XIII–XXII, the CGMPs that we are establishing in subpart B explicitly address allergen cross-contact, with some revisions requested by comments.

(Comment 64) Some comments ask us to clarify that allergen cross-contact has a meaning that is distinct from “contamination.”

(Response 64) We previously noted that, in the past, inadvertent incorporation of an allergen into a food was referred to as “contamination” or “cross-contamination,” but that more recently the term “cross-contact” (rather than “contamination” or “cross-contamination”) has been applied with respect to unintentional transfer of allergenic proteins from a food containing the proteins to one that does not, because an allergen is a normal component of food, and not itself a contaminant (78 FR 3646 at 3693). Given this shift in the scientific literature distinguishing “cross-contact” from “contamination” and “cross-contamination,” we tentatively concluded that we should begin using the term “cross-contact” (now “allergen cross-contact”) to describe inadvertent incorporation of an allergen into food, rather than the general term “contamination,” for purposes of clarity. In this final rule, we affirm that tentative conclusion.

To further improve clarity, we reviewed the provisions of the rule directed to preventing both allergen cross-contact and preventing contamination and made editorial changes throughout. For example, § 117.10(b)(1) requires that hygienic practices must include wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials. For additional provisions that include these editorial changes, see table 52.

#### *D. Proposed Revisions for Consistency With the Definition of “Food”*

We proposed to retain the definition for “food” as already defined in § 110.3 (78 FR 3646 at 3693). Food means food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients. For consistency with the definition of food (which refers to “raw materials and ingredients” rather than “raw materials and other ingredients”), we proposed to change the title of current § 110.80(a) (which would be proposed § 117.80(b)) to “Raw materials and ingredients” rather than “Raw materials and other ingredients.” As a

companion change to this change in title, we proposed to substitute “ingredients” for “other ingredients” throughout provisions in current § 110.80 that refer to both raw materials and ingredients (78 FR 3646 at 3693–3694).

(Comment 65) Some comments ask us to add a definition for “raw materials.”

(Response 65) We decline this request. During a previous rulemaking to revise the umbrella CGMPs, we explained that it is not possible to categorically distinguish raw materials and other ingredients because raw materials are ingredients, and both raw materials and ingredients are food within the meaning of the FD&C Act (51 FR 22458 at 22461, June 19, 1986). We have broadly defined “food” in this rule to include both raw materials and ingredients.

However, we have decided to retain the current phrase “raw materials and other ingredients” (rather than the proposed phrase “raw materials and ingredients”) throughout the rule to make it clear that raw materials are ingredients. See the regulatory text of §§ 117.80(b), 117.80(c)(6), (7), and (9); and 117.130(c)(2)(iii).

(Comment 66) Some comments ask us to revise the current definition of food

(see Comment 87, Comment 88, and Comment 89).

(Response 66) See Response 87, Response 88, and Response 89 for our reasons for declining to revise the definition of “food” in this rule.

*E. Proposed Revisions To Address Guidance in Current part 110*

We proposed to delete some non-binding provisions of current part 110 (e.g., provisions using “should” or “compliance may be achieved by”) (78 FR 3646 at 3694 and 3714–3717). We also requested comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or to simply retain them as useful provisions of a comprehensive CGMP (78 FR 3646 at 3694 and 3728–3729).

(Comment 67) Some comments ask us to retain the provisions we proposed to delete—e.g., because the information helps to clarify the intended effect of the regulations, suggests means of compliance with the requirements, and can educate small, new, or foreign companies. These comments assert that the benefits to both the regulated industry and to the general public of retaining the information we proposed to delete far outweigh any stylistic or

other concerns. Likewise, some comments ask us to retain any non-binding provisions that we proposed to re-establish as requirements if, after considering comments, we do not finalize these provisions as requirements.

(Response 67) We agree that the non-binding provisions we proposed to delete, or considered re-establishing as requirements, provide useful information for reasons such as those mentioned in the comments. However, these provisions are more appropriately included in guidance, and we are deleting those non-binding provisions of part 110 that we are not establishing as requirements. We intend to transfer some of the CGMP recommendations that are currently in part 110, but that will be deleted from part 117, to guidance with editorial changes and changes that reflect current technology and industry practices. For a list of non-binding provisions that we are deleting, see table 7 in this document and table 8 in the 2013 proposed human preventive controls rule (78 FR 3646 at 3714–3717). See Response 321 for a discussion of our reasons for deleting the recommendation listed in table 7 in this document.

TABLE 7—NONBINDING PROVISIONS THAT WE ARE DELETING IN ADDITION TO THE NON-BINDING PROVISIONS LISTED IN TABLE 8 IN THE 2013 PROPOSED HUMAN PREVENTIVE CONTROLS RULE

Designation in part 110	Description
§ 110.80(a)(1) (Processes and controls—raw materials and ingredients—final sentence).	Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

*F. Proposed Editorial Changes*

We proposed to revise current part 110 to make five editorial changes: (1) Refer to the “Federal Food, Drug, and Cosmetic Act” rather than to “the act”; (2) replace the term “shall” with the term “must”; (3) replace the phrase “includes, but is not limited to” with “includes”; (4) replace the phrase “adulteration within the meaning of the act” with the single term “adulteration”; and (5) replace the term “whenever” with “when.”

We received no comments that disagreed with our proposed editorial changes regarding “Federal Food, Drug, and Cosmetic Act,” “must,” “adulteration,” and “when” and are finalizing these editorial changes as proposed.

(Comment 68) Some comments ask us to either retain “includes, but is not limited to” wherever the list which follows is not intended to be exhaustive,

or replace “includes, but is not limited to” with “such as,” to make clear that a following list is not complete.

(Response 68) The word “include” means to have (someone or something) as part of a group or total; to contain (someone or something) in a group or as a part of something (Ref. 22). The word “includes” does not need to be followed by “but is not limited to” to clearly communicate that a following list is not complete.

We proposed that two provisions (proposed § 117.80(c)(14) and (15)) replace the term “such as” with the term “including” (or variations of “including”). In light of the comment’s view that “such as” would be clearer, we have retained the term “such as” in those provisions. We decline the request to more broadly revise the rule to replace “includes” with “such as.” In many cases the term “such as” cannot replace “includes” when used as a verb. We note that several provisions of the

rule do use “such as” when that term is grammatically appropriate, such as in parenthetical phrases (see, e.g., the definitions of “holding” and “packing” in § 117.3).

*G. General Comments on Current Part 110 (Final Part 117)*

We proposed specific revisions and deletions to our long-standing umbrella CGMP requirements to modernize them. We also proposed to redesignate some of these CGMP requirements. For example, we proposed to redesignate the provisions found in six sentences that precede current § 110.80(a) by creating paragraph designations (a)(1) through (6) in new § 117.80. As corresponding changes, we proposed to redesignate current § 110.80(a) as § 117.80(b) and to redesignate current § 110.80(b) as § 117.80(c).

Several comments suggest specific modifications to the umbrella CGMPs beyond what we proposed to revise. In



this section and in sections XIII through XXII, we address these specific suggestions and have amended the regulatory text where warranted.

(Comment 69) Some comments ask us to reorganize some of the current provisions to reduce redundancy, such as by combining provisions that address similar topics or deleting some provisions that the comments view as unnecessary in light of other provisions. For example, one comment suggests we move § 117.80(b)(5) (storage of raw materials, other ingredients, and rework) to § 117.80(a)(1) (general requirements) and another comment suggests we delete requirements in § 117.80(b)(1) for storing raw materials and ingredients because they are redundant with the storage requirements in § 117.80(b)(7).

(Response 69) We decline these requests. We acknowledge that there is some redundancy in subpart B and that we could improve the logical structure of subpart B by moving some of the requirements as recommended by some comments. However, these provisions have been in effect for decades, either since 1969 (when the umbrella CGMPs were first established (34 FR 6977, April 26, 1969) or since 1986 (when we last revised the umbrella CGMPs (51 FR

22458, June 19, 1986), and the comments do not provide examples of how we have been interpreting these provisions in a way that does not accomplish the goal of the umbrella CGMPs. Furthermore, we disagree with some of the comments on whether some provisions are redundant. For example, we disagree that § 117.80(b)(1) is redundant with § 117.80(b)(7) because § 117.80(b)(7) is narrowly directed to raw materials and other ingredients received in bulk and § 117.80(b)(1) is more generally directed to all raw materials and other ingredients.

Rather than reorganize and combine requirements, or delete requirements that some comments view as redundant with other requirements, we have focused on comments requesting specific changes to the current requirements to reflect current practices in the manufacturing, processing, packing, and holding of human food and to make these current requirements clearer (see sections XIII through XXII). Doing so is consistent with the goals of modernizing the umbrella CGMP requirements. However, we have declined many of these requests to make specific changes to particular CGMP provisions. In general, in evaluating the requested specific changes, we

considered whether the comments described a problem with the current regulatory text, or instead focused on hypothetical problems that could occur in the future. Because most of these comments do not explain how the long-standing regulatory text has created a problem, we have declined many of these requests.

Likewise, in this document, we describe several editorial revisions that we made to improve the clarity of the CGMP requirements. However, we do not discuss comments that suggest editorial changes that simply suggest using different words in the regulatory text, but without explaining why the editorial revisions would improve the clarity of the provisions. These long-standing CGMPs have been in place and interpreted for decades, and we see no reason to revise them without a reason to do so.

(Comment 70) Some comments ask us to specify that several of the CGMP requirements in subpart B only apply “where the potential for contamination exists.” (See table 8.) Other comments ask us to change some requirements to recommendations or to specify that they only apply “as appropriate.” (See table 8.)

TABLE 8—CGMP REQUIREMENTS THAT COMMENTS ASK US TO APPLY “WHERE THE POTENTIAL FOR CONTAMINATION EXISTS” OR ASK US TO CHANGE TO RECOMMENDATIONS

Examples of CGMP requirements that comments ask us to apply “where the potential for contamination exists”	Examples of CGMP requirements that comments ask us to change to recommendations
§ 117.20(a)—Management responsibility for maintaining grounds ..... § 117.20(b)—Suitability of plant construction and design ..... § 117.35(a)—General maintenance ..... § 117.35(c)—Pest control ..... § 117.37—Sanitary facilities and controls ..... § 117.40(a)(1)—Design of plant equipment and utensils ..... § 117.40(a)(3)—Installation and maintenance of equipment ..... § 117.40(b)—Seams on food-contact surfaces ..... § 117.40(c)—Construction of equipment ..... § 117.40(d)—Holding, conveying, and manufacturing systems. § 117.80(a)(1)—Adequate sanitation principles. § 117.80(a)(3)—Supervision of overall sanitation.	§ 117.35(a)—General maintenance. § 117.35(b)(1)—Cleaning Compounds and Sanitizing Agents. § 117.35(b)(2)—Identification and Storage of Toxic Materials. § 117.35(c)—Pest control. § 117.35(d)—Sanitation of food-contact surfaces. § 117.40(a)(6)—Maintenance of food-contact surfaces. § 117.40(b)—Seams on food-contact surfaces. § 117.40(c)—Construction of equipment. § 117.40(e)—Freezer and cold storage compartments.

(Response 70) We decline these requests. These long-standing provisions apply generally to the plant, equipment and utensils in the plant, sanitary operations and sanitary facilities in a plant, and operations conducted in a plant. To suggest otherwise is inconsistent with the precepts of good manufacturing practices.

For example, as required by § 117.20(a), an establishment must have control of its grounds regardless of the specific food being produced, because litter, waste, weeds, and grass can all attract and harbor pests, and the first

step for pest control in the plant is to avoid attracting pests. As required by § 117.20(b), a plant requires suitable construction and design regardless of the specific potential for contamination at any particular location in the plant. Each of the seven more specific provisions governed by § 117.20(b) adds the context that the requirements are directed to what is “adequate” (e.g., adequate space, adequate precautions, and adequate cleaning), and the defined term “adequate” provides context that the purpose of the requirements for plant construction and design are related to public health. As required by

§ 117.40, a plant requires clean and sanitary equipment regardless of the specific potential for contamination associated with a particular piece of equipment or the type of food being produced, because dirty equipment at one location in a plant can attract pests or become a harborage for environmental pathogens that can eventually lead to contamination in multiple locations in the plant. As required by § 117.80(a)(10), a food plant requires adequate sanitation regardless of the specific potential for contamination, and the term “adequate” provides flexibility for how an

establishment designs and implements its sanitation program when the potential for contamination is low. As required by § 117.80(a)(3), a plant requires adequate sanitation regardless of the specific potential for contamination, and someone must be in charge of sanitation to determine what needs to be done, where it needs to be done, and how often it needs to be done. The individual(s) who supervises the sanitation of the plant has flexibility in the design and implementation of a sanitation program when the potential for contamination is low.

In addition, the CGMP requirements are flexible requirements that each establishment can adapt to its own operations, equipment, and food products. For example, § 117.35(a) requires that buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials. The standards established by the requirement are to protect against contamination and allergen cross-contact, and the defined term “adequate” provides the context that the specific measures adopted by an establishment are related to public health.

(Comment 71) Some comments ask us to change the phrase “work-in-process” to “in-process materials” in several provisions throughout proposed subpart B because they believe “in-process materials” to be more familiar, straightforward, and commonly understood than “work-in-process.”

(Response 71) “Work-in-process” is the common industry term used in widely disseminated industry publications (Ref. 23) (Ref. 24) and has been in use for more than 30 years in the umbrella CGMPs. In addition, we did not receive any comments objecting to the use of this term when we proposed to include it in previous revisions to the umbrella CGMPs (proposed rule 44 FR 33238 at 33247, June 8, 1979; final rule, 51 FR 22458, June 19, 1986). Therefore, we have retained the phrase “work-in-process” in the final rule.

#### VIII. Subpart A: Comments on Proposed § 117.1—Applicability and Status

We proposed to redesignate § 110.5 as proposed § 117.1, and to add a provision relevant to FSMA’s statutory provisions

for a prohibited act under section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)). Some comments support the proposed provisions without change. For example, one comment expresses the view that one strength of the long-standing CGMPs is their applicability to the broad spectrum of food manufacturing, from the manufacture of processed products and packaging of fresh produce to production of food additives and GRAS substances. (We note that some packaging of fresh produce (e.g., packaging of RACs on a farm) is not subject to the CGMPs.)

Some comments that support the proposed provisions ask us to clarify how we will interpret the provisions (see, e.g., Comment 72).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the provisions as proposed, with editorial and conforming changes as shown in table 52.

##### A. Comments on Proposed § 117.1(a)—Applicability

We proposed that the criteria and definitions in part 117 apply in determining whether a food is adulterated: (1) Within the meaning of section 402(a)(3) of the FD&C Act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the FD&C Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. We also proposed that the criteria and definitions in part 117 also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(Comment 72) Some comments ask us to clarify that part 117 does not apply to activities that are subject to the requirements for CGMPs, hazard analysis and risk-based preventive controls for animal food and feed by inserting “intended for consumption by humans” after “food” in § 117.1(a).

(Response 72) We decline this request. As discussed in Response 6, the applicability of these regulations to human food is specified in the regulatory text by the title of the rule and by its placement in Subchapter B, rather than Subchapter E, of 21 CFR.

(Comment 73) Some comments assert that there is a clear difference between the criteria in proposed § 117.1(a)(1) used to describe adulterated food and

the referenced criteria in section 402(a)(3) of the FD&C Act, in that proposed § 117.1(a)(1) describes manufacturing conditions whereas section 402(a)(3) of the FD&C Act describes actual adulterated product.

(Response 73) We disagree with these comments. We interpret “otherwise unfit for food” in this long-standing statement of applicability to be broader than physical properties of the food and to apply to the manufacturing conditions of the food.

(Comment 74) Some comments note that FSMA granted FDA mandatory recall authority for adulterated food. These comments express concern that theoretically we could use a violation of the requirements for hazard analysis and risk-based preventive controls to determine that food is adulterated, thereby providing the basis for a mandatory recall of that food. These comments raise three issues regarding how we will apply § 117.1(a), with consequences for a potential mandatory recall of food.

First, these comments note that the regulatory text stating that the “criteria and definitions” apply in making a determination of adulteration appears to encompass the entirety of the rule. As a result, farms or facilities that violate any of the requirements in the proposed rule, including components not directly related to the safety of the food (such as recordkeeping requirements), could face a risk that we would deem their food adulterated.

Second, these comments assert that the regulatory text suggests that we would not automatically consider a food adulterated as a result of a violation of the proposed rule, because it states that the criteria and definitions “apply in determining” whether a food will be considered adulterated, rather than that the food “is” adulterated.

Third, these comments state that it is not clear how the exemption applicable to qualified facilities is included in the “criteria and definitions” used in making a determination of adulteration. These comments ask us to clarify that we will not just automatically assume that qualified facilities are selling adulterated food because they are by definition exempt from the requirements for hazard analysis and risk-based preventive controls.

(Response 74) The comments are correct that the criteria and definitions “apply in determining” whether a food will be considered adulterated, rather than that the food “is” adulterated. In determining whether a food that is manufactured, processed, packed, or held in violation of part 117 (including a violation of the recordkeeping

requirement) is adulterated, we would consider the totality of the available data and information about the violation and the food before reaching a conclusion that the food is adulterated.

Although this rule does not address the mandatory recall provisions of FSMA, the statutory provisions establish two basic criteria. (See section 423(a) of the FD&C Act (21 U.S.C. 350l).) First, we must determine that there is a “reasonable probability” that the food is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. A violation of part 117 would be relevant to determining whether a food is adulterated under section 402. Second, we must determine that there is a reasonable possibility that the use of, or exposure to, that food will cause serious adverse health consequences or death to humans or animals. Not all food that is adulterated has a reasonable probability of causing serious adverse health consequences or death to humans or animals. For examples of food contamination with a reasonable probability of causing serious adverse health consequences or death to humans or animals, see the annual reports of the Reportable Food Registry (RFR) (Ref. 25) (Ref. 26) (Ref. 27) (Ref. 28).

A facility that is exempt from any requirement of part 117, including the requirements for hazard analysis and risk-based preventive controls, would not be in violation of part 117 if it did not comply with provisions that it is not subject to.

*B. Comments on Proposed § 117.1(b)—Prohibited Act*

We proposed that the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States is a prohibited act under section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)) if the owner, operator,

or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C, D, E, or F of part 117 (proposed § 117.1(b)).

(Comment 75) Some comments from State regulatory agencies note that this new provision is not covered under the applicable State statute and that making any changes to the State statute can be a lengthy process that takes up to 3 years to complete.

(Response 75) See Response 5 for a discussion of our approach to working with our food safety partners in the States.

*C. Comments on Proposed § 117.1(c)—Specific CGMP Requirements*

We proposed to redesignate § 110.5(b) as proposed § 117.1(c) with no changes. We received no comments that disagreed with our proposal, and are finalizing the proposed provision without change.

**IX. Subpart A: Comments on Proposed § 117.3—Definitions**

We proposed to revise some definitions that had been established in part 110, redesignate and re-establish the remaining definitions in part 117 (except for the definition of “shall,” which we proposed to delete), and establish several new definitions in part 117. Some comments support one or more of these proposed definitions without change. For example, some comments state that they support the proposed definitions for the following terms with no suggested revisions: critical control point, facility, food allergen, food-contact surfaces, microorganism, mixed-type facility, monitor, plant, safe-moisture level, subsidiary, and validation. Some comments support our proposal, in the 2014 supplemental preventive controls notice, to use the phrase “chemical (including radiological)” in the

definition of “hazard,” noting that doing so is consistent with FSMA, current industry practice, and Codex and global HACCP standards. Some comments that support a proposed definition suggest alternative or additional regulatory text, such as adding examples to make the definition clearer (see, e.g., Comment 81 and Comment 87). Some comments that support a proposed definition ask us to clarify how we will interpret the definition (see, e.g., Comment 77 and Comment 87).

In the following sections, we discuss comments that ask us to clarify the proposed definitions or that disagree with, or suggest one or more changes to, the proposed definitions. After considering these comments, we have revised the proposed requirements as shown in table 9, with editorial and conforming changes as shown in table 52. We also have deleted the definition of “should,” because the final rule does not use that term.

We also discuss definitions for additional terms (*i.e.*, “audit,” “correction,” “defect action level,” “full-time equivalent employee,” “qualified facility exemption,” “raw agricultural commodity,” “supply-chain-applied control,” “written procedures for receiving raw materials and other ingredients,” and “unexposed packaged food”) that we are establishing in the final rule to simplify the regulatory text throughout the regulations and improve clarity. We also discuss a new name (*i.e.*, “preventive controls qualified individual”) for the definition of a term that we had proposed to name “qualified individual” and are establishing a new definition for the term “qualified individual.” Finally, we discuss definitions that comments ask us to add, but that we did not add, to the final rule.

TABLE 9—DEFINITIONS THAT WE PROPOSED TO ESTABLISH IN § 117.3

Definition	Current definition (§ 110.3) or new definition?	If current, did we propose any revisions?	Did we receive any comments that disagreed with the definition we proposed to include in part 117?	Did we make any changes to the proposed definition other than the editorial and conforming changes listed in Table 52?
Acid foods or acidified foods .....	Current .....	No .....	No .....	No.
Adequate .....	Current .....	No .....	Yes .....	No.
Affiliate .....	New .....	N/A .....	Yes .....	No.
Allergen cross-contact .....	New .....	N/A .....	Yes .....	No.
Audit .....	New in the final rule ....	N/A .....	N/A .....	N/A.
Batter .....	Current .....	No .....	No .....	No.
Blanching .....	Current .....	No .....	No .....	No.
Calendar day .....	New .....	N/A .....	No .....	No.
Correction .....	New in the final rule ....	N/A .....	N/A .....	N/A.
Critical control point .....	Current .....	Yes .....	Yes .....	No.
Defect action level .....	New in the final rule ....	N/A .....	N/A .....	N/A.
Environmental pathogen .....	New .....	N/A .....	Yes .....	Yes.

TABLE 9—DEFINITIONS THAT WE PROPOSED TO ESTABLISH IN § 117.3—Continued

Definition	Current definition (§ 110.3) or new definition?	If current, did we propose any revisions?	Did we receive any comments that disagreed with the definition we proposed to include in part 117?	Did we make any changes to the proposed definition other than the editorial and conforming changes listed in Table 52?
Facility .....	New .....	N/A .....	Yes .....	No.
Farm .....	New .....	N/A .....	See discussion of § 1.227 in section IV.B.	No. <sup>1</sup>
FDA .....	New .....	N/A .....	No .....	No.
Food .....	Current .....	No .....	Yes .....	No.
Food allergen .....	New .....	N/A .....	Yes .....	No.
Food-contact surfaces .....	Current .....	Yes .....	No .....	No.
Full-time equivalent employee .....	New in the final rule .....	N/A .....	N/A .....	N/A.
Harvesting .....	New .....	N/A .....	See discussion of § 1.227 in section IV.C.	Yes.
Hazard .....	New .....	N/A .....	Yes .....	Yes.
Holding .....	New .....	N/A .....	See discussion of § 1.227 in section IV.D.	Yes.
Known or reasonably foreseeable hazard ...	New .....	N/A .....	Yes .....	Yes.
Lot .....	Current .....	No .....	Yes .....	Yes.
Manufacturing/processing .....	New .....	N/A .....	See discussion of § 1.227 in section IV.E.	Yes.
Microorganisms .....	Current .....	Yes .....	Yes .....	No.
Mixed-type facility .....	New .....	N/A .....	See discussion of § 1.227 in section IV.F.	No.
Monitor .....	New .....	N/A .....	Yes .....	Yes.
Packaging (when used as a verb) .....	New .....	N/A .....	Yes .....	The final rule does not include a definition of packaging (when used as a verb).
Packing .....	New .....	N/A .....	See discussion of § 1.227 in section IV.G.	No.
Pathogen .....	New .....	N/A .....	Yes .....	No.
Pest .....	Current .....	No .....	Yes .....	No.
Plant .....	Current .....	Yes .....	Yes .....	Replace the term “establishment” with “structure”.
Preventive controls .....	New .....	N/A .....	Yes .....	No.
Preventive controls qualified individual .....	New .....	N/A .....	Yes .....	No, except to change the name of the term from “qualified individual” to “preventive controls qualified individual”.
Qualified auditor .....	New .....	N/A .....	Yes .....	Yes.
Qualified end-user .....	New .....	N/A .....	Yes .....	Yes.
Qualified facility .....	New .....	N/A .....	Yes .....	No.
Qualified facility exemption .....	New in the final rule .....	N/A .....	N/A .....	N/A.
Qualified individual .....	New in the final rule .....	N/A .....	N/A .....	N/A.
Quality control operation .....	Current .....	No .....	No .....	No.
Raw agricultural commodity .....	New in the final rule .....	N/A .....	N/A .....	N/A.
Ready-to-eat (RTE) food .....	New .....	N/A .....	Yes .....	No.
Receiving facility .....	New .....	N/A .....	Yes .....	No.
Rework .....	Current .....	No .....	No .....	No.
Safe-moisture level .....	Current .....	Yes .....	No .....	No.
Sanitize .....	Current .....	Yes .....	Yes .....	Yes.
Should .....	Current .....	No .....	No .....	Deleted the definition.
Significant hazard .....	New .....	N/A .....	Yes .....	Yes, including changing the term to “hazard requiring a preventive control”.
Significantly minimize .....	New .....	N/A .....	Yes .....	No.
Small business .....	New .....	N/A .....	Yes .....	Yes.
Subsidiary .....	New .....	N/A .....	Yes .....	No.
Supplier .....	New .....	N/A .....	Yes .....	Yes.
Supply-chain -applied control .....	New in the final rule .....	N/A .....	N/A .....	N/A.
Unexposed packaged food .....	New in the final rule .....	N/A .....	N/A .....	N/A.

TABLE 9—DEFINITIONS THAT WE PROPOSED TO ESTABLISH IN § 117.3—Continued

Definition	Current definition (§ 110.3) or new definition?	If current, did we propose any revisions?	Did we receive any comments that disagreed with the definition we proposed to include in part 117?	Did we make any changes to the proposed definition other than the editorial and conforming changes listed in Table 52?
Validation .....	New .....	N/A .....	Yes .....	Yes.
Verification .....	New .....	N/A .....	Yes .....	Yes.
Very small business .....	New .....	N/A .....	Yes .....	Yes.
Water activity .....	Current .....	No .....	No .....	No.
Written procedures for receiving raw materials and other ingredients.	New in the final rule .....	N/A .....	N/A .....	N/A.
You .....	New .....	N/A .....	No .....	No.

<sup>1</sup> The “farm” definition in § 117.3 is a cross-reference to the “farm” definition in the section 415 registration regulations. Although we did revise the “farm” definition in the section 415 registration regulations (see section IV.B), the cross-reference we are establishing in § 117.3 is unchanged.

*A. Redesignation*

We proposed to redesignate all definitions in § 110.3(a) through (r) as proposed § 117.3, eliminate paragraph designations (such as (a), (b), and (c)), and add new definitions in alphabetical order. We received no comments that disagreed with our proposal, and are finalizing the proposed redesignations.

*B. Definitions in Current Part 110 That We Proposed To Delete*

We proposed to delete the definition of “shall” and use “must” instead. We received no comments that disagreed with our proposal, and are deleting the definition of “shall” as proposed.

*C. Definitions That We Proposed To Establish in Part 117*

1. Adequate

We proposed to define the term “adequate” to mean that which is needed to accomplish the intended purpose in keeping with good public health practice.

(Comment 76) Some comments assert that the definition is vague and ask us to clarify what constitutes “adequate” for systems such as operating systems for waste treatment and disposal. Other comments ask us to develop guidance on thresholds and processes that qualify as “adequate.” Other comments assert that the word “adequate” must be used in combination with the word “reasonable” to properly describe the intended measures and precautions. As an example, these comments assert that the definition of “adequate” could lead to excessive requirements when applied to the provisions for disease control and hygiene (§ 117.10).

(Response 76) We disagree that this long-standing definition of the term “adequate” is vague. The comments do not provide any examples of how we have interpreted this definition in the past in a way that creates practical

problems when applying CGMP requirements, including requirements directed to the management of waste or the provisions for disease control and hygiene. Our intent in using the term “adequate” is to provide flexibility for a food establishment to comply with the requirement in a way that is most suitable for its establishment. We decline the request to develop guidance to explicitly address “thresholds” or to describe processes that qualify as adequate. The CGMPs established in this are broadly applicable procedures and practices rather than very specific procedures and practices where additional interpretation from FDA might be appropriate.

2. Affiliate and Subsidiary

We proposed to define the term “affiliate” to mean any facility that controls, is controlled by, or is under common control with another facility. We proposed to define the term “subsidiary” to mean any company which is owned or controlled directly or indirectly by another company. These proposed definitions would incorporate the definition in sections 418(l)(4)(A) and (D) of the FD&C Act and would make the meanings of these terms clear when used in the proposed definition of “qualified facility.”

(Comment 77) Some comments ask us to clarify that a facility that has no material connection with another food processing operation would not be considered as an “affiliate” of that operation.

(Response 77) It is not clear what the comments mean by “no material connection with another food processing operation.” To the extent that a facility does not control, is not controlled by, or is not under common control with another facility, we agree that the facility would not be considered an affiliate of that food processing operation.

(Comment 78) Some comments assert that the definitions of “affiliate” and “subsidiary” fail to account for the legal differences between a piece of property (*i.e.*, a facility) and a business entity or person. These comments ask us to consider amending the proposed definition of “qualified facility” to clarify what sales to include in determining whether a facility so qualifies.

(Response 78) See Response 118.

3. Allergen Cross-Contact

We proposed to define the term “allergen cross-contact” to mean the unintentional incorporation of a food allergen into a food.

(Comment 79) Some comments assert that the term “incorporation” used in the definition is a vague term that has entirely different meanings when used by different segments of the food industry (*e.g.*, the term would mean something different to a produce wholesaler than to a cereal manufacturer). These comments ask us to provide either a clarification or a definition for the term “incorporation.”

(Response 79) By “unintentional incorporation of a food allergen into food” we mean that the food allergen would be in a food when the producer of the food did not intend it to be in the food—*e.g.*, if a milk-based beverage contains soybeans in addition to milk. Several provisions of the rule require that a facility take steps to prevent such unintentional incorporation of a food allergen into food. See our previous discussion of the importance of preventing allergen cross-contact (78 FR 3646 at 3693).

4. Critical Control Point

We proposed to revise the definition for “critical control point” to mean a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate

a food safety hazard or reduce such hazard to an acceptable level.

(Comment 80) Some comments ask us to specify that a critical control point is essential to reduce the presence of hazards such as microorganisms to “minimize the risk of foodborne illness” rather than to “reduce such hazard to an acceptable level.” These comments assert that this revision would be consistent with the approach in the proposed produce safety rule. Other comments disagree with the proposed definition because it does not define a term (*i.e.*, acceptable level) used in the definition.

(Response 80) We decline to modify the definition as requested by these comments. The proposed definition matches the statutory definition in section 418(o)(1) of the FD&C Act and is consistent with definitions in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry (78 FR 3646 at 3695). The proposed produce safety rule, which did not propose to define “critical control point,” focused on biological hazards. However, critical control points may be established to control chemical or physical hazards in addition to biological hazards. The standard suggested by the comments is not inconsistent with the definition we proposed for “critical control point” in the human preventive controls rule, because preventing or eliminating a food safety hazard or reducing such hazard to an acceptable level would minimize the risk of foodborne illness. However, the standard suggested by the comments was narrowly directed to biological hazards, because chemical and physical hazards generally cause injury rather than illness.

We do not need to define every term used in the definition. By specifying that a point, step, or procedure in a food safety process would reduce a hazard to an “acceptable level,” the definition provides flexibility for a facility to determine an appropriate level in a particular circumstance. Consistent with the approach recommended in the proposed produce safety rule (78 FR 3504 at 3545), a facility could use current FDA guidance on microbiological hazards (*e.g.*, Ref. 29 and Ref. 30) to inform its decision on what constitutes an acceptable level. In those documents, we use the phrase “adequately reduce” to mean capable of reducing the presence of *Salmonella* to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness usually is determined by the estimated extent to which *Salmonella* spp. may be present in the

food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1000 (*i.e.*, 3 logs) *Salmonella* organisms in the food, and a safety factor of 100 (*i.e.*, 2 logs) is employed, a process adequate to reduce *Salmonella* spp. would be a process capable of reducing *Salmonella* spp. by 5 logs.

##### 5. Environmental Pathogen

We proposed to define the term “environmental pathogen” to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. We also proposed to specify that environmental pathogen does not include the spores of pathogenic sporeformers.

(Comment 81) Some comments ask us to include *Salmonella* spp. and *L. monocytogenes* in the regulatory text as examples of environmental pathogens because of the likelihood that these environmental pathogens could contaminate ready-to-eat (RTE) food. Other comments ask us to provide a broader list (including *Escherichia coli*, *Campylobacter*, pathogenic *Vibrio*, *Staphylococcus aureus*, *Clostridium botulinum*, *Shigella*, *Yersinia enterocolitica*, and viruses such as rotoviruses and noroviruses) in the preamble to the final rule or in guidance, and to make clear that the list is not all-inclusive. Some comments emphasize the need for flexible language because any list of microorganisms might change over time, particularly as new environmental pathogens emerge.

Some comments ask us to include the indicator organism *Listeria* spp. in the regulatory text, because analysis of *Listeria* spp. is faster than analysis of *L. monocytogenes*. Other comments ask us to include pathogens that have been associated with RACs, as reported by CDC.

(Response 81) We agree that *Salmonella* spp. and *L. monocytogenes* are useful examples of environmental pathogens and have added these two examples to the proposed definition, which had not included examples. As the comments point out, adding these two examples to the definition does not mean that these two pathogens are the only environmental pathogens that a facility must consider in its hazard analysis. New environmental pathogens can emerge at any time, and other

pathogens (*e.g.*, *Cronobacter* spp.) can also be environmental pathogens (78 FR 3646 at 3816).

We have not included the indicator organism *Listeria* spp. as an example of an environmental pathogen, whether in the regulatory text, in the preamble of this document, or in guidance. Although we agree that *Listeria* spp. is an appropriate indicator organism when conducting verification testing for sanitation controls, the definition in question is for a pathogen, not for indicators of a pathogen. Other provisions of the rule are more appropriate to provide the context that a facility has flexibility for how to conduct verification testing for an environmental pathogen, including an option to test for an indicator organism. (See, *e.g.*, § 117.165(a)(2) and (3).)

*L. monocytogenes*, *Salmonella* spp., and some of the other pathogens mentioned in the comments have been associated with RACs. To the extent that the comments are asking us to identify some environmental pathogens that have been associated with RACs, by identifying these pathogens in the regulatory text or in this preamble we have done so. However, it is important to note that the term “environmental pathogen” as defined in this rule is directed to pathogens in the food processing environment (such as the insanitary conditions in a facility that packed cantaloupes linked to an outbreak of listeriosis (78 FR 3646 at 3814)), not to pathogens present in the growing environment for a RAC.

(Comment 82) Some comments ask us to define “environmental pathogen” as a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, and holding environment of the food being prepared.

(Response 82) We decline this request. The definition of “environmental pathogen” should not change depending on the food being prepared in a particular facility. As a practical matter, the facility will consider the manufacturing, processing, packing, and holding environment of the food being prepared when it conducts its hazard analysis (§ 117.130).

(Comment 83) Some comments ask us to focus attention on the areas where environmental monitoring is particularly important by modifying the definition to address the risk of contamination to RTE food and to foods exposed to the environment after a lethality step. Other comments ask us to consider the number and types of different products produced, the complexity of processing procedures,

the amount of product produced, and whether an environmental sampling program is in place.

(Response 83) We decline these requests, which are asking us to specify in a definition factors associated with developing an environmental monitoring program. The purpose of a definition is to simply explain what a term means, not to establish requirements, or provide guidance about requirements, that use the term.

(Comment 84) Some comments ask us to clarify the meaning of the term “persisting” as used in the definition, such as whether it means that a sanitation process will not remove the microorganism.

(Response 84) We use the term “persisting” to mean that a pathogen can become established if cleaning is not adequate. Once a pathogen becomes established, appropriate sanitation measures can remove the pathogen. However, sanitation procedures necessary to eliminate an environmental pathogen that has become established generally are more aggressive than routine sanitation procedures.

(Comment 85) Some comments ask us to revise the definition to specify that the microorganisms are “potentially” of public health significance.

(Response 85) We decline this request. The definition is only directed at those microorganisms that are of public health significance.

(Comment 86) One comment asserts that the proposed definition of “environmental pathogen” excludes the waterborne pathogens *Cyclospora* and *Cryptosporidium* and asks us to revise the definition so that these pathogens will be considered “environmental pathogens” for the purposes of the human preventive controls rule. The comment asserts that excluding these waterborne pathogens does not take into account the considerable food safety hazard of “spores” of “pathogenic sporeformers” that can be present in and delivered to a food processing facility by processing and ingredient water, both well water and surface water from either private or municipal supply, in both domestic and foreign facilities. The comment asks us to delete the statement that an environmental pathogen does not include the spores of pathogenic sporeformers so that, according to the comment, *Cyclospora* and *Cryptosporidium* would fall within the definition of “environmental pathogen.”

(Response 86) We disagree that the pathogens *Cyclospora* and *Cryptosporidium* should be considered “environmental pathogens” as we use that term in this rule. Our definition of

“environmental pathogen” is directed to those pathogens that are capable of surviving and persisting within the manufacturing, processing, packing, or holding environment of a food establishment, not the water that is used in a food processing establishment. See the discussion of environmental pathogens in the food processing environment in section I.D of the Appendix to the 2013 proposed human preventive controls rule (78 FR 3646 at 3813–3815, with corrected reference numbers at 78 FR 17142 at 17144–17146). As discussed in that Appendix, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with *Salmonella* spp. and *L. monocytogenes*. Such contamination has led to recalls and to outbreaks of foodborne illness. As a result, the rule includes several provisions directed to those pathogens, such as *Salmonella* spp. and *L. monocytogenes*, that are capable of surviving and persisting within a food establishment (thereby serving as a source of contamination of the food establishment environment) and uses the defined term “environmental pathogens” to describe those pathogens. These specific provisions do not apply to waterborne pathogens that do not survive and persist within a food establishment.

By “pathogenic sporeformers,” we mean “pathogenic sporeforming bacteria,” and we are substituting the term “pathogenic sporeforming bacteria” for “pathogenic sporeformers” in the definition of “environmental pathogen” to make that clearer. Both of the waterborne pathogens discussed by this comment are protozoan parasites, not bacteria (Ref. 31).

The fact that waterborne organisms such as *Cyclospora* and *Cryptosporidium* are not “environmental pathogens” as that term is used in this rule does not mean that a facility has no responsibility to evaluate whether *Cyclospora* or *Cryptosporidium* are known or reasonably foreseeable hazards that require a preventive control. For example, when a fresh-cut produce processing facility receives produce from a geographic region where *Cyclospora* or *Cryptosporidium* have been associated with food safety problems, the facility likely would address the potential for contamination of incoming produce with *Cyclospora* or *Cryptosporidium* in its supply-chain program (see subpart G for the requirements of the supply-chain program).

## 6. Facility

We proposed to define the term “facility” to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act in accordance with the requirements of 21 CFR part 1, subpart H. Comments directed to the meaning of the term “facility” address its meaning as established in the section 415 registration regulations, rather than this definition established in part 117. See Comment 4 and Response 4.

## 7. Farm

We proposed to define the term “farm” by reference to the definition of that term in proposed § 1.227 rather than by repeating the full text of the “farm” definition in part 117. See section IV.B for a discussion of the “farm” definition that we are establishing in § 1.227.

## 8. Food

We proposed to define the term “food” to mean food as defined in section 201(f) of the FD&C Act and to include raw materials and ingredients. Under section 201(f), the term “food” means: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(Comment 87) Some comments ask us to include examples in the definition, particularly dietary supplements and dietary ingredients. These comments also ask us to clarify whether the definition applies to food for human consumption, animal consumption, or both.

(Response 87) We decline the request to include examples in the definition. Dietary supplements and dietary ingredients are articles used for food or drink for man, as are many other articles. There are many examples of food and adding a limited list of examples could be confusing rather than helpful. Although the definition of food includes food for both human consumption and animal consumption, the provisions of the rule are clearly directed to food for human consumption (see Response 6 and Response 72).

(Comment 88) Some comments ask us to consider fundamental and important differences between food additives and GRAS substances and finished food. These comments explain that food additives and GRAS substances may be synthesized using various chemical and biochemical processes, or may be extracted, hydrolyzed or otherwise modified from their natural sources, and result in food safety hazards that are quite different from finished food

preparations. These comments also explain that food additives and GRAS substances are often produced using processes that minimize microbial contamination hazards and are almost always used in food products that undergo further downstream processing. These comments assert that food additives and GRAS substances generally present a significantly lower public health hazard compared to finished food and should be regulated accordingly.

(Response 88) Substances such as food additives and GRAS substances are food and are subject to the requirements of this rule. Both the CGMP requirements in subpart B and the requirements for hazard analysis and risk-based preventive controls in subparts C and G provide flexibility to address all types of food. (As discussed in section XLII, the final rule establishes the requirements for a supply-chain program in subpart G, rather than within subpart C as proposed. As a result, this document refers to subparts C and G when broadly referring to the requirements for preventive controls.) Some comments point out that one strength of the long-standing CGMPs is their applicability to the broad spectrum of food manufacturing, from the manufacture of processed products to production of food additives and GRAS substances (see section VIII). A manufacturer of a food additive or GRAS substance has flexibility to comply with the requirements of the rule based on the nature of the production processes and the outcome of the hazard analysis for that food substance. (See also Response 221.)

(Comment 89) Some comments ask us to limit the definition of “food” as it would apply to the new requirements for hazard analysis and risk-based preventive controls to only cover produce and processed foods covered by the rules, rather than all food (human and animal, produce and non-produce, low-risk and high-risk).

(Response 89) We decline this request. It is not necessary to modify the definition of “food” to limit applicability of the rule to human food. (See Response 6.) The umbrella CGMPs that we are establishing in subpart B are long-standing provisions that establish basic requirements for the manufacturing, processing, packing, and holding of food to prevent adulteration and are not “one-size-fits-all.” (See Response 221.) The new requirements for hazard analysis and risk-based preventive controls likewise are not “one-size-fits-all,” and facilities that are subject to the rule would consider the risk presented by the products as part of

their hazard evaluation; a facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components. (See Response 222.)

#### 9. Food Allergen

We proposed to define the term “food allergen” to mean a major food allergen as defined in section 201(qq) of the FD&C Act.

(Comment 90) Some comments ask us to narrow the definition of food allergen by specifying that a substance is only a food allergen when it is not disclosed on the product label.

(Response 90) We decline this request, which appears to confuse the distinction between what a food allergen is and when a product would be misbranded under section 403(w) of the FD&C Act. The substances listed in section 201(qq) of the FD&C Act are food allergens; if any of those substances are not disclosed on the product label, then the product would be misbranded under section 403(w) of the FD&C Act.

(Comment 91) Some comments ask us to expand the existing exemption for RACs from the definition of major food allergen in section 403(w)(1) of the FD&C Act to include raw fish.

(Response 91) This comment is unclear and appears to be confusing the definition of “major food allergen” in section 201(qq) of the FD&C Act with criteria for when a food shall be deemed to be misbranded under section 403(w) of the FD&C Act. Under section 403(w), a food shall be deemed misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless certain labeling requirements are met. Under section 201(r) of the FD&C Act, the term “raw agricultural commodity” means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. Fish are food and, thus, raw, unprocessed fish are RACs within the meaning of section 403(w). Thus, the misbranding provisions of section 403(w) would not apply to raw, unprocessed fish, because those misbranding provisions do not apply to RACs. However, the exemption in section 403(w) from the conditions under which a food shall be deemed to be misbranded do not establish an exemption for RACs in the definition of “major food allergen” in section 201(qq).

To the extent that the comment is asking us to revise either the statutory definition of “major food allergen” in section 201(qq) of the FD&C Act, or to revise the criteria for when a food shall be deemed misbranded under section 403(w) of the FD&C Act, we do not have authority to do so.

(Comment 92) Some comments ask us to include an example of an ingredient derived from an allergen in the definition.

(Response 92) We decline this request. The definition of “major food allergen” in section 201(qq) of the FD&C Act is sufficient to define the term. Casein and whey protein, each of which are derived from milk, are examples of ingredients that would satisfy the definition of “major food allergen” in section 201(qq).

#### 10. Harvesting

We proposed to establish in § 117.3 the same definition of “harvesting” as we proposed to establish in §§ 1.227 and 1.328. See section IV.C for a discussion of comments we received to the proposed definition of “harvesting” in §§ 1.227 and 1.328, and our responses to those comments.

#### 11. Hazard

We proposed to define the term “hazard” to mean any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(Comment 93) Some comments express concern that the rule would refer to four levels of “hazard”—*i.e.*, “hazard,” “known or reasonably foreseeable hazard,” “significant hazard,” and “serious adverse health consequences or death to humans or animals” hazard. These comments ask us to provide sufficient clarity to be able to distinguish between these types of hazards and to provide examples in guidance as to how these terms will be applied in determining compliance with the rule. Other comments express concern that the definitions do not establish a meaningful distinction between “hazard” and “significant hazards” and do not sufficiently distinguish between the hazards identified in the first and second steps of the hazard analysis (first narrowing hazards to “known or reasonably foreseeable hazards” and then narrowing the “known or reasonably foreseeable hazards” to “significant hazards”).

(Response 93) The rule uses three of these terms (*i.e.*, “hazard,” “known or reasonably foreseeable hazard,” and the proposed term “significant hazard”) to



establish a tiered approach to the requirements for hazard analysis and risk-based preventive controls. The term “hazard” is the broadest of these three terms—any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury. To conduct its hazard analysis, a facility starts by first narrowing down the universe of all potential hazards to those that are “known or reasonably foreseeable” for each type of food manufactured, processed, packed, or held at its facility. The outcome of the facility’s hazard analysis is a determination of “significant hazards”—*i.e.*, the subset of those known or reasonably foreseeable hazards that require a preventive control.

To make this clearer, we have: (1) Revised the proposed definition of “hazard”; (2) changed the term “significant hazard” to “hazard requiring a preventive control”; and revised the definition of “hazard requiring a preventive control” (formerly “significant hazard”). See Response 94, Response 126, Response 127, Response 128, and Response 129.

The rule does not define the term “serious adverse health consequences or death to humans or animals” hazard. However, the requirements for a supply-chain program refer to a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans (see § 117.430(b)). For additional information on how we interpret “serious adverse health consequences or death to humans or animals,” see our guidance regarding the Reportable Food Registry (Ref. 32) (Ref. 33), which addresses statutory requirements regarding “reportable foods.” As explained in that guidance, a “reportable food” is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. The guidance includes examples of circumstances under which food might be reportable.

(Comment 94) Some comments assert that the distinction between the definitions of “hazard” and “significant hazard” is not discernable because the proposed definition of “hazard” currently takes into account whether or not a “hazard” is or is not controlled. These comments ask us to delete the phrase “in the absence of its control” from the definition of “hazard” to clarify that hazards are simply the agents that are reasonably likely to

cause illness or injury. Likewise, other comments assert that any hazard that is “reasonably likely to cause illness or injury in the absence of its control” will, if known or reasonably foreseeable, likely be controlled by any knowledgeable person.

(Response 94) We have deleted the phrase “in the absence of its control” from the definition of “hazard.” As previously discussed, the phrase “in the absence of its control” is not included in the definition of “hazard” in the Codex HACCP Annex, our HACCP regulation for seafood, or the HACCP regulation for meat and poultry, although it is included in the NACMCF HACCP Guidelines and our HACCP regulation for juice (78 FR 3646 at 3697). We agree that deleting this phrase from the definition of “hazard” will more clearly distinguish between the terms “hazard” and “hazard requiring a preventive control” that we are establishing in this rule. We see no reason to propose an analogous change to the definition of “hazard” in our HACCP regulation for juice because that regulation only defines the single term “hazard” and, thus, the issue discussed in these comments does not apply.

We also replaced the phrase “that is reasonably likely to cause illness or injury” with “that has the potential to cause illness or injury” to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard.” This increases the alignment of the definition of “hazard” in this rule with the Codex definition of “hazard.”

(Comment 95) Some comments ask us to add that the term hazard also means any agent that would cause a food to become adulterated under section 402 of the FD&C Act.

(Response 95) The suggested addition is inconsistent with current national and international understanding of what constitutes a hazard (Ref. 34) (Ref. 35) because it would include agents such as filth, which would adulterate food within the meaning of section 402(a)(4) of the FD&C Act but would be unlikely to cause illness or injury (Ref. 36).

## 12. Holding

We proposed to establish in § 117.3 the same definition of “holding” as we proposed to establish in §§ 1.227 and 1.328. See section IV.D for a discussion of comments we received to the proposed definition of “holding” in §§ 1.227 and 1.328, and our responses to those comments.

## 13. Known or Reasonably Foreseeable Hazard

We proposed to define the term “known or reasonably foreseeable

hazard” to mean a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

(Comment 96) Some comments support the definition as proposed, noting that it implies that the implementation of a preventive control is based both on the severity and likelihood of the hazard, can help to distinguish between the requirements of this rule and HACCP requirements, and provides for the proper consideration of both the food and the facility when determining whether a hazard is “known or reasonably foreseeable.” Other comments ask us to modify the definition to specify that the term means a hazard “that is known to be, or has the potential to be,” associated with the facility or the food” to better align with the term as FDA proposed to define it in the proposed FSVP rule. (See 79 FR 58574 at 58595.)

(Response 96) We have revised the definition as requested by the comments to better align with the proposed FSVP rule.

(Comment 97) Some comments ask us to revise the definition so that it addresses a hazard that is known to be, or has the potential to be, associated with a food, the facility in which it is manufactured/processed, or the location or type of farm on which it is grown or raised. These comments assert that the type of farm may affect those hazards that are known or reasonably foreseeable.

(Response 97) We decline this request, which appears related to another difference between the definition proposed in this rule and the definition of this term in the proposed FSVP rule. The proposed FSVP rule would define “known or reasonably foreseeable hazard” as a hazard that is known to be, or has the potential to be, associated with a food or the facility “in which it is manufactured/processed.” (See 79 FR 58574 at 58595.) In this rule, we do not need to specify that the applicable facility is the one “in which the food is manufactured/processed” because this rule applies to the owner, operator, or agent in charge of the facility in which the food is manufactured, processed, packed, or held, and that applicability does not need to be repeated in each provision. To the extent that this comment is expressing concern about raw materials or other ingredients that a facility would receive from a farm, those concerns would be considered in the facility’s hazard analysis, which would include a hazard evaluation that considers factors such as those related to the source of

raw materials and other ingredients (see § 117.130(c)(2)(iii)).

(Comment 98) Some comments ask us to include “food allergens” in the parenthetical where we list radiological hazards as a type of chemical hazard.

(Response 98) We decline this request. As previously discussed, the definitions of “hazard” or “food hazard” in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry all define hazard with respect to biological, chemical, and physical agents, and we proposed to include radiological agents to implement section 418(b)(1)(A) of the FD&C Act (78 FR 3646 at 3697). We subsequently proposed to include radiological hazards as a subset of chemical hazards because comments recommended that we do so, and we believe that facilities in the past have considered radiological hazards as chemical hazards when conducting a hazard analysis for the development of HACCP plans (79 FR 58524 at 58557).

In this document, we affirm our proposal to implement section 418(b)(1)(A) of the FD&C Act by specifically including radiological hazards in the definition of hazard. We acknowledge that food allergen hazards (together with pesticide and drug residues, natural toxins, decomposition, and unapproved food or color additives) also are a subset of chemical hazards but do not find it necessary to list all examples of chemical hazards in the definition of hazard, just as we do not find it necessary to list multiple examples of biological and physical hazards in the definition of hazard. The requirement to consider food allergen hazards in the hazard analysis is already explicit in the requirements for hazard identification (see § 117.130(b)(1)(ii)).

(Comment 99) Some comments suggest using the phrase “reasonably anticipated contaminants” as a useful phrase that clearly defines all hazards, whether deliberate or accidental, that can cause adulteration in the food supply.

(Response 99) We decline this request. We see no meaningful difference between “reasonably expected” and “reasonably anticipated.” We also see no benefit in specifying that a hazard is a “contaminant” rather than an “agent” (which is the term used in the definition of “hazard”).

#### 14. Lot

We proposed to define “lot” to mean the food produced during a period of time indicated by a specific code.

(Comment 100) Some comments ask us to modify the proposed definition to make it more flexible and robust. These comments assert that the proposed definition appears to ignore other potential definitions, such as products with common characteristics (such as origin, variety, type of packing, packer, consignor, markings) and that multiple “lots” can be produced during the same time but with different lot designations. Other comments ask us to modify the proposed definition so that it is not limited by a period of time and suggest using an approach that would allow for a lot to be defined by either time or by a specific identifier. Other comments express the view that the individual operators should be able to define their lot designations and make these definitions available to FDA upon request. Other comments assert that the proposed definition is too prescriptive and inflexible in that timeframe is not necessarily the most logical way to identify a lot (*e.g.*, for batch production). Some comments suggest specific changes to the text of the proposed definition, such as “Lot means a body of food designated by the facility with common characteristics, *e.g.*, origin, variety, type of packing, packer, consignor, markings or time of harvest, packing or processing, which is separable by such characteristics from other bodies of food.”

(Response 100) As judged by these comments, the long-standing definition of “lot” has the potential to be misinterpreted to mean that the “specific code” must be based on time, such as a date. This is not the case. Although the term “lot” is associated with a period of time, an establishment has flexibility to determine the code, with or without any indication of time in the code. For example, a code could be based on a date, time of day, production characteristic (such as those mentioned in the comments), combination of date/time/production characteristic, or any other method that works best for the establishment. To clarify that the rule does not require that time be “indicated” by the code, and emphasize the establishment’s flexibility to determine the code, we have revised “period of time indicated by a specific code” to “period of time and identified by an establishment’s specific code.”

(Comment 101) Some comments ask us to clarify the purpose of the “specific code” associated with the lot (*i.e.*, that it should give insight into production history of the associated food) and to define a term such as “lot code” or “production code.”

(Response 101) The purpose of the specific code associated with a lot is to identify the food and associated production records—*e.g.*, when investigating a food safety problem or conducting a recall. We decline the request to define a term such as “lot code” or “production code.” The definition of “lot” is intended to provide flexibility for an establishment to determine the mechanism of assigning a code that is best suited to the food it produces.

(Comment 102) Some comments ask us to clarify the factors that can affect the size of a “lot.” These comments assert that minimizing the size of a lot could be beneficial to an establishment if a recall is needed and express concern that our proposed definition may differ from that used by a specific establishment.

(Response 102) The definition provides a company with flexibility to determine an appropriate size of a lot.

#### 15. Manufacturing/Processing

We proposed to establish in § 117.3 the same definition of “manufacturing/processing” as we proposed to establish in §§ 1.227 and 1.328. See section IV.E for a discussion of comments we received to the proposed definition of “manufacturing/processing” in §§ 1.227 and 1.328, and our responses to those comments.

#### 16. Microorganisms

We proposed to define the term “microorganisms” to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species having public health significance. We also proposed that the term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

(Comment 103) Some comments express concern that the term “undesirable microorganisms” includes microorganisms that subject food to decomposition. These comments assert that the definition would expand regulation beyond food safety and ask us to clarify that decomposition means a degradation of product that is only relevant when it affects the safety of the product, rather than simple spoilage, because the presence of microorganisms that can cause spoilage is an unavoidable condition of fresh produce.

(Response 103) We have not modified the regulatory text of this long-standing definition of the term “undesirable microorganisms” regarding

microorganisms that subject food to decomposition. As we noted during the rulemaking to first establish this definition, the regulations are designed to prevent the growth of undesirable microorganisms, and the scope of the definition is not limited to pathogens because these regulations are also concerned with sanitation, decomposition, and filth (51 FR 22458 at 22460). The comments do not provide any examples of how we have interpreted this provision in the past in a way that creates practical problems to the fresh produce industry when applying CGMP requirements directed to preventing the growth of undesirable microorganisms.

(Comment 104) Some comments ask us to specify that the term “undesirable microorganisms” includes microorganisms that are resistant to drugs or antibiotics.

(Response 104) We decline this request. The requirements of this rule directed to preventing contamination with microorganisms are intended to keep microorganisms out of food regardless of whether a particular strain of a specific microorganism (including a pathogen, a microorganism that subjects food to decomposition, and a microorganism that indicates that food is contaminated with filth) has the particular characteristic of being resistant to drugs or antibiotics.

(Comment 105) Some comments ask us to provide lists of microorganisms that we consider indicative of “contamination with filth” and our rationale for such consideration.

(Response 105) We decline this request, which is better suited for guidance. In other circumstances, we have discussed coliforms and fecal coliforms as indicators that food has been contaminated by manufacturing practices conducted under insanitary conditions (see, e.g., the discussion in the proposed rule to establish Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula, 61 FR 36154 at 36171, July 9, 1996). As another example, “Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity” provides that dairy products may be considered adulterated within the meaning of section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, when (nontoxicogenic) *E. coli* is found at certain levels (Ref. 37).

#### 17. Mixed-Type Facility

We proposed to establish in § 117.3 the same definition of “mixed-type facility” as we proposed to establish in §§ 1.227 and 1.328. See section IV.F for a discussion of comments we received to the proposed definition of “mixed-typed facility” in §§ 1.227 and 1.328, and our responses to those comments.

#### 18. Monitor

We proposed to define the term “monitor” to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(Comment 106) Some comments assert that our proposed definition of monitoring is directed to the narrow circumstance of monitoring that would be applied to a CCP under the NACMCF HACCP guidelines and the Codex HACCP Annex. These comments also assert that, using such definitions, monitoring would not apply to control measures for which parameters cannot be established and that are not amenable to documentation. These comments suggest that we use a definition of monitoring consistent with that provided in ISO 22000:2005 (conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended) to clarify that monitoring may be conducted where appropriate for preventive controls that are not CCPs. (ISO is an abbreviation for “International Organization for Standardization.” ISO develops and publishes international standards.) According to these comments, an advantage of this definition is that it also would clarify the difference between monitoring activities (observations conducted during the operation of a control measure to ensure that it is under control) and verification activities (to evaluate performance of a control measure).

(Response 106) We have revised the definition of monitor to mean to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. We agree that the revised definition, which reflects an international standard, more effectively communicates that monitoring also applies to controls that are not at CCPs and may apply to control measures for which parameters cannot be established. However, we disagree that this definition signals that it is not possible to obtain documentation when monitoring preventive controls that are

not at CCPs, such as for controls that are not process controls and do not involve parameters and maximum or minimum values, or combinations of values, to which a parameter must be controlled to significantly minimize or prevent a hazard requiring a preventive control. For example, it is possible to monitor that a specific sanitation control activity has taken place, such as the cleaning of a piece of equipment to prevent allergen cross-contact.

The requirement for documenting monitoring in records is established by the requirements for monitoring, not by the definition of monitor. As discussed in Response 468, we have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary.

#### 19. Packaging (When Used as a Verb)

We proposed to establish in § 117.3 the same definition of “packaging (when used as a verb)” as we proposed to establish in §§ 1.227 and 1.328.

(Comment 107) Some comments express concern about establishing the definition of “packaging (when used as a verb)” in part 117. These comments ask us to clarify how this proposed definition relates to other uses of the word “packaging” in part 117, including use as an adjective in the common phrase “food-packaging materials,” and including some provisions directed to controlling allergen cross-contact and contamination in “food-packaging materials.” Some comments ask us to establish definitions for terms such as “food-packaging materials” or “primary packaging” to clarify the meaning of the term “packaging” as it has previously been used in part 110. Other comments ask us to clarify that provisions directed to preventing allergen cross-contact and contamination in “food-packaging materials” apply only to “food-contact packaging,” not “secondary packaging.” Some comments focus on the differences between the definition of the term “packing” and “packaging” with respect to activities conducted on RACs. Some comments ask us to clarify how the term “packaging (when used as a noun)” would apply when used in part 117, even though we did not propose to establish a definition for “packaging (when used as a noun)” in part 117.

(Response 107) We have decided not to establish the definition “packaging (when used as a verb)” in part 117. That definition was established in the section 415 registration regulations, in part, to identify those food establishments that would be subject to those regulations based, in part, on the activity of placing food into a container that directly

contacts the food and that the consumer receives. In addition, because the term “packaging” (when used as a noun) can be used in a very general way to refer to both the container that directly contacts the food and to the outer packaging of food that does not contact the food, the section 414 recordkeeping regulations established a definition of “packaging” (when used as a noun) to narrowly refer to “the outer packaging of food that bears the label and does not contact the food,” because this narrow definition was also necessary for the purposes of those recordkeeping regulations.

However, the term “packaging” has long been used as a noun in the CGMPs to generally refer to the container that directly contacts the food, rather than to the outer packaging of food that does not contact the food (as it means in the section 414 recordkeeping regulations). Thus, the very specific connotation for the term “packaging” (when used as a noun) that was established in the section 414 recordkeeping regulations does not apply, and is causing confusion. As the comments point out, our proposed definition of “packaging (when used as a verb)” is already causing confusion in the context of part 117. Therefore, for clarity and simplicity in part 117 we are not including in the final rule a definition of “packaging (when used as a verb).” A definition for “packaging (when used as a verb)” remains in the section 415 registration regulations, where a business can continue to use the definition for purposes of determining whether either or both of those regulations applies to its business.

Part 117 establishes requirements for manufacturing, processing, packing, and holding human food. The definition of “manufacturing/processing” we are establishing in this rule makes clear that “packaging” (when used as a verb) is a manufacturing/processing activity and, thus, that requirements that apply to manufacturing or processing activities apply to packaging activities. Because part 117 is not the regulation that describes whether a food establishment is subject to the section 415 registration regulations or the section 414 recordkeeping regulations, it is not necessary for part 117 to do more.

The comments that express concern about the distinction between “packing” and “packaging (when used as a verb)” with respect to activities conducted on RACs no longer apply in light of the revised “farm” definition that we are establishing in the section 415 registration regulations. The revised “farm” definition provides for packaging RACs when packaging does

not involve additional manufacturing/processing (such as cutting).

#### 20. Packing

We proposed to establish in § 117.3 the same definition of “packing” as we proposed to establish in §§ 1.227 and 1.328. See section IV.G for a discussion of comments we received to the proposed definition of “packing” in §§ 1.227 and 1.328, and our responses to those comments.

#### 21. Pathogen

We proposed to define the term “pathogen” to mean a microorganism of public health significance.

(Comment 108) Some comments ask us to revise the definition to mean a “microorganism of such severity and exposure that it would be deemed of public health significance” because the significance of pathogens to public health depends on the organism’s severity and the nature of exposure.

(Response 108) We decline this request. Our purpose in defining the term pathogen was to simplify the regulations, including our long-standing CGMP regulations, by substituting a single term (*i.e.*, “pathogen”) for a more complex term (*i.e.*, “microorganism of public health significance”) throughout the regulations. These comments appear to be objecting to the use of the long-standing phrase “microorganism of public health significance,” which has been in our CGMP regulations for decades, rather than to our proposal to define and use a simpler term in its place. These comments fail to explain how we have interpreted the current term “microorganism of public health significance” in a way that does not take into account factors such as the severity of illness and the route of exposure.

#### 22. Pest

We proposed to define the term “pest” to refer to any objectionable animals or insects including birds, rodents, flies, and larvae.

(Comment 109) Some comments ask us to include reptiles in the definition due to a past instance of *Salmonella* linked to lizard feces in an RTE nut-manufacturing facility.

(Response 109) We decline this request. This long-standing definition does not limit pests to those already included as examples. Reptiles are objectionable animals that are known to carry human pathogens and are considered pests.

(Comment 110) Some comments ask us to clarify the meaning of the term “objectionable.” These comments state that, under the Canadian Pest Control Products Act, objectionable means that

an animal does not belong in a food processing environment and suggest that we follow this meaning of “objectionable.” These comments also note that there may be circumstances where the presence of an animal is acceptable, such as the use of guide dogs.

(Response 110) We decline this request. The meaning of the term “objectionable” as described in these comments is consistent with our interpretation of this long-standing definition of “pest,” but we do not believe it is necessary to provide a definition. See the provisions for pest control (§ 117.35(c)), which allow the use of guard, guide, and pest-detecting dogs.

#### 23. Plant

We proposed to define the term “plant” to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food. See Comment 63 for the comments on the definition of “plant” and Response 63 for our response to those comments.

#### 24. Preventive Controls

We proposed to define the term “preventive controls” to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

(Comment 111) Some comments ask us to clarify the meaning of “current scientific understanding” because scientific understanding can vary depending on the risk profile of a commodity.

(Response 111) By “current scientific understanding,” we mean to emphasize that scientific information changes over time and a facility needs to keep current regarding safe handling and production practices such that the facility has the information necessary to apply appropriate handling and production practices.

#### 25. Preventive Controls Qualified Individual

We proposed to define the term “qualified individual” to mean a person who has successfully completed training in the development and application of risk-based preventive

controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system. We have changed the proposed term “qualified individual” to “preventive controls qualified individual” because we are establishing a new definition for “qualified individual,” with a meaning distinct from “preventive controls qualified individual.” To minimize the potential for confusion for when the term “qualified individual” refers to the proposed meaning of the term and when the term “qualified individual” refers to the meaning of that term as finalized in this rule, in the remainder of this document we use the new term “preventive controls qualified individual” whenever we mean “a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system,” even though the proposed rule used the term “qualified individual.” Likewise, we use the new term “preventive controls qualified individual” for the proposed term “qualified individual” when describing the comments to the proposed rule, even though those comments use the term “qualified individual.”

In the following paragraphs, we discuss comments on this proposed definition. (See also our discussion (in section XXXVI) of the requirements applicable to the preventive controls qualified individual (§ 117.180(c)).)

(Comment 112) Some comments assert that the proposed definition of preventive controls qualified individual is ambiguous.

(Response 112) The comments provide no basis for asserting that this definition is ambiguous, such as difficulties in how we have interpreted similar regulatory text in enforcing our HACCP regulations for seafood and juice (§§ 123.10 and 120.13(b), respectively). The proposed definition includes a performance standard (qualified to develop and apply a food safety system), two criteria for how a person can become qualified (specialized training or job experience), and a description of the type of applicable training (development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum). The proposed definition

provides flexibility for how an individual can become qualified, but this flexibility does not make the definition ambiguous.

(Comment 113) Some comments ask us to expand the definition so that it includes a team of preventive controls qualified individuals, not just a single person.

(Response 113) We decline this request. The definition applies to each preventive controls qualified individual that a facility relies on to satisfy the requirements of the rule without limiting the number of such preventive controls qualified individuals. The requirements of the rule make clear that a facility may rely on more than preventive controls qualified individual (see, e.g., § 117.180(a)).

(Comment 114) One comment asks us to include “trusted trader” (*i.e.*, a company or entity in the supply chain proven to be low risk) in the definition of preventive controls qualified individual.

(Response 114) We decline this request. The concept of “trusted trader” applies to a facility’s suppliers, not to individuals qualified to develop and apply a food safety system.

#### 26. Qualified Auditor

We proposed to define the term “qualified auditor” to mean a person who is a preventive controls qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 117.180(c)(2). As discussed in Response 569, we have revised the definition to specify that “qualified auditor” means a person who is a “qualified individual” as that term is defined in this final rule, rather than a “preventive controls qualified individual,” because some auditors may be auditing businesses (such as produce farms) that are not subject to the requirements for hazard analysis and risk-based preventive controls, and it would not be necessary for such an auditor to be a “preventive controls qualified individual.” We also have clarified that the technical expertise is obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function to align the description of applicable education, training, and experience with the description of “qualified individual” (see § 117.3).

(Comment 115) Some comments ask us to revise the definition of qualified auditor to include persons who have technical expertise obtained by a

combination of training, experience, or education appropriate to perform audits. Some comments ask us to recognize that training and/or experience can make a person a qualified auditor; the comments state that people with experience performing audits likely have applicable training but might not have completed a specific regimen of courses. Some comments maintain that we should recognize the role of the education of a potential qualified auditor, as well as training and experience to meet the criteria.

(Response 115) We agree that a qualified auditor might obtain the necessary auditing expertise in part through education, as well as through training and experience, and we have revised the definition of qualified auditor accordingly. However, we conclude that a person must have at least some actual experience in auditing to meet the definition of a qualified auditor, *i.e.*, the necessary technical expertise cannot be obtained solely through education and/or training. Therefore, the revised definition retains the proposed criterion that a qualified auditor has technical expertise obtained by experience, as well as by education and training.

(Comment 116) Some comments that support the proposed definition ask us to revise the definition to specify certain individuals who would be considered qualified auditors, such as FDA inspectors, properly trained Federal auditors, and State and private auditors operating under a contract with the Federal Government.

(Response 116) We have revised the regulatory text to specify that examples of a qualified auditor include: (1) A government employee, including a foreign government employee and (2) an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M (*i.e.*, regulations in our forthcoming third-party certification rule implementing section 808 of the FD&C Act (21 U.S.C. 348d)). Although we agree that it is useful to include examples of individuals who would have the appropriate qualifications, the example of an audit agent of a certification body that has been accredited in accordance with regulations in our forthcoming third-party certification rule adds context about the standard for such individuals. Because paragraph (2) of the new provision refers to provisions in a future third-party certification rule, we will publish a document in the **Federal Register** announcing the effective date of paragraph (2) once we finalize the third-party certification rule.

## 27. Qualified End-user

We proposed to define the term “qualified end-user” to mean, with respect to a food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that: (1) Is located (a) in the same State as the qualified facility that sold the food to such restaurant or establishment; or (b) not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. We have revised the definition of “qualified end-user” to add “or the same Indian reservation” to clarify for purposes of this rule so that “in the same State” under section 418(l)(4)(B)(ii)(I) of the FD&C Act includes both within a State and within the reservation of a Federally-Recognized Tribe.

(Comment 117) Some comments object to the description of a qualified end-user as being not more than 275 miles from a facility that sold the food and assert that there is no scientific or risk-based reason to support the distance of 275 miles. Other comments ask us to clarify whether the criterion of not more than 275 miles from a facility that sold the food would provide for qualified end-users to be located across State lines and/or international borders relative to the facility that sold the food. Other comments ask us to revise the definition of “restaurant or retail food establishment” to include businesses such as supermarkets, supermarket distribution centers, food hubs, farm stands, farmers markets, and CSA.

(Response 117) We have not revised the definition of “qualified end-user,” which reflects section 418(l)(4) of the FD&C Act, in response to these comments. As discussed in Response 581, we intend to focus on records demonstrating that a facility is a very small business (*i.e.*, financial records demonstrating that a business averages less than a specified dollar threshold) rather than records demonstrating sales directly to qualified end-users. Likewise, we have not revised the definition of “restaurant or retail food establishment” to clarify whether particular businesses such as those mentioned in the comments would be considered as “qualified end-users.” Focusing on whether a facility is a very small business makes it unnecessary to determine whether an enterprise that receives the food is a retail food establishment. However, as discussed in section I.E, we have issued a separate proposed rule to amend the definition of

“retail food establishment” in the section 415 registration regulations. We intend to issue a final rule to amend the definition of “retail food establishment” in the section 415 registration regulations in the near future. (See also Response 4.)

## 28. Qualified Facility

We proposed to define “qualified facility” by incorporating the description of “qualified facility” in section 418(l)(1) of the FD&C Act with editorial changes to improve clarity. That definition includes two types of facilities: (1) A facility that is a very small business as defined in this rule; and (2) A facility to which certain statutory criteria apply regarding the average monetary value of food sold by the facility and the entities to whom the food was sold.

Some comments discuss issues related to the definition of very small business. See Comment 154, Comment 156, Comment 157, and Comment 158 and our associated responses.

(Comment 118) Some comments assert that the definitions of “affiliate” and “subsidiary” in the definition of “qualified facility” fail to account for the legal differences between a piece of property (*i.e.*, a facility) and a business entity or person. These comments ask us to consider revising the proposed definition of “qualified facility” to clarify what sales to include in determining whether a facility so qualifies.

(Response 118) We have not revised the proposed definition of “qualified facility” as requested by these comments. The sales to be included when a facility determines whether it meets the definition of a qualified facility are the sales of human food by a business entity, which includes the parent company and all its subsidiaries and affiliates. The total sales are applicable to each entity, whether it is the parent, the subsidiary, or the affiliate. We intend to address issues such as these in guidance as directed by section 418(l)(2)(B)(ii) of the FD&C Act. (See also Comment 77 regarding the definitions of “affiliate” and “subsidiary” and our associated responses. See also Response 154 regarding the applicability of the monetary threshold of sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee).)

(Comment 119) Some comments ask us to clarify who will determine whether a particular facility is a qualified facility.

(Response 119) Any facility that determines that it satisfies the criteria for a “qualified facility” must notify FDA of that determination (see § 117.201) and, thus, the first determination will be made by the facility itself. During inspection, the investigator could ask to see the records that support the facility’s determination to verify the facility’s determination.

(Comment 120) Some comments address that part of the definition that discusses “average annual monetary value of the food manufactured, processed, packed, or held at such facility, that is sold.” These comments ask us to clarify whether the operative word in the clause is “held” or “sold.”

(Response 120) The operative word, for the purpose of calculating the average monetary value of that food, is “sold.” (See also Response 154 regarding the applicability of the monetary threshold of sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee).)

## 29. Ready-to-Eat Food (RTE Food)

We proposed to define the term “ready-to-eat food” to mean any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards.

(Comment 121) Some comments ask us to substitute “reasonably expected” for “reasonably foreseeable.”

(Response 121) We decline this request. We see no substantive difference between “reasonably expected” and “reasonably foreseeable.” The term “reasonably foreseeable” is used in other provisions of the rule, including the defined term “known or reasonably foreseeable hazard.”

(Comment 122) Some comments ask us to clarify the distinction between a food that satisfies the definition of “ready-to-eat” and a food that satisfies the definition of a RAC. Some of these comments express concern that if tree fruits are classified as “RTE food” rather than as a RAC, we could force packers to do mandatory product testing.

(Response 122) The terms RTE food and RAC are not mutually exclusive. Some RACs (such as lettuce, tomatoes, berries, and apples) are ready-to-eat, whereas other RACs (such as artichokes and potatoes) are not. The requirements for product testing as a verification activity are flexible requirements that depend on the facility, the food, and the

nature of the preventive control (see § 117.165). See also Response 525.

### 30. Receiving Facility

We proposed to define the term “receiving facility” to mean a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

(Comment 123) Some comments ask us to modify the definition to specify that the receiving facility could receive the raw material or ingredient directly from a supplier or by means of an intermediary entity. These comments assert that without this added regulatory text the proposed definition implies that the material or ingredient must be received directly from the supplier.

(Response 123) We decline this request. As discussed in Response 658, the two parties that are critical to the supplier verification program are the receiving facility and the supplier, even if there are entities in the supply chain between the two. The definition of receiving facility does not preclude the participation of intermediary entities in the supply chain, and the rule does provide for such participation (see Response 657). However, the definition of receiving facility does highlight the fact that a receiving facility must have a link to a supplier.

(Comment 124) Some comments that support the definition of receiving facility ask us to clarify that a cold storage facility is not by definition a receiving facility because it is not engaged in manufacturing/processing, but could be a supplier if temperature controls are needed to control a significant hazard.

(Response 124) We agree that a cold storage facility is not likely to be a receiving facility if it is not engaged in manufacturing/processing. However, it is the nature of the activity as manufacturing/processing, rather than the use of a preventive control for purposes other than manufacturing/processing, that is relevant here. By definition, the supplier must also be engaged in manufacturing/processing, raising animals, or growing food (see the definition of “supplier” in § 117.3). A cold storage facility has a responsibility to maintain foods that require temperature control for safety at an appropriate temperature, but generally does not engage in manufacturing/processing. However, a cold storage facility in the supply chain between the supplier and the receiving facility could participate in supplier verification activities (see Response 657).

### 31. Sanitize

We proposed to define “sanitize” to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. We proposed to revise this otherwise long-standing definition by inserting the term “cleaned” before “food-contact surfaces” because chemical sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (78 FR 3646 at 3697).

(Comment 125) Some comments ask us to adopt a definition of “sanitize” similar to that found in the Pasteurized Milk Ordinance (PMO), which recognizes that cleaning and sanitizing do not always have to be separate, sequential steps. These comments report that the definition in the PMO is “the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable.” Other comments agree with the proposed definition as it applies to chemical sanitizers, but disagree that clean surfaces are required for effective sanitizing for those systems that use steam and dry heat, such as those authorized by Appendix F of the PMO. These comments ask us to clarify that the “cleaning” should be appropriate to the specific food system and method used for sanitizing, and that cleaning should only be required when the sanitizing process alone would not be effective without a prior cleaning step.

Some comments express concern about whether the proposed definition of “sanitize” would preclude the continued, routine use of dry cleaning methods with no sanitizing step. These comments note that adding routine aqueous-based cleaning and sanitizing procedures could create a public health risk in certain operations such as low-moisture food production. These comments also note that dry cleaning procedures can result in equipment that, while sanitary, is neither visibly clean nor suitable for aqueous chemical sanitizers.

(Response 125) We consider that systems such as steam systems clean the surfaces, as well as sanitize them and, thus, satisfy the definition of “sanitize.” The definition of “sanitize” does not preclude the continued use of dry cleaning methods with no sanitizing step because the definition describes the

meaning of the term “sanitize” without establishing any requirement for when equipment must be sanitized.

We have revised the definition so that it means adequately treating “surfaces” rather than “food-contact surfaces.” Doing so is consistent with the definition of “sanitize” in the PMO. As a technical matter, adequately treating any surface—regardless of whether it is a food-contact surface—by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer, is “sanitizing” the surface. Clarifying this technical meaning of the term “sanitize” imposes no requirements to sanitize surfaces other than food-contact surfaces; the requirements for sanitizing surfaces are established by provisions such as § 117.37(d), not by the definition of the term “sanitize.”

### 32. Significant Hazard (Hazard Requiring a Preventive Control)

We proposed to define the term “significant hazard” to mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food. The rule would use the term “significant hazard” rather than “hazard reasonably likely to occur” to reduce the potential for a misinterpretation that all necessary preventive controls must be established at CCPs (79 FR 58524 at 58526).

(Comment 126) Comments support using a term other than “hazard reasonably likely to occur” and agree that using a term other than “hazard reasonably likely to occur” throughout the rule will reduce the potential for a misinterpretation that all necessary preventive controls must be established at CCPs.

Some comments support the regulatory text of the proposed definition of the term “significant hazard.” These comments state that the proposed regulatory text more closely aligns with the principles in FSMA (“reasonably foreseeable” and “significantly minimize or prevent”) and provides operators the flexibility to implement a range of preventive controls that are commensurate with the risk and probability posed by a specific hazard. Some comments agree that the proposed regulatory text can clarify the difference between HACCP rules and the human preventive controls rule.

Some comments state that the proposed regulatory text plainly reflects the concept that significant hazards are those hazards to be addressed through the very broad category of preventive controls, and the rule is explicit that preventive controls may be controls other than at CCPs. Some comments state that the definition reflects the risk-based nature (*i.e.*, both the severity of a potential hazard and the probability that the hazard will occur) of the requirements and provides additional flexibility so that facilities can take into account the nature of the preventive control in determining when and how to establish and implement appropriate preventive control management components. Some comments support including the phrase “based on the outcome of a hazard analysis” in the definition because it ensures that identification of significant hazards will be risk based. Some comments ask us to preserve in the final definition two key aspects that grant the food industry the flexibility that it needs: (1) The logical conclusion that not all hazards will have the same impact or will even constitute “significant hazards” at all, depending on the facility’s products and position in the supply chain; and (2) the fact that a “person knowledgeable about the safe manufacturing, processing, packing, or holding of food” must be knowledgeable about the specific food produced at that facility and in that specific sector of the food industry.

Some of the comments that support the regulatory text of the proposed

definition nonetheless express concern about the term “significant hazard.” Some of these comments express concern that a facility may not recognize hazards that need to be controlled because they do not rise to the commonly understood meaning of “significant.” Other comments express concern that the adjective “significant” is subject to many interpretations and suggest that the term “hazard requiring control” would be more straightforward, accurate, and suitable.

Other comments express concern that the term “significant hazard” could cause confusion because it has implications in HACCP systems. For example, “significant hazard” is often used in the context of CCPs, and preventive controls are not necessarily established at CCPs. Some of these comments suggest that we eliminate the term and instead use the full regulatory text of the proposed definition in place of “significant hazard” throughout the regulations. Other comments suggest using a term such as “food safety hazard” or “actionable hazard” instead of “significant hazard” to avoid a term that has HACCP implications. Other comments state that the term “significant hazard” has implications for facilities that follow the Codex HACCP Annex and express concern that foreign facilities would be especially likely to be confused by the term “significant hazard.”

Some comments ask us to ensure that the term “significant hazard” is used consistently and express the view that some regulatory text refers to a “hazard”

or “known or reasonably foreseeable hazard” where “significant hazard” should instead be used. As discussed in Comment 93, some comments express concern that the rule would refer to multiple levels of hazard and ask us to provide sufficient clarity to be able to distinguish between these types of hazards.

(Response 126) We have changed the term “significant hazard” to “hazard requiring a preventive control.” The new term uses the explicit language of FSMA (*i.e.*, “preventive control”), is consistent with the specific suggestion of one comment (*i.e.*, hazard requiring a control”), and is not commonly associated with HACCP systems. We decline the request to use the term “food safety hazard” because that term already is established in Federal HACCP regulations for seafood and meat/poultry, and the comments are particularly concerned about using a term that has implications for HACCP systems. We also decline the request to use the term “actionable hazard,” because the term “actionable” is associated with violations at a food processing plant.

We reviewed the full regulatory text of proposed subpart C and replaced “significant hazard” with “hazard requiring a preventive control” in most cases. See table 10 for the provisions where we made that change and for an explanation of those provisions where we replaced “significant hazard” with “hazard” or “hazard requiring a process control.”

TABLE 10—SUBSTITUTIONS FOR THE TERM “SIGNIFICANT HAZARD”

Section	Description	Term substituted for “significant hazard”	Reason for substituting a term other than “hazard requiring a preventive control”
117.130(a)(1) .....	Requirement to conduct a hazard analysis.	Hazard requiring a preventive control.	N/A. <sup>1</sup>
117.135(a)(1) .....	Requirement to identify and implement preventive controls.	Hazard requiring a preventive control.	N/A. <sup>1</sup>
117.135(c)(2)(ii) .....	Maximum and minimum values associated with process controls.	Hazard requiring a process control.	The provision is narrowly directed to a specific category of preventive controls— <i>i.e.</i> , process controls.
117.139 .....	Recall plan .....	Hazard requiring a preventive control.	N/A. <sup>1</sup>
117.160 .....	Validation .....	Hazard .....	Specifying that a facility must validate that the preventive controls are adequate to control “the hazard” adequately communicates the requirement. In contrast, specifying that a facility must validate that the preventive controls are adequate to control the “hazard requiring a preventive control” would be unnecessarily bulky and awkward.



TABLE 10—SUBSTITUTIONS FOR THE TERM “SIGNIFICANT HAZARD”—Continued

Section	Description	Term substituted for “significant hazard”	Reason for substituting a term other than “hazard requiring a preventive control”
117.165(a) .....	Activities for verification of implementation and effectiveness of preventive controls.	Hazard .....	Specifying that a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing “the hazards” adequately communicates the requirement. In contrast, specifying that a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing “the hazards requiring a preventive control” would be unnecessarily bulky and awkward.
117.165(a)(3) .....	Requirement for environmental monitoring to verify implementation and effectiveness of preventive controls.	Hazard requiring a preventive control.	N/A. <sup>1</sup>

<sup>1</sup> N/A = Not applicable.

We also reviewed the full regulatory text of proposed subpart C to evaluate whether there were any circumstances where the regulatory text should more appropriately refer to “hazard requiring a preventive control” rather than “hazard” or “known or reasonably foreseeable hazard.” The term “known or reasonably foreseeable hazard” appears only once, in the requirement for a facility to conduct a hazard analysis (§ 117.130(a)). We are retaining “known or reasonably foreseeable hazard” in that requirement because it is necessary to implement the tiered approach to the requirements for hazard analysis and risk-based preventive controls (see Response 93). To reinforce this tiered approach, and emphasize that the facility only conducts a hazard analysis for known or reasonably foreseeable hazards, we revised “hazard” to “known or reasonably foreseeable hazard” in two additional provisions in the requirements for hazard identification (see the introductory regulatory text for § 117.130(b)(1) and (2)).

In our review of the full regulatory text of proposed subpart C, we did not identify any circumstances where we believe it is appropriate and necessary to specify “hazard requiring a preventive control” in place of “hazard.” It is not necessary for the regulatory text of requirements for preventive controls, the supply-chain program, the recall plan, corrective actions, and verification to specify “hazard requiring a preventive control” every time that the requirements use the term “hazard” because the context of

the requirement establishes the applicability to “hazards requiring a preventive control.” Although we acknowledge that using “hazard requiring a preventive control” in place of “hazard” throughout applicable provisions of proposed subpart C would emphasize the tiered approach to the requirements for hazard analysis and risk-based preventive controls, doing so would make the regulatory text unnecessarily bulky and awkward and would be inconsistent with comments that ask us to make the regulatory text understandable (see Comment 13).

(Comment 127) Some comments express concern that the proposed definition of “significant hazard,” which contains the phrase “for which a person . . . would establish controls” is problematic in that facilities are likely to have already established preventive controls for a variety of hazards that may not rise to the level of control management required for a “significant hazard” and would instead routinely be addressed in “prerequisite programs.” These comments express particular concern that identification of these hazards in and of themselves should not elevate control of these hazards to the category of being a “significant hazard.” Some comments ask us to allow facilities to continue to implement existing controls outside the framework of this rule (*i.e.*, outside the framework that requires preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the food safety system) when

a hazard addressed by the existing controls does not rise to the level of “significant hazard.”

Other comments express concern that the term “significant hazard” may create a disincentive for facilities to voluntarily implement preventive controls for hazards that only pose a remote risk or are very rarely encountered, because implementing preventive controls for hazards of very low probability and severity may be misinterpreted as requiring preventive controls applicable to a “significant hazard” even if the hazard does not meet the definition of “significant hazard” established in the rule. Some comments ask us to revise the definition to provide facilities with the flexibility and discretion to establish appropriate preventive controls for hazards that do not rise to the criteria of a “significant hazard,” as well as ensuring that preventive controls that address remote or very unlikely hazards not be subject to the preventive control management requirements for a “significant hazard.”

(Response 127) We have revised the definition to specify that the term “hazard requiring a preventive control” applies when a knowledgeable person would, based on the outcome of a hazard analysis, “establish one or more preventive controls” rather than “establish controls.” By narrowing “controls” to “one or more preventive controls,” we mean to signify that the proposed term “significant hazard” (which we now refer to as “hazard requiring a preventive control”) only applies to those controls that the facility establishes to comply with the

requirements of subparts C and G for hazard analysis and risk-based preventive controls. A facility that establishes other controls (such as those that the comments describe as “prerequisite programs,” or controls directed to hazards of very low probability and severity) for hazards that are not, based on the outcome of the facility’s hazard analysis, “hazards requiring a preventive control” would not need to establish preventive control management components for such controls. However, some controls previously established in “prerequisite programs” would be considered “preventive controls.” We provide some flexibility for facilities with respect to how they manage preventive controls, and the preventive control management components may be different for hazards that have been managed as “prerequisite programs” compared to those managed with CCPs. A facility that is concerned about the potential for an investigator to disagree during inspection that certain controls are not directed to “hazards requiring a preventive control” could, for example, include information relevant to its classification of those other controls in its hazard analysis, whether by merely listing the “other controls” or by providing a brief explanation why such controls are not “preventive controls” as that term is defined in this rule.

(Comment 128) Some comments assert that the proposed definition of “significant hazard” is tautological because it essentially establishes a “significant hazard” to be a known or reasonably foreseeable hazard (*i.e.*, the type of hazards identified in the first step of the analysis) for which preventive controls should be implemented. These comments assert that the proposed definition of “significant hazard” would collapse the second step of hazard analysis into the first, which in turn would lead to the unintended consequence of facilities identifying the same hazards in the second step as in the first. Other comments ask us to revise the definition to clarify and distinguish the two steps of the hazard analysis by specifying within the definition that a significant hazard is a known or reasonably foreseeable hazard for which there is a reasonable probability, based on experience, illness data, scientific reports, or other information relevant to the food or the facility, that adverse health consequence or death will occur in the absence of its control. Some comments ask us to revise the definition to include evaluation of severity and probability, because these concepts are

integral for making a proper determination of whether a hazard is significant. Other comments ask us to revise the definition to better reflect the risk-based approach that preventive controls be implemented to control hazards that have a higher probability of resulting in public health consequence in the absence of control.

(Response 128) We have revised the definition of “significant hazard” (which we now refer to as “hazard requiring a preventive control”) to specify that the hazard analysis includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. By specifying that the determination of a “significant hazard” is based on the outcome of a hazard analysis, the proposed definition did, as requested by the comments, include the risk-based nature of the determination. However, explicitly adding that the hazard analysis is based on probability and severity (*i.e.*, risk) makes the risk-based nature of the determination clearer.

We disagree that the proposed definition was tautological and would collapse the second step of hazard analysis into the first. As discussed in Response 93, a facility begins its hazard analysis by narrowing down the universe of all hazards to those that are “known or reasonably foreseeable” for each type of food manufactured, processed, packed, or held at its facility. The outcome of the facility’s hazard analysis is a determination of a subset of those known or reasonably foreseeable hazards—*i.e.*, those hazards requiring a preventive control. To the extent that these comments are asserting that the tautology was created by the phrase “in the absence of its control” in the proposed definition of “hazard,” we have deleted that phrase from the final definition of “hazard” (see Response 94).

We decline the request to modify the definition to specify that a hazard requiring a preventive control is one for which there is a reasonable probability, based on experience, illness data, scientific reports, or other information relevant to the food or the facility, that adverse health consequence or death will occur in the absence of its control. The standard for harm in the definition of “hazard” is illness or injury. We disagree that the standard for harm in the definition of “hazard requiring a preventive control” should be different from (*i.e.*, adverse health consequences), or greater than (*i.e.*, death), the standard for harm in the definition of “hazard.” We also disagree that the definition of

“hazard requiring a preventive control” needs to be modified to state that preventive controls are implemented to control hazards that have a higher probability of resulting in public health consequence in the absence of control. The definition already communicates the role of risk (*i.e.*, severity and probability) in conducting the hazard analysis that identifies those hazards requiring a preventive control.

We also decline the request to repeat in the definition of “hazard requiring a preventive control” the requirement for the types of information that a facility would consider in conducting its hazard analysis. The requirements for hazard analysis clearly specify that a facility must conduct its hazard analysis based on experience, illness data, scientific reports, and other information (see § 117.130(a)).

(Comment 129) Some comments that broadly address the overall framework for the new requirements for hazard analysis and risk-based preventive controls ask us to consistently refer to “the nature of the preventive control” (rather than simply to “the preventive control”) when communicating the flexibility that a facility has in identifying preventive controls and associated preventive control management components. (See Comment 455). Other comments that broadly address the overall framework for the new requirements for hazard analysis and risk-based preventive controls ask us to emphasize that the requirements for preventive control management components convey not only that the application of a particular element is appropriate (*i.e.*, capable of being applied), but also necessary for food safety. Some comments recommend that we do so by specifying that preventive control management components take into account the role of the preventive control in the food safety system. (See Comment 455.)

(Response 129) We agree with these comments and have revised the definition of “hazard requiring a preventive control” to specify that preventive control management components are established as appropriate to “the nature of the preventive control and its role in the facility’s food safety system.” (See also Response 455, where we describe additional provisions that we have revised to clarify that preventive control management components are established as appropriate to the nature of the preventive control and its role in the facility’s food safety system.)

(Comment 130) Some comments ask us to modify the definition of “significant hazard” to specify that the

preventive control management components be established as appropriate to both the food and the intended use of the food.

(Response 130) We decline this request. It is not necessary to repeat in the definition of “hazard requiring a preventive control” the requirement for the hazard evaluation to consider the intended use of the food. The requirements for hazard evaluation clearly specify that a facility must consider the intended or reasonably foreseeable use of the food (see § 117.130(c)(2)(viii)).

(Comment 131) Some comments assert that the problem is how to separate the hazards addressed by “HACCP” from those addressed by CGMPs. These comments suggest that control measures that are implemented for hazards from ingredients and food-contact packaging material, and from production and process, be called CCPs and that control measures that are implemented for hazards from personnel, equipment, and the plant be called preventive controls.

(Response 131) The facility must control hazards through the application of CGMPs and preventive controls as appropriate to the hazard. Although some preventive controls will be established at CCPs, and “CCP” is a term commonly used in HACCP systems, this rule establishes requirements for hazard analysis and risk-based preventive controls, not “HACCP,” and this rule provides that preventive controls include controls at CCPs, if there are any CCPs, as well as controls, other than those at CCPs, that are also appropriate for food safety (see § 117.135(a)(2)).

Under the rule, some hazards may be addressed by CGMPs and others by preventive controls. For example, if a facility manufactures egg biscuit sandwiches, it could establish a preventive control, as a CCP, for cooking the eggs and establish CGMP controls to address the potential for personnel to contaminate the cooked egg and the egg biscuit sandwiches. As another example, a facility could control a physical hazard such as metal using screens and magnets under CGMPs and then use a metal detector as a preventive control. See also Response 437, in which we give examples regarding when a facility might control food allergen hazards through a combination of CGMP controls and “food allergen controls,” which are a particular type of preventive control (see § 117.135(c)(2)).

(Comment 132) Some comments ask us to add examples throughout the regulatory text (e.g., in the requirements for hazard analysis, preventive controls,

and recall plan) to reflect food allergens as a significant hazard.

(Response 132) We decline this request. Food allergens are included as an example of a chemical hazard that a facility must consider when determining whether there are any known or reasonably foreseeable hazards requiring a preventive control (§ 117.130(b)(1)(ii)), and the rule specifically provides for food allergen controls where relevant. It is not necessary to include examples of food allergens as hazards requiring a preventive control throughout the regulatory text.

(Comment 133) Some comments express concern that too much flexibility may make it harder for us to inspect conditions in a facility over time. These comments emphasize that we must not permit facilities to interpret the term “significant hazard” as allowing them to substitute inadequate sanitation programs—which may not require documentation of monitoring or verification measures—for necessary critical control points.

(Response 133) We acknowledge that there can be a tension between the need for flexible requirements that must apply to diverse food processing facilities and the regulatory need to evaluate compliance with requirements. See Response 5 regarding our approach to enforcing the rule. Although preventive controls, such as sanitation controls, are not always directed to critical control points (see § 117.135(a)(2)(ii)), we agree that there could be circumstances where we would disagree with a facility about the measures it has in place regarding sanitation. We will address such circumstances on a case-by-case basis.

(Comment 134) Some comments express concern that the term “significant hazard” may lead to misunderstanding by medium and smaller processors and ask how businesses with limited food safety experience will understand the difference between a food safety hazard that is “reasonably likely to occur” (and, thus, must be controlled by a full HACCP Plan) and a “Significant Hazard” that can be controlled by a preventive control plan.

(Response 134) In most cases, it will not be necessary for a food processor to understand the difference between a hazard that is “reasonably likely to occur” in the concept of HACCP requirements and a “hazard requiring a preventive control” in the context of this rule. Instead, a food processor must identify those regulations that apply to it. For example, a processor of juice products is subject to our HACCP

regulations for juice, but is not subject to the requirements of this rule.

(Comment 135) Some comments express concern about the potential for divergent interpretations of the definition by industry and regulators. Some comments state that a baseline understanding between industry and regulatory officials will need to be established as to what constitutes a “significant hazard” and what preventive controls will be deemed to be adequate to control such a hazard. Some comments ask us to provide guidance or allow “inter-state compacts” to provide guidelines on what constitutes significant hazards in major food industries. Other comments assert that the FSPCA provides the best forum to identify what constitutes “significant hazards” in food, and to develop timely and appropriate guidance and training for addressing such hazards. Other comments ask to engage with us early and often on the development of applicable guidance documents regarding what constitutes a “significant hazard” for produce industry operations and provide an opportunity to explain and discuss current industry best practices and preventive controls to address identified significant hazards. Some comments ask us to develop an administrative procedure to adjudicate differences in professional opinion between a regulated firm and a Federal or State regulatory agency regarding hazard “significance.”

(Response 135) We agree that guidance will help create an understanding between industry and regulatory officials as to FDA recommendations for hazards that require preventive controls and appropriate preventive controls for those hazards. See Response 2 and Response 5. We decline the request to develop an administrative procedure to adjudicate differences in professional opinion between a regulated firm and a Federal or State regulatory agency regarding hazard “significance.” We note that existing procedures provide for an outside party to obtain internal agency review of a decision by an employee other than the Commissioner (see § 10.75). The comments do not explain what they mean by “inter-state compacts” or provide any examples of “inter-state compacts” and, thus, it is not clear what, if any, role an “inter-state compact” could play in determining what constitutes a significant hazard in major food industries.

(Comment 136) Some comments ask us to concur that “temporal hazards” in milk and dairy products (specifically,

aflatoxin, pesticides, and radiological contamination) do not represent “significant hazards” that require monitoring and verification activities on an ongoing basis. These comments also ask us to acknowledge that in many cases the testing done by FDA and others is sufficient for protecting public health and that it is not necessary to require ongoing monitoring by individual dairy facilities to comply with the rule.

(Response 136) We decline these requests because such a determination should be facility specific. However, we have revised the considerations for the hazard evaluation to clarify that in making the determination as to what hazards require preventive controls, the facility can consider factors such as the temporal nature of the hazard (see § 117.130(c)(2)(x) and Response 407). In determining the appropriate preventive control management components, the facility can take into account the nature of the preventive control and its role in the facility’s food safety system (see § 117.140(a)).

(Comment 137) One commenter asserts that municipal drinking water supplies can be variable such that they could be a hazard that is reasonably likely to occur and that relying on municipal water will compromise food safety. The commenter asks us to “close the gap” in Federal risk assessment policies by adding regulatory text to the proposed definition of “significant hazard” to specify that the hazards are based on the outcome of a hazard analysis that includes any water used by the facility, whatever its source. The commenter further asserts that FDA must require full scientific water risk analysis and written water safety plans and water treatment where necessary and that the written water safety plans must comply with FSMA standards for accurate and precise measurement instruments, monitoring, verification, and documentation. The commenter asserts that in lieu of a full assessment and testing, the plant could disinfect all incoming water to a preventive control standard, and track and document compliance. The commenter further asserts that its commercially available technology provides the most cost effective disinfection for a wide range of sporeformers, bacteria, viruses, algae and molds.

In addition, the commenter asserts that food manufacturers who are not required to make a special effort to understand the status of their water supply through a required risk assessment process will not be aware of the need to institute preventive controls for their water supply. To support its

position, the commenter makes assertions about the purpose of water standards established by the U.S. Environmental Protection Agency (EPA), the risk presented by water quality to the production of safe food, and the impact to food safety of EPA’s 2013 changes to the National Primary Drinking Water regulations (EPA’s NPDW regulations; 41 CFR parts 141 and 142) regarding total coliforms (EPA’s total coliform rule) (78 FR 10270, February 13, 2013).

The commenter asserts that EPA’s NPDW regulations hold public water suppliers to a standard that is protective of drinking water, not food manufacturing water. For example, the commenter describes EPA’s NPDW regulations as requiring water suppliers to treat at least 95 percent of the water they distribute to the public to the treatment technique standard of the treatment they use and then argues that a user of the water would not necessarily know if it was getting some of the “allowable 5 percent off-spec water.” The commenter also asserts that current standards in EPA’s NPDW regulations are not universally achieved by all public water systems. The commenter also asserts that EPA’s total coliforms rule further reduces the applicability of municipal water standards to food manufacturing (*e.g.*, because it reduced the frequencies of water monitoring and public notices about water quality and instead shifted the regulatory scheme towards corrective action).

According to the commenter 95,000 public water systems do not disinfect the water they provide to the public, and some studies have found infective viruses in drinking water samples in communities that did not disinfect their water. According to the commenter, water supplies close to aquifers that were not disinfected before distribution have recently had boil water advisories, demonstrating that problems with the water supply are reasonably likely to occur. The commenter questions whether the food manufacturing plants using that water had water safety back-up plans, stopped production, had monitoring measures in place to determine the impact of the unsafe water, or recalled product manufactured during the period when the municipal water systems had coliform positive tests but had not yet confirmed these tests and therefore had not yet issued the advisory. The commenter also asks whether the facilities relied on the traditional assumption that if they use municipal water their food safety risk analysis does not have to cover water, they do not need a written water safety

plan, and they do not need to monitor the safety of their water.

(Response 137) We decline the request to change the regulatory text to explicitly require that the hazard analysis address any water used by the facility, whatever its source. Many of the commenter’s assertions address issues under the jurisdiction of EPA, such as “allowing” “5 percent off-spec water”; whether current standards are universally achieved by all public water systems; and whether it is appropriate to allow some water systems to not disinfect the water they supply. Such issues that are under the jurisdiction of EPA are outside the scope of this rulemaking. We consider that water standards directed to drinking water for household use would also be adequate for the production of food products and, thus, have no reason to question whether a facility can rely on the standards in EPA’s NPDW regulations to satisfy the long-standing CGMP requirement that any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality (§ 117.37(a)). For example, we consider that water standards that EPA concludes are appropriate for drinking water are also appropriate for the production of water-based beverages, which are mostly water. We also see no reason to specifically require that a facility that satisfies the CGMP requirement for water also address water quality in its hazard analysis. Further, if a facility chooses to address the safety of water in its hazard analysis (*e.g.*, water used in washing fresh-cut produce), we consider it more likely that the facility would treat the water onsite, obtain the water supplier’s records documenting the results of its water testing, or simply test the water on a periodic basis, rather than conduct a risk assessment for the water source.

Under § 117.37(a), we expect any food establishment—regardless of whether it is a facility subject to FSMA’s requirements for hazard analysis and risk-based preventive controls—to be vigilant regarding public health advisories such as a “boil water advisory” and to take appropriate action in light of such advisories. It is not necessary for the regulatory text to specify each potential problem or to specify the actions a food establishment must take to address each potential problem.

### 33. Significantly Minimize

We proposed to define the term “significantly minimize” to mean to reduce to an acceptable level, including to eliminate.

(Comment 138) Some comments assert that the definition of “acceptable level” for fresh produce is unclear because of the presence of spoilage microorganisms, which subject food to decomposition and reduce quality, but are not a public health concern. These comments ask us to revisit and change regulatory text that either does not clarify, or over-steps the intention of, the rule.

(Response 138) We proposed to define “significantly minimize” to give context to the term used in FSMA to define “preventive control.” Thus, in this rule the term “significantly minimize” relates to hazards that will be addressed by preventive controls. The term “significantly minimize” would not be relevant to spoilage microorganisms unless the facility determines, through its hazard analysis, that the spoilage microorganisms are a hazard requiring a preventive control. The standard of “acceptable level” is a flexible standard. By “acceptable level,” we mean a level that will not cause illness or injury or result in adulterated food.

#### 34. Small Business

We proposed to define the term “small business” to mean, for the purposes of part 117, a business employing fewer than 500 persons. As previously discussed, we conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 19) and used the results of the study in defining the term “small business” (78 FR 3646 at 3700 to 3701). We made the results of the Food Processing Sector Study available in Docket No. FDA-2011-N-0920 and requested public comment on that study.

(Comment 139) Some comments express concern that the Food Processing Sector Study is not comprehensive. Some comments assert that FDA did not sufficiently collaborate with USDA, and that FDA significantly underestimated the number of mixed-use facilities, particularly by neglecting to count farms that perform the processing steps on RACs to become a processed food. Other comments assert that the Food Processing Sector Study is woefully inadequate and must be undertaken again to comply with the law.

(Response 139) We previously acknowledged the limitations of the Food Processing Sector Study (78 FR 3646 at 3700–3701). We have revised and extended the results of our earlier study by expanding our data sources and by including representatives from USDA’s Economic Research Service, USDA’s Agricultural Marketing Service,

and the American Farm Bureau to help oversee the revised study. The revised Food Processing Sector Study is available in the docket of this rule (Ref. 21).

Our original analysis was based on the merger of Dun & Bradstreet data and FDA’s Food Facility Registration data to help us estimate the number of manufacturing facilities that are also classified as farms. We have updated that data source and added data sources. To better account for farms that perform processing activities, we included Census of Agriculture (Ag Census) data both to provide a count of total U.S. farms and to estimate the number of farms conducting food processing activities, to the extent that the data identifies processing activities. We also included the Agricultural Resource Management Survey (ARMS) data because it included questions about some processing activities for select commodities.

Both the Ag Census and ARMS are silent about many processing activities. Therefore, we also obtained estimates from commodity specialists at trade associations, USDA, and universities with in-depth knowledge of the processing activities for specific agricultural commodities. We also reached out to directors of promotion and marketing boards, and considered marketing agreements and marketing orders for various vegetables, fruits, and tree nuts to obtain information about the portion of farms that conduct food processing activities for use in this study.

(Comment 140) Some comments ask us to explain how to calculate the number of full-time equivalent employees—*e.g.*, with respect to temporary workers, seasonal workers, and part-time workers.

(Response 140) As previously discussed, we proposed to establish the same definition for small business as that which has been established by the U.S. Small Business Administration (SBA) under 13 CFR part 121 for most food manufacturers, and the limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility (78 FR 3646 at 3701). We will base the calculation on “full-time equivalent employees” and use the same approach to calculating full-time equivalent employees for the purpose of this rule as we used to calculate full-time equivalent employees in the section 414 recordkeeping regulations (see § 1.328). This approach is similar to the approach we used to calculate the small business exemption for nutrition labeling of food (21 CFR 101.9(j)(18)(iv)(D)). Under this

approach, the number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity claiming the exemption and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks).

We received similar comments during the rulemaking to establish the section 414 recordkeeping regulations, and in response to those comments we established the definition of “full-time equivalent employee” in the definitions for that rule. As with the section 414 recordkeeping regulations and the nutrition labeling regulations, the calculation for the number of employees affects exemptions (*i.e.*, the exemptions for on-farm, low-risk activity/food combinations in § 117.5(g) and (h), which apply only to small and very small businesses), not just compliance dates. Therefore, we are establishing the definition of “full-time equivalent employee” in the definitions for this rule (§ 117.3) and modifying the definition of “small business” to use the term “500 full-time equivalent employees” rather than “500 persons.”

(Comment 141) Some comments ask us to base the definition of “small business” on the amount of sales, rather than on the number of employees, for consistency with the definition of “very small business.”

(Response 141) We decline this request. As previously discussed, we based the definition of “very small business” on sales because the criterion of being a “very small business” plays a significant role in determining whether a facility is a “qualified facility,” and because the other principal criterion for being a “qualified facility” is based on sales (section 418(l)(1)(C) of the FD&C Act; see 79 FR 58524 at 58556). In contrast, section 418(l) of the FD&C Act does not specify any particular criterion (whether sales or number of employees) for the definition of “small business,” other than direct us to consider the results of the Food Processing Sector Study. Basing the definition of “small business” on the number of employees is consistent with our approach to defining “small business” for our HACCP regulation for juice (§ 120.1(b)(1)), the section 414 recordkeeping regulations (69 FR 71562, December 9, 2004), and our CGMP regulation for manufacturing, packaging, labeling, or holding operations for dietary supplements (72 FR 34752, June 25, 2007).

(Comment 142) Some comments assert that the specified number of

employees (*i.e.*, 500) has no relevance to food safety.

(Response 142) The definition of “small business” is relevant to two aspects of this rule. First, it is relevant to the compliance date for the establishment, and provides an additional year for establishments satisfying the definition to comply with the rule. As discussed in the Final Regulatory Impact Analysis (FRIA) (Ref. 38), we estimate that the number of small businesses that will be eligible is 45,936, accounting for 5.4 percent of the food supply. Although the purpose of the rule is to improve food safety, delaying the effective date for approximately 6 percent of the food supply will not significantly affect food safety in the long term.

Second, the definition of “small business” is relevant to the statutory exemptions for on-farm, low-risk activity/food combinations for manufacturing/processing, packing, and holding food by farm mixed-type facilities. These statutory exemptions, although expressly authorized only for small and very small businesses, encompass risk and are limited, because a small or very small farm mixed-type facility is only eligible for the exemption if the only activities that the facility conducts are the specified on-farm low-risk activity/food combinations.

(Comment 143) Some comments assert that the specified number of employees (*i.e.*, 500) may or may not be indicative of business size. As an example, the comment notes that harvest employees may operate under contract rather than be the grower’s employees.

(Response 143) If a farm mixed-type facility that is subject to this rule employs harvest employees under contract, the facility would include these employees in its calculation of full-time equivalent employees and would adjust for the temporary, seasonal nature of the increased number of employees when it calculates the 12 month average number of full-time equivalent employees. (See Response 140 for the calculation of full-time equivalents.)

(Comment 144) Some comments assert that the human preventive controls rule and the produce safety rule should use the same definition of “small business.”

(Response 144) We tailored the definitions of “small business” to the characteristics of the sectors of industry subject to the two rules.

(Comment 145) Some comments assert that the definition of a small business as less than 500 employees

makes the very small business exemption irrelevant. These comments ask us to create a simple and broad small business exemption for any small business conducting “low-risk activities.”

(Response 145) We disagree that the definition of a small business makes the very small business exemption irrelevant and decline the request to create a “simple and broad small business exemption” for any small business conducting “low-risk activities.” Although both small and very small businesses are eligible for the exemption for such businesses that only conduct specified low-risk activity/food combinations, other provisions apply solely to very small businesses. For example, the compliance date for a very small business is different from the compliance date for a small business, and a very small business (but not a small business) is eligible for modified requirements.

### 35. Supplier

We proposed to define the term “supplier” to mean the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

As discussed in Response 32, we have revised the “farm” definition to explicitly include business models in which one operation grows crops but does not harvest them, and another operation, not under the same management, harvests crops but does not grow them. As also discussed in Response 32, this revision represents a change from the existing and proposed “farm” definitions, which describe a “farm” as an entity “devoted to the growing *and* harvesting of crops” (emphasis added). We proposed the “supplier” definition in the context of a single business entity “devoted to the growing *and* harvesting of crops” (emphasis added). We used the term “harvesting,” rather than “growing,” to reflect the last stage of production on a farm, except for packing.

Because the proposed “supplier” definition contemplated that the same business entity that grows crops also harvests them, we have revised the “supplier” definition so that the grower remains the supplier when the harvester is under separate management. Specifically, “supplier” is now defined to include an establishment that “grows” food rather than an

establishment that “harvests” food. Doing so focuses the requirements for the supply-chain program (see subpart G) on the entity that produces the food, rather than on the entity that removes the food from the growing area, when the grower and the harvester are not under the same management. Doing so also simplifies the determination of who the supplier is in complex business models, such as when a “handler” arranges for harvest by another business entity.

As discussed in Response 22, we consider a farm to be a type of “establishment” even though we revised the “farm” definition to refer to an “operation” rather than an “establishment” within that definition.

(Comment 146) Some comments assert that the definition of supplier is not workable because the status of warehouses and brokers is unclear in the definition. Other comments ask us to modify the definition to specify, in addition to the proposed definition, that the supplier could be an intermediary entity that takes responsibility on behalf of the receiving facility to ensure that the food meets the requirements of this part.

(Response 146) As discussed in Response 657, we agree that the role of intermediaries in the supply chain is critical, and we have added options for entities other than the receiving facility to perform certain supplier verification activities, provided that the receiving facility reviews and assesses the documentation produced by the other entity and documents that review and assessment. However, this does not mean that these entities take on the role of the supplier. As discussed in Response 658 and Response 123, we believe it is important to supplier verification to retain the identities of two parties involved—the receiving facility and the supplier. Therefore, we are retaining our definition of supplier.

(Comment 147) Some comments regarding RACs ask us to modify the definition of supplier in the case of commingled RACs, such that the supplier would be the person immediately back from the receiving facility in the supply chain provided that this entity (presumably a warehouse or aggregator) voluntarily complies with the requirements of subpart C of this part.

(Response 147) We decline this request. As discussed in Response 657, we recognize that doing supplier verification with commingled products will be a challenge. However, we believe it is important that there be a link between the receiving facility (which is manufacturing/processing the

food) and the supplier (who controlled the hazard(s) in the food). We are allowing an entity such as an aggregator or distributor to perform some verification activities, so the outcome requested by these comments will be achieved while maintaining the identities of the two primary parties in the supplier verification relationship (see Response 657).

(Comment 148) One comment asks us to clarify who would be the supplier in a situation in which dairy farms are providing milk to a cooperative collecting milk.

(Response 148) In this example, the dairy farms would be the suppliers because they are raising the animals.

(Comment 149) One comment asks us to clarify that the proposed definition of supplier does not include sources of processing aids or chemicals required for post-harvest treatments and packing processes (including waxes, fungicides, detergents and sanitizers).

(Response 149) As defined, the supplier is the establishment growing the food, not those establishments providing inputs (such as waxes, fungicides, detergents and sanitizers) to that entity.

### 36. Validation and Verification

We proposed to define the term “validation” to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. We proposed to define the term “verification” to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

(Comment 150) Some comments ask us to revise the definitions of “validation” and “verification” to be consistent with the Codex definitions. (Codex defines “validation” to mean obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. Codex defines “verification” to mean the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (Ref. 39).)

Some comments ask us to more clearly distinguish between “validation” and “verification.” Some comments assert that validation is not an element of verification as stated in our proposed definition and suggest that we clearly separate requirements for

validation from requirements for verification—*e.g.*, by moving the proposed requirements for verification to a distinct section in the regulatory text.

(Response 150) We have explained how our proposed definitions for “validation” and “verification” align with a variety of widely recognized definitions, including definitions established by Codex, the NACMCF HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry (78 FR 3646 at 3700). We disagree that validation is not an element of verification, but acknowledge it is not necessary to say so within the definition of “validation.” Although we have moved the details of the requirements for validation from its proposed location within the requirements for verification (*i.e.*, proposed § 117.155(a)) to a separate section (§ 117.160), we did so as an editorial change to improve clarity and readability rather than as a substantive change to signal that validation is not an element of verification (see table 8 in the 2014 supplemental human preventive controls notice, 79 FR 58524 at 58557).

We agree that validation can apply to a specific control measure as specified in the Codex definition. We also agree that validation can apply to a combination of control measures as specified in the Codex definition. The food safety plan is one example of a combination of control measures.

Although we likewise agree that verification can apply to a specific control measure as specified in the Codex definition, we disagree that to be consistent with the Codex definition we should adopt a definition that excludes the application of verification to the food safety plan. It is well established that some verification measures, such as testing for a pathogen, verify that multiple control measures operated as intended. (See, *e.g.*, Codex’s discussion of verification for uncooked fermented sausages (Ref. 39)).

To more clearly distinguish between “validation” and “verification,” the definition of “validation” we are establishing in this rule specifies that validation means obtaining and evaluating scientific evidence that a control measure, combination of control measures, or the food safety plan as a whole, *when properly implemented*, is capable of effectively controlling the identified hazards (emphasis added). We also made conforming changes associated with the revised definition of “validation” in the requirements for validation (see § 117.160(b)(2)). The definition of “verification” we are

establishing in this rule specifies that verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures *is or has been operating as intended* and to establish the validity of the food safety plan as a whole (emphasis added). Consistent with the request of the comments, the definition of “verification” uses the Codex description of verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring.

### 37. Very Small Business

We proposed to define the term “very small business” to mean, for the purposes of proposed part 117, a business that has less than \$1,000,000 in total annual sales of human food, adjusted for inflation. As discussed in the proposed rule, we conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 19) and used the results of the study in defining the term “very small business” (78 FR 3646 at 3700 to 3702). We made the results of the Food Processing Sector Study available in Docket No. FDA–2011–N–0920 and requested public comment on that study. As discussed in Response 139, we have updated that study (Ref. 21).

(Comment 151) Some comments support the proposed dollar threshold of \$1,000,000, noting that it would provide sufficient flexibility to companies that receive the exemption to allow them to continue to operate. Some comments that support the proposed dollar threshold of \$1,000,000 state that this threshold is consistent with Congress’s mandate that the FSMA rules provide flexibility for all sizes and types of businesses and facilities, including small processing facilities co-located on farms, and provide special considerations for small and very small businesses. These comments also state that our proposal to adopt the \$1,000,000 threshold is appropriate in light of the two options Congress provided for facilities to qualify for modified requirements, and that although Congress directed us to consider the Food Processing Sector Study in establishing the very small business definition, it did not otherwise establish parameters for us to use in setting this definition, leaving it largely to our discretion. These comments argue that although Congress set out two options whereby facilities could qualify for modified requirements, Congress did not bind us to using both options. These comments express the view that when

Congress is silent on an issue, the agency may reasonably interpret its authority. These comments state that proposing the \$1,000,000 threshold for a very small business is entirely reasonable given that businesses this size account for such a small percentage of the food supply, and given Congress's mandate that FDA establish flexible standards considering the effects of the rules on small and very small businesses.

Other comments disagree with the proposed dollar threshold of \$1,000,000. Some of these comments assert that the proposed dollar threshold of \$1,000,000 would create a new category of exemption not contemplated by FSMA and will create confusion for both those who may be subject to the rule and those trying to enforce it. These comments ask us to instead adopt the \$500,000 threshold we considered as "Option 2" in the 2013 proposed preventive controls rule (78 FR 3646 at 3702). Some comments assert that the proposed \$1,000,000 threshold would expose a larger number of consumers to a heightened risk of contracting a foodborne illness.

Other comments reiterate their previous assertions that any dollar threshold that exceeds \$250,000 would be contrary to Congressional intent and conflict with section 418(l) of the FD&C Act. Some of these comments assert that adopting a \$1,000,000 threshold would conflict with the statutory structure of the qualified facility program in a way that effectively nullifies a section of the law. Some of these comments assert that the discussion in the 2014 supplemental human preventive controls notice did not adequately address their comments submitted to the 2013 proposed human preventive controls rule because that discussion does not explain why we believe the proposed \$1,000,000 threshold is consistent with the statute's definitions of a qualified facility in section 418(l)(1) of the FD&C Act. These comments assert that the discussion in the 2014 supplemental human preventive controls notice clearly indicates that the definition is intended to abrogate the definition of a qualified facility under section 418(l)(1)(C) of the FD&C Act because the "definition would . . . simplify a facility's determination of whether it is a qualified facility because the facility would only need to calculate its total sales of human food rather than determine how much food was sold to qualified end-users." The comments assert that this discussion shows that we have made a deliberate decision to write qualified facilities under section 418(l)(1)(C) and the limitations on sales

under section 418(l)(4)(B) out of the law and state that an agency has no authority to repeal a well-considered act of Congress by fiat in a rulemaking.

(Response 151) We are establishing a \$1,000,000 threshold for the definition of "very small business." We disagree that a \$1,000,000 threshold would create a new category of exemption not contemplated by FSMA. Under section 418(l)(1)(A) and (B) of the FD&C Act, a very small business is a qualified facility; under the exemption authorized in section 418(l)(2) of the FD&C Act, a qualified facility is subject to modified requirements rather than the requirements for hazard analysis and risk-based preventive controls. We have acknowledged that a \$1,000,000 threshold exempts a greater portion of the food supply than thresholds of either \$250,000 or \$500,000 (79 FR 58524 at 58555), but reaffirm that under the \$1,000,000 threshold the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness; businesses that fall within this definition of "very small business," collectively, produce less than 0.6 percent of the food supply (Ref. 38). In addition, most of these facilities will be subject to the CGMP requirements in subpart B; the only exemption from those CGMP requirements is the exemption in § 117.5(k) (which applies to: (1) Farms; (2) certain fishing vessels; (3) establishments solely engaged in the holding and/or transportation of one or more RACs; (4) activities of "farm mixed-type facilities" that fall within the definition of "farm"; and (5) establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing)).

We disagree that a \$1,000,000 threshold for the definition of "very small business" will create confusion for both those who may be subject to the rule and those trying to enforce it; in contrast, it is our view that a \$1,000,000 threshold will be less burdensome for both the qualified facilities and FDA. (See Response 581, where we explain that for compliance purposes we intend to focus on financial records demonstrating that a business averages less than the specified dollar threshold rather than records demonstrating that the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during a three-year period exceeded the average annual monetary value of the

food sold by the facility to all other purchasers.)

We reaffirm our view, expressed in the 2014 supplemental human preventive controls notice, that section 418 of the FD&C Act does not limit how we may define "very small business" other than by requiring us to consider the Food Processing Sector Study, and we have done so. (See also Response 152.) Therefore, we disagree that adopting a \$1,000,000 threshold would conflict with the statutory structure of the qualified facility program in a way that effectively nullifies an entire section of the law. We also disagree that our explanation in the 2014 supplemental human preventive controls notice demonstrates that we have made a deliberate decision to write qualified facilities under section 418(l)(1)(C) of the FD&C Act, and the limitations on sales under section 418(l)(4)(B) of the FD&C Act, out of the law. Likewise, we disagree that we are in any way "repealing" a well-considered act of Congress by fiat in a rulemaking.

(Comment 152) Some comments that support a dollar threshold of \$250,000 rather than \$1,000,000 assert that the rationale we presented in the 2014 supplemental human preventive controls notice for a \$1,000,000 threshold is inconsistent with the rationale we presented in our "original draft" of the 2013 proposed human preventive controls rule. These comments quote that "original draft" of the 2013 proposed human preventive controls rule as follows: "FDA is proposing to define the term 'very small business' to mean, for the purposes of part 110, a business that has less than \$250,000 in total annual sales of foods, adjusted for inflation. We are proposing to define very small business using a dollar amount that is, for practical purposes, the same as the dollar amount of sales by a qualified facility to end users other than those that would satisfy the definition of 'qualified end users.'" The proposed definition is consistent with the findings of a study that we conducted as required by section 418(l)(5) of the FD&C Act." These comments note that we acknowledged, in the 2014 supplemental preventive controls notice, that section 418(n)(1)(B) of the FD&C Act requires us to consider the Food Processing Sector Study for the purpose of defining "very small business" (79 FR 58524 at 58555) and argue that it is difficult to see how the same study that supported defining a very small business as one that has less than \$250,000 in total annual sales of food now supports a definition that puts that threshold at less than \$1,000,000.



(Response 152) These comments are citing a rationale in a draft version of the 2013 proposed human preventive controls rule, which we submitted to the Office of Management and Budget in 2011 (Ref. 40, p. 259). In that draft, we proposed a single option for the definition of “very small business” (*i.e.*, less than \$250,000) and explained the reasons for proposing that single option, including an explanation that the option was consistent with the findings of the Food Processing Sector Study. In contrast, in the published 2013 proposed human preventive controls rule that we issued for public comment we identified three options as part of a co-proposal for the definition of very small business, and provided a basis to support each option. For each option of the co-proposal, we made the same statement regarding the Food Processing Sector Study when we discussed the impact of the option on mixed-type facilities—*i.e.*, that it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. We see no conflict between a statement (made in the context of a single proposed option for the definition of “very small business”) that a specific proposed definition was consistent with the findings of the Food Processing Sector Study and a statement (made in the context of three proposed options for the definition of “very small business”) that it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. (See also Response 139 regarding the Food Processing Sector Study.)

(Comment 153) Some comments assert that the proposed \$1,000,000 threshold would be inconsistent with our explanation, in the 2014 proposed sanitary transportation rule, of the definition of a “non-covered business” as one having less than \$500,000 in total annual sales. These comments note that we considered whether a less than \$1 million threshold should be applied but concluded: “[W]e believe such an expansion would result in a greater risk of food becoming adulterated during transport due to insanitary food transportation practices.” (Ref. 41) These comments assert that if we were to apply the same analysis we used in the 2014 proposed sanitary transportation rule to the human preventive controls rule, the threshold for a very small business would be below \$500,000.

(Response 153) The \$500,000 threshold we proposed in the 2014 proposed sanitary transportation rule would apply to “non-covered businesses”—*i.e.*, businesses that would

be completely exempt from the requirements of the sanitary transportation rule. In contrast, the \$1,000,000 threshold we are establishing in this rule applies to very small businesses that will be subject to modified requirements rather than be completely exempt. A very small business will have two options to comply with the modified requirements in the human preventive controls rule (the food safety practices option and the option to demonstrate compliance with other applicable non-Federal food safety law; see § 117.201(a)(2) and the discussion in sections XXXVIII.C.2 and XXXVIII.C.3). Regardless of which option a very small business chooses to comply with the modified requirements, we will inspect the business for compliance with the CGMPs and the modified requirements. In contrast, if the final sanitary transportation rule excludes a “non-covered business” as would be defined in that rule, that business would be completely exempt rather than subject to modified requirements and, thus, would be not be inspected for compliance with any aspect of the sanitary transportation rule.

(Comment 154) Some comments ask us to clarify how to classify the size of a business that does not take ownership of or directly sell food (*e.g.*, warehouses and re-packing facilities) to determine status as a qualified facility.

(Response 154) We have revised the definition to specify that the \$1,000,000 threshold applies to sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee). When there are no sales of human food, market value of the human food manufactured, processed, packed, or held without sale is a reasonable approach to calculating the dollar threshold for very small business.

(Comment 155) Some comments ask us to specify that the monetary threshold for the definition be based on average sales during a three-year period on a rolling basis because otherwise firms may be subject to significant changes in status from year to year. These comments also ask us to clarify that the sales are to be evaluated retrospectively, not prospectively.

(Response 155) We have revised the definition of very small business to specify that it is based on an average during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee). The applicable calendar year is the year after the 3 calendar years

used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the 3 calendar years used to determine whether a facility is a very small business are 2021–2023. The exception is when 3 calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

As a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis by no later than July 1 of each calendar year (see § 117.201(c)(1)). Although this requirement was implicit in the proposed requirement that a facility must resubmit a notification to FDA if its status changes as a qualified facility (proposed § 117.201(c)(2), which we are finalizing as § 117.201(c)(3)), we are making this requirement explicit to clarify the responsibility of the facility to affirmatively determine its status when the calendar years that apply to the 3-year average change. The July 1 deadline for a facility to determine its status provides facilities with 6 months to make the determination after the end of the previous 3 calendar years.

We also are establishing an earlier compliance date for the financial records that a facility maintains to support its status as a very small business that is eligible for the qualified facility exemption in § 117.5(a). Specifically, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016. Even with this earlier compliance date for these records, we realize that although the calculation for “very small business” in the regulatory text is based on 3 calendar years, a facility will only be required to have 2 calendar years of records as of the general compliance date for very small businesses. Specifically, by September 17, 2018 a facility that begins retaining applicable financial records on January 1, 2016, would only have such records for 2 previous calendar years. Therefore, it would be reasonable for a facility to make the calculation based on the 2 previous calendar years. If a facility has records for 3 previous calendar years, the facility could make the calculation based on the longer time period. During inspection in 2018, when a facility has

records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years, we will accept records for the preceding 2 calendar years as adequate to support status as a qualified facility. We note that in some situations, a shorter time period is sufficient to determine that a facility is not a very small business. For example, a facility with sales exceeding \$3,000,000 for the preceding calendar year cannot qualify as a very small business because no amount of sales from other years will reduce average sales below the threshold of \$1,000,000.

The available financial records for a facility that begins operations between January 1, 2017 and September 17, 2018 would not cover even 2 calendar years by September 17, 2018. During the first 3 years of such a facility's operation, it would be reasonable for a facility to make the calculation based on records it has (*i.e.*, for one or two preceding calendar years), and we will accept records for the preceding one or two years as adequate to support status as a qualified facility in these circumstances.

When a facility does not begin operations until after January 1, 2018, it would be reasonable for the facility to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the facility's number of FTEs. After the facility has records for one or two preceding years, it would be reasonable for the facility to make the calculation based on records it has (*i.e.*, for one or two preceding calendar years) and we will accept records for the preceding one or two calendar years as adequate to support status as a qualified facility in these circumstances.

(Comment 156) Some comments ask us to only include the total annual sales of food in the United States, adjusted for inflation, for foreign facilities that export food to the United States.

(Response 156) We decline this request. The purpose of the definition of "very small business" is principally to enable such businesses to comply with modified requirements, because they have fewer resources to direct to full compliance with the rule. A foreign business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if less than that threshold dollar amount reflects sales to the United States. Likewise, a domestic business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if that domestic business exports some of its food and, as a result, less than that threshold

dollar amount reflects sales within the United States.

As discussed in Response 154, to address facilities such as those warehouses and re-packing facilities that do not take ownership or directly sell food we have revised the definition of "very small business" to specify that the \$1,000,000 threshold applies to sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee). As with "sales," facilities such as those warehouses and re-packing facilities that pack or hold more than the \$1,000,000 threshold would have more resources than the facilities being excluded.

(Comment 157) Some comments ask us to apply the rule to dairy farms with sales greater than \$1 million annually of processed or packaged dairy products, rather than bulk sales of fluid milk. Other comments ask us to only include the annual monetary value of food covered by the preventive controls rule, rather than all human food. In particular, these comments argue that food covered by the produce safety rule should not be counted in the calculation of the sales of food for the purpose of defining very small business for the preventive controls rule. Some of these comments assert that basing the threshold on the monetary value of food covered by the preventive controls rule, rather than all human food, would be necessary to be consistent with the approach used in the proposed animal preventive controls rule, in which the sales threshold was based on sales of animal food (*i.e.*, the product regulated by the rule).

(Response 157) We decline these requests. As discussed in Response 156, the purpose of the definition of "very small business" is principally to enable such businesses to comply with modified requirements, because they have fewer resources to direct to full compliance with the rule. Because of the exemptions in the human preventive controls rule (*e.g.*, for processors of seafood, juice, low-acid canned foods (LACF), and dietary supplements), basing the threshold on the monetary value of food covered by the preventive controls rule, rather than all human food, could lead to a situation where a very large food processor (such as a juice processor with more than \$20,000,000 in annual sales) would not need to comply with the human preventive controls rule for milk- and soy-based beverages that it produces, if the annual sales of milk- and soy-based beverages is less than \$1,000,000.

We disagree that a threshold based on sales of human food, rather than food

covered by the preventive controls rule, would be inconsistent with the threshold we proposed for the animal preventive controls rule. The threshold we proposed for the animal preventive controls rule was based on "total annual sales of food for animals, adjusted for inflation," which is exactly parallel to our proposal to base the threshold on "total annual sales of human food, adjusted for inflation." We proposed several exemptions to the animal preventive controls rule (see proposed § 507.5 (proposed 21 CFR 507.5)) and, thus, not all food for animals will be subject to the animal preventive controls rule.

(Comment 158) Some comments ask us to base the threshold on the total "volume of product" or "amount of product" handled or sold. These comments assert that an approach using product volume or amount would be more risk-based because it would correlate more closely to consumer exposures than dollar amounts, which can be skewed by product values.

(Response 158) We use sales as a proxy for volume. We acknowledge that dollar amounts can be skewed by product values and, thus, sales are an imperfect proxy for volume. However, we are not aware of a more practical way to identify a threshold based on volume or amount of product that could be applied across all product sectors, and the comments provide no suggestions for how their recommendation could be carried out.

(Comment 159) Some comments assert that our conclusion that our proposed definition of very small business is controlled by the two references in sections 418(l)(5) and 418(n)(1)(B) of the FD&C Act does not provide a reasonable justification for our decision. These comments assert that it is equally true that those two provisions would not prevent us from adopting one threshold (less than \$250,000) for purposes of defining a qualified facility (and for a very small business conducting on-farm low-risk activity/food combinations) and another (less than \$1 million) for setting compliance dates. These comments also assert that this is exactly the determination we made for our proposed animal preventive controls rule, where we proposed to define very small business, under the constraints of these same two references, as one with less than \$2,500,000 in sales. To give full effect to the design of the qualified facility program while providing an adequate compliance deadline, these comments ask us to revise the definition of very small business to mean "a business that has less than \$250,000 in total annual

sales of human food, adjusted for inflation, except that for purposes of the effective dates in section 103(i) of the FDA Food Safety Modernization Act (21 U.S.C. 350g note) the term means less than \$1,000,000 in total annual sales of human food.”

(Response 159) These comments are unclear. We agree that we proposed to define very small business, for the purposes of the animal preventive controls rule, as one with less than \$2,500,000 in sales (79 FR 58476 at 58510), but disagree that we proposed to adopt one threshold for purposes of defining a qualified facility and another threshold for setting compliance dates. Regardless, we decline the request to adopt a threshold lower than \$1,000,000 for purposes of defining a qualified facility, which appears to be the principal request of these comments (see Response 151).

(Comment 160) Some comments support the proposed dollar threshold of \$1,000,000, provided that we also make changes to the “farm” definition to encompass activities of food hubs performing low-risk packing and holding activities on RACs for distribution in local food markets. If we do not revise the “farm” definition to encompass such activities, these comments assert that a threshold dollar amount of \$2,000,000 would be necessary to allay concerns that making food hubs subject to the requirements for hazard analysis and risk-based preventive controls would cause many food hubs to fail, and would prevent the start of new food hubs.

(Response 160) See Response 23 and Response 25. Food hubs that pack and hold RACs are covered by the “farm” definition if the farm(s) that grow or raise the majority of the RACs packed and held by the food hub own, or jointly own, a majority interest in the food hub. Thus some food hubs will not be required to register as a food facility and, thus, will not be subject to the requirements for hazard analysis and risk-based preventive controls. Those food hubs that exceed the specified dollar threshold for a very small business and are not within the “farm” definition would be subject to the requirements for hazard analysis and risk-based preventive controls. However, the preventive controls that the food hub would establish and implement would depend on the food hub, the food, and the outcome of the facility’s hazard analysis, and the preventive control management components that the food hub would establish and implement for its preventive controls would be established as appropriate to ensure the

effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components. (See Response 222).

(Comment 161) Some comments express concern that establishing a threshold based on U.S. dollars would place domestic firms at a disadvantage relative to foreign firms whose sales are often denominated in currencies valued lower than the dollar and often reflect much lower costs for factors such as land, labor, and environmental compliance. These comments ask us to base the threshold on an alternate measure, such as number of employees, or to calculate the sales of foreign very small businesses using an appropriate measure of purchasing power parity, if there is a straightforward way to do so.

(Response 161) We decline these requests. As previously discussed, we use dollar estimates to evaluate the percentage of all food produced in the United States that would not be covered by the rule (79 FR 58524 at 58555). We acknowledge that the definition of “small business” is based on number of employees, and that two exemptions (*i.e.*, the exemptions in § 117.5(g) and (h) for on-farm, low-risk activity/food combinations) apply to small businesses. However, the exemptions for on-farm, low-risk activity/food combinations are limited to a narrow sector of the food industry, whereas the exemption applicable to a very small business will apply to all sectors of the food industry.

We do not know of a straightforward way to calculate the sales of foreign very small businesses using an appropriate measure of purchasing power parity and are basing the threshold only on U.S. dollars.

(Comment 162) Some comments assert that the reach of potential harm from foods imported from very small businesses that would meet the proposed threshold of \$1,000,000 may be greater because they are more likely to be ingredients, such as spices, and argue that small amounts of spice can contaminate a large volume of food and, thus, cause widespread illnesses. Other comments assert that it is very likely that more facilities in exporting countries will be exempt under the definition, thus putting those located in the United States at a disadvantage. These comments assert that the

definition of “very small business” should reflect the probability and severity of potential hazards in order to align with the rest of the regulation and promote public health interests.

(Response 162) We acknowledge that ingredients such as spices, which have been associated with outbreaks of foodborne illness and large recalls, can contaminate a large volume of food (78 FR 3646 at 3665 and 3737). However, the suggestion that we define “very small business” in a way that reflects the probability and severity of potential hazards is neither practical nor aligned with a size-based nature of the term.

The comments asserting that it is very likely that more facilities in exporting countries will be exempt under the definition, thus putting those located in the United States at a disadvantage, provided no basis for the assertion. As discussed in Response 156, we have declined the request to only include the total annual sales of food in the United States, adjusted for inflation, for foreign facilities that export food to the United States.

(Comment 163) Some comments express concern that the Food Processing Sector Study is not comprehensive.

(Response 163) See Response 139 regarding the Food Processing Sector Study.

### 38. You

We proposed to define the term “you” for purposes of part 117, to mean the owner, operator, or agent in charge of a facility. We received no comments that disagreed with this proposed definition and are finalizing it as proposed.

### *D. Comments Asking FDA To Establish Additional Definitions or Otherwise Clarify Terms Not Defined in the Rule*

#### 1. Corrections

(Comment 164) Some comments assert that clearly distinguishing between the terms “corrective actions” and “corrections” will be imperative for industry to comply with the rule and for regulators to enforce the rule. Some comments ask us to use the ISO definitions of “corrective actions” and “corrections.” (According to ISO 22000:2005 definition 3.13, a “correction” is action to eliminate a detected nonconformity; according to ISO 22000:2005 definition 3.14, corrective action is action to eliminate the cause of a detected nonconformity or other undesirable situation.) Other comments ask us to eliminate the term “correction” and instead revise the rule to clarify the type of situation in which “corrective actions” are neither

necessary nor appropriate. As an example, these comments suggest that the proposed provisions for corrections could refer to “prompt actions taken in response to minor and isolated deviations that do not directly impact product safety.”

Other comments agree with the concept of simple “corrections” but assert that the term “corrections” is unnecessary and could be confusing because different facilities may use the term differently. These comments explain that sometimes “correction” is used to refer to the action taken to fix a deviation, and may or may not be part of an overall corrective action taken to identify the root cause of the deviation and to prevent a similar occurrence. These comments suggest that the provisions explain that prompt actions taken to address minor and isolated deviations are not subject to the same requirements as corrective actions to address potentially systemic concerns, without defining the term “corrections.”

(Response 164) We are defining the term “correction” to mean an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce). We agree that clearly distinguishing between the terms “corrective actions” and “corrections” will be important for both industry and regulators. We acknowledge that one way to distinguish between “corrective actions” and actions that we would consider “corrections” could be to avoid the term “corrections” and instead say what we mean each time the rule uses the term “corrections.” However, after reviewing the full regulatory text of proposed subpart C we concluded that it was not practical to do so, because the term “corrections” was used more often in a title or a cross-reference than in a provision where the full text of what we mean by the term “corrections” is necessary to communicate a requirement. Our definition of “corrections” focuses on the first step in a “corrective action procedure” (*i.e.*, identify and correct the problem) and also specifies those aspects of a corrective action procedure that do not apply to a correction (*i.e.*, actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce). (A note to the ISO 22000:2005 definition of corrective action indicates that it includes cause analysis and is taken to prevent

recurrence.) We believe that this definition will be adequate to distinguish “corrective actions” from “corrections.”

As an example, if a facility applies sanitation controls for an environmental pathogen such as *L. monocytogenes* and food residue is observed on “clean” equipment prior to production, corrections would involve re-cleaning and sanitizing the equipment before it is used. Because the observation of food residue was made prior to production of food, no food is affected, and no actions are needed with respect to food. Although there are actions that can be taken to prevent reoccurrence, such as re-training sanitation personnel, these types of actions are not always needed.

## 2. Defect Action Level

(Comment 165) Some comments that address the proposed provisions regarding “defect action levels” (proposed § 117.110) ask us to define that term so that its meaning will be clear.

(Response 165) We have added a definition of the term “defect action level” to mean a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action under section 402(a)(3) of the FD&C Act. This definition derives from the definition in our long-standing “Defect Levels Handbook” (Ref. 36), which we continue to reference in the provisions established in this rule regarding defect action levels. This definition also derives from the long-standing provisions in § 110.110, which referred to natural or unavoidable defects in food for human use that present no health hazard and noted that some foods contain natural or unavoidable defects that at low levels are not hazardous to health. These long-standing provisions also noted that we establish maximum levels for these defects in foods produced under current good manufacturing practice and use these levels in deciding whether to recommend regulatory action.

## 3. Food-Packaging Material

(Comment 166) Some comments point out that the proposed human preventive controls rule would amend certain provisions requiring prevention of contamination and allergen cross-contact of food and food-contact surfaces to add “food-packaging materials,” a term which is not defined. These comments ask us to clarify that “food-packaging materials” is limited to packaging materials that are capable of contaminating food and does not

include shipping containers such as cartons and crates that pose no risk of introducing contaminants or food allergens into food.

(Response 166) For the purposes of the provisions that require protection against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials, the term “food-packaging materials” does not include shipping containers such as cartons and crates that pose no risk of introducing contaminants or food allergens into food. We are not adding a definition of “food-packaging materials” to the definitions in § 117.3 because the provisions requiring protection against contamination are long-standing provisions that have been applied in the manner requested by the comment and, thus, adding a definition is not necessary to address the comment’s request.

## 4. Must

(Comment 167) Some comments ask us to define the term “must.”

(Response 167) We decline this request. The term “must” has a common meaning, and it is not necessary to establish a specific meaning for this term specifically for this rule.

## 5. Parameter and Value as Used in the Requirements for Process Controls

(Comment 168) Some comments ask us to define the terms “parameter” and “value” used in the requirements for preventive controls (§ 117.135). These comments ask us to define “parameter” as a measurable attribute and “value” as a specific measurement.

(Response 168) We decline this request. Both of these terms are used in the context of process controls and both have common meanings when associated with process controls. Therefore, it is not necessary for the rule to define them.

## 6. Raw Materials

Some comments ask us to define “raw materials” (see Comment 65). As discussed in Response 65, we have declined to do so.

## 7. Qualified Facility Exemption

(Comment 169) Some comments note that some of the terminology associated with the exemption for qualified facilities in the human preventive controls rule is different from terminology associated with an exemption in the proposed produce safety rule. These comments point out that the exemption in the proposed produce safety rule refers to “qualified exemptions” (§ 112.5), whereas the

exemption in the proposed human preventive controls rule refers to “exemptions” and “qualified facilities” (§ 117.5(a)). These comments ask us to harmonize the terminology associated with the exemption for qualified facilities in the human preventive controls rule with the terminology associated with “qualified exemptions” in the proposed produce safety rule.

(Response 169) We have revised the human preventive controls rule in two ways to better harmonize the terminology associated with the exemption for qualified facilities in the human preventive controls rule with an analogous exemption in the proposed produce safety rule. First, we have added a definition for the term “qualified facility exemption,” to mean an exemption applicable to a qualified facility under § 117.5(a) (see the regulatory text in § 117.3). Second, we also have made conforming changes throughout the rule to use the term “qualified facility exemption” when it applies. (See table 52.) It is not practical to fully harmonize the relevant terminology in these two rules due to differences in the framework applicable to food businesses subject to section 418 of the FD&C Act compared to the framework applicable to farms subject to section 419 of the FD&C Act. For example, a farm is not a “facility” and, thus, it would be confusing to refer to the applicable exemption established in the final produce safety rule as a “qualified facility exemption” or to refer to the business entities that would be exempt from the final produce safety rule as “qualified facilities.”

#### 8. Unexposed Packaged Food

As discussed in section XII, some comments ask us to clarify that modified requirements for packaged food that is not exposed to the environment only apply to such food that requires time/temperature control for safety (TCS food). To do so, we are defining the term “unexposed packaged food” to mean packaged food that is not exposed to the environment and using this term throughout the rule. Doing so simplifies the regulatory text and makes it clearer.

(Comment 170) Some comments note that certain fruits and vegetables must be stored and distributed in vented packaging to allow for proper air circulation and the escape of gases produced in the ripening process. These comments ask us to interpret “not exposed to the environment” in a way that would include produce packed in such vented crates. Some comments assert that “exposed to the environment” must be meaningful from

a food-safety standpoint and that produce shipped in vented crates presents virtually no food-safety risk because its environmental exposure is minimal. Some comments state that they do not believe Congress intended the term “not exposed to the environment” to mean only airtight, sealed containers.

(Response 170) We acknowledge that certain fruits and vegetables may need to be distributed in vented crates but disagree that such produce is “packaged food not exposed to the environment.” We consider “packaged food not exposed to the environment” and “unexposed packaged food” to mean that the food is in a form that prevents any direct human contact with the food (78 FR 3646 at 3712). Although environmental exposure to produce packed in vented crates would be less than environmental exposure to produce packed in open crates, a vented crate can subject produce to contamination from condensate in aerosols carried by the air handling system, moisture dripping onto containers, particulates blown through the facility by the air handling system, fingers of handlers during handling of crates, objects that may be inadvertently inserted through the vents, pests that can access the produce through the vents, etc. We believe it is appropriate for facilities storing produce in vented crates to conduct a hazard analysis and evaluate whether there are hazards that would require a preventive control.

(Comment 171) Some comments ask us to interpret “not exposed to the environment” to mean packaged with food grade material that is impermeable to outside bacteria or other contamination. These comments state that materials that prevent human contact with the food can nonetheless permit passage of contaminants and express concern about migration of chemicals, not approved as food-contact substances, from outer wrappers.

(Response 171) We decline this request. A facility that packages “unexposed packaged food” is responsible for complying with all applicable requirements for the production of the food, including requirements established under section 409 of the FD&C Act (21 U.S.C. 348) regarding indirect food additives and food contact substances when packaging food. Likewise, a facility that packs “unexposed packaged food” in outer wrappers is responsible to ensure the safety of the food it packed, including ensuring that food is not contaminated from chemicals in the outer wrappers. The exemption applicable to “unexposed packaged food” applies to

the storage of such foods, not the manufacturing, processing, or packing of such foods. For practical purposes, food that is not exposed to the environment will be protected from outside bacteria by the packaging. See also the discussions in Response 170 and Response 232 regarding produce packed in “vented crates,” which is not “unexposed packaged food.”

#### E. Additional Definitions To Clarify Terms Not Defined in the Proposed Rule

##### 1. Audit

As already noted, some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other, and we have worked to align the provisions of this rule with the provisions of the FSVP rule to the extent practicable. (See Comment 9 and Response 9.) To align these provisions, we are establishing in this final rule a definition of “audit” analogous to the definition of “audit” we proposed for the FSVP rule. For the purposes of this rule, “audit” means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier’s food safety processes and procedures.

##### 2. Full-Time Equivalent Employee

As discussed in Response 140, we have established a definition for “full-time equivalent employee” as a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

##### 3. Raw Agricultural Commodity

We have added a definition of the term “raw agricultural commodity” to have the meaning given in section 201(r) of the FD&C Act. We decided to define this term in the rule to simplify the provisions in part 117 that refer to raw agricultural commodities.

##### 4. Supply-Chain-Applied Control

We have added a definition of the term “supply-chain-applied control” to mean a preventive control for a hazard

in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. We decided to define this term in the rule to simplify the provisions in part 117, and in the discussions in this document, that refer to preventive controls applied by a supplier before receipt by a receiving facility.

5. Written Procedures for Receiving Raw Materials and Other Ingredients

We have added a definition of the term “written procedures for receiving raw materials and other ingredients” to mean written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use). We decided to define this term in the rule to simplify the provisions in part 117, and in this document, that refer to these procedures.

6. Qualified Individual

As discussed in section X.A., we are clarifying in new § 117.4(b)(1) that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. To better align with the FSVP rule, we using the term “qualified individual” in new § 117.4(b)(1) and are defining the term “qualified individual” to mean a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

**X. Subpart A: Comments on Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food**

In 2002, FDA convened a CGMP Modernization Working Group (CGMP Working Group) to determine whether part 110 is in need of further revision. In 2005, the CGMP Working Group issued a report (CGMP Working Group Report) summarizing the comments we received, as well as our key findings (78 FR 3646 at 3651). One of the specific areas identified in the CGMP Working Group Report that presented an opportunity to modernize the regulation was to “require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products.” (78 FR 3646 at 3729)

As previously discussed, FSMA recognizes the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls, which identifies supervisor, manager, and employee hygiene training, and CGMPs under part 110, as some of the procedures, practices, and processes that may be included as preventive controls (see sections 418(o)(3)(B) and 418(o)(3)(F) of the FD&C Act, respectively) (78 FR 3646 at 3729).

We proposed to re-establish part 110’s recommendations for training as proposed § 117.10(c) (FR 3646 at 3720). In addition, we requested comment on how best to revise part 110’s current recommendations to implement section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group with respect to training (FR 3646 at 3729). Specifically, we requested comment on whether we should merely replace the current recommendations for personnel education and experience with requirements or whether more detail would be appropriate. As examples of additional specificity, we requested comment on whether the rule

should specify that each person engaged in food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) must receive training as appropriate to the person’s duties; specify the frequency of training (e.g., upon hiring and periodically thereafter); specify that training include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility; and specify that records document required training of personnel and, if so, specify minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained). We also requested comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both.

In the following paragraphs, we discuss comments that respond to our requests for comment on potential requirements for education and training and for whether to establish any requirements in subpart B, subpart C, or both. After considering these comments, we are establishing requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding food in new § 117.4 in subpart A, with associated recordkeeping requirements established in § 117.9 in subpart A. The regulatory text makes clear that these requirements, established in subpart A, apply to individuals engaged in manufacturing, processing, packing, or holding food regardless of whether the individuals conduct these activities under the framework of the CGMPs established in subpart B or the framework for hazard analysis and risk-based preventive controls established in subparts C, D, E, and G. The regulatory text also makes clear that the qualification requirements apply to the recordkeeping requirements of subpart F. See table 11 for a description of these provisions.

TABLE 11—PROVISIONS FOR QUALIFICATIONS OF INDIVIDUALS WHO MANUFACTURE, PROCESS, PACK, OR HOLD FOOD

Final section designation	Proposed section designation	Description
117.4(a)(1) .....	N/A .....	Applicability to individuals who manufacture, process, pack, or hold food subject to subparts B and F.
117.4(a)(2) .....	N/A .....	Applicability to individuals who manufacture, process, pack, or hold food subject to subparts C, D, E, F, or G.
117.4(b)(1) .....	N/A .....	Each individual engaged in manufacturing, processing, packing, or holding food must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties.
117.4(b)(2) .....	117.10(c) .....	Required training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene.
117.4(c) .....	117.10(d) .....	Additional qualifications of supervisory personnel.
117.4(d) .....	N/A .....	Records of required training.

TABLE 11—PROVISIONS FOR QUALIFICATIONS OF INDIVIDUALS WHO MANUFACTURE, PROCESS, PACK, OR HOLD FOOD—Continued

Final section designation	Proposed section designation	Description
117.9 .....	N/A .....	The required records are subject to the recordkeeping requirements of subpart F.

*A. Applicability and Qualifications of All Individuals Engaged in Manufacturing, Processing, Packing, or Holding Food (Final § 117.4(a), (b), and (d))*

(Comment 172) Some comments support changing the current recommendations for training to requirements, e.g., by replacing “should” with “must.” However, some of these comments also ask that the requirement allow sufficient flexibility for establishments to determine the scope and frequency of the training based on the establishment, types of products, and job responsibilities of the employee. Some of these comments assert that this position is consistent with the concept in the food safety plan of tailoring controls to the specific facility and operations, and also aligns with the Global Food Safety Initiative guidance document, which was based on the recommendations of the Codex Alimentarius Commission (Codex). Some of these comments ask that we specify “as applicable to the plant operation” and “applicable to their assigned duties” to allow establishments flexibility in establishing risk-based training requirements specific to their operations.

Other comments prefer more detail and ask that we establish requirements addressing all of the recommendations of the CGMP Working Group. Some of these comments note that doing so would be consistent with the proposed training requirements for the produce safety rule.

Other comments prefer that we continue to only provide recommendations for education and training and allow the food industry to determine the appropriate level of specific employee training that may be needed. These comments assert that overly prescriptive and binding requirements may not consider variables such as training course content, training provider, effectiveness of the course, and instructor and frequency of training per topic. In addition, comments assert that factors such as an employee’s type and length of experience, nature of formal education, and the food product type and point in the food supply chain at which the employee works with the

food product (close to the farm or close to the fork) will need to be considered. Other comments ask us to establish the recommendations of the CGMP Working Group in guidance rather than in the rule.

Some comments recommend that employees be trained “initially” and “periodically thereafter” but ask that we recognize the seasonal nature of a facility’s workforce. Some comments ask that the training include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene as applied at the facility.

Some comments ask that training requirements be established in subpart B so that the requirements apply to all establishments that manufacture, process, pack, or hold food, including establishments that are not subject to FSMA’s requirements for hazard analysis and risk-based preventive controls. These comments assert that this broad training requirement would improve food safety overall. Some comments that recommend establishing the training requirement in subpart B assert that training is more appropriately considered a prerequisite program than a preventive control that would belong in subpart C.

Other comments ask that the training and related recordkeeping requirements for the facility’s preventive controls qualified individuals be established under subpart C because this is directly related to the facility’s food safety plan. Other comments ask that training requirements be established in both subpart B and subpart C. Other comments assert that including requirements for education and training in both subparts B and C would be confusing.

(Response 172) We are establishing a series of requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding food in new § 117.4. First, to clarify how these qualification requirements apply to establishments subject to subparts B and F, we are requiring that the management of an establishment ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F are qualified to perform their

assigned duties (§ 117.4(a)(1)). To clarify how these qualification requirements apply to facilities, we are requiring that the owner, operator, or agent in charge of a facility ensure that all individuals who manufacture, process, pack, or hold food subject to subparts C, D, E, F, or G are qualified to perform their assigned duties (§ 117.4(a)(2)).

We are not requiring training specific to the person’s assigned duties. Each establishment engaged in the manufacturing, processing, packing, and holding of food for human consumption would already have procedures in place to ensure that all individuals who manufacture, process, pack, or hold food know how to do their jobs.

However, to emphasize that we expect all individuals who conduct such activities to know how to do their jobs, we are specifying that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties (§ 117.4(b)(1)). To better align with the forthcoming FSVP rule, we are using the term “qualified individual” in new § 117.4(b)(1) and are defining the term “qualified individual” to mean a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. See the discussion of the term “preventive controls qualified individual” in section IX.C.25, including a discussion of how we have changed the proposed term “qualified individual” to “preventive controls qualified individual” because we are establishing a new definition for “qualified individual,” with a meaning distinct from “preventive controls qualified individual.”

We also are requiring that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof,

receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the person's assigned duties (see § 117.4(b)(2)). Records that document this required training must be established and maintained and are subject to the recordkeeping requirements of subpart F (§§ 117.4(d) and 117.9). The rule does not specify the frequency of the required training. We expect that production employees will receive training before working in production operations. Based on a 2010 survey of the domestic food manufacturing industry, we expect that most facilities will also provide some form of refresher training (Ref. 54).

We disagree that we should continue to only provide recommendations for education and training. Although the comments express concern about overly prescriptive requirements that may not consider variables that would affect an establishment's training program (such as training course content, training provider, effectiveness of the course and instructor and frequency of training per topic, an employee's type and length of experience, nature of formal education, and the food product type and point in the food supply chain at which the employee works with the food product), the training requirement we are establishing in the rule provides flexibility for each establishment to provide training, and determine the scope and frequency of the training, in a way that works best for the establishment.

We agree that it is appropriate to establish training requirements so that the requirements apply to all establishments that manufacture, process, pack, or hold food, including establishments that are not subject to FSMA's requirements for hazard analysis and risk-based preventive controls, and we are establishing the qualification and training requirements in subpart A to clarify the applicability of these requirements to all establishments and facilities subject to part 117. Although we agree that employees in facilities that are subject to the requirements for hazard analysis and risk-based preventive controls need to understand their responsibilities under the facility's food safety plan, we are setting forth a training requirement focused on the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as recommended in the report of the CGMP Working Group (Ref. 3). We consider training in the principles of food hygiene and food safety, including the importance of

employee health and personal hygiene, to be fundamental to the concept of CGMPs. We agree that establishing a training requirement in both subpart B and subpart C could be confusing.

(Comment 173) Some comments ask that training not be limited to a narrow class of processors. Other comments assert that anyone who works in the food industry should have mandatory training and re-training.

(Response 173) The training applies to all individuals engaged in manufacturing, processing, packing, or holding food, consistent with the requests of these comments.

(Comment 174) Some comments agree that training should be documented and assert that those records should show the date of training, a description of the training, and the name of the person trained. However, comments ask that we allow flexibility in the way these records are kept. Other comments assert that requiring that records document required training of personnel is burdensome, arbitrary, and capricious.

(Response 174) The rule requires that records that document training required by § 117.4(b)(2) be established and maintained without prescribing any content of those records. Although one approach to documenting training would be to provide the date of training, a description of the training, and the name of the person trained, the rule provides flexibility for each establishment to document its training in a way that works best for that establishment. We disagree that requiring records to document required training is burdensome, arbitrary, and capricious in light of the strong support in the comments regarding CGMP modernization for records documenting training and the flexibility provided by the rule for the content of training records.

(Comment 175) Some comments that support mandatory training nonetheless caution us to be flexible towards the development and deployment of mandatory training, including issuance of certificates, so as not to create road blocks for third-party service providers. These comments state that education and training and/or capacity building is a growing, rapidly evolving, and well-developed third-party service industry today, and that food companies often deliver their training to other raw material suppliers and contract manufacturers. Some comments assert that the training and education programs should be developed and implemented in close cooperation with State agencies, public institutions, and stakeholder organizations.

(Response 175) The requirements do not address issuance of certificates or any other provisions that could create road blocks for third-party providers. An establishment has flexibility to develop or otherwise provide training in cooperation with public and private organizations in a manner that suits its needs.

(Comment 176) Some comments agree that any requirements should include training appropriate to the person's duties but emphasize that the decision as to what is appropriate to the person's assigned duties should be determined by the establishment.

(Response 176) The requirement for employees to receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the person's assigned duties, provides flexibility for the establishment to provide training that is appropriate for its employees in light of each person's assigned duties. However, the rule does not require training specific to the person's assigned duties.

(Comment 177) Some comments assert that the training requirement would be an unreasonable burden for small businesses and that companies may incur substantial cost for the time that workers would be in training rather than in production. Some comments ask us to provide non-specific training recommendations for smaller food processors that need flexibility to control the cost of training. Some comments assert that the training and education requirements must be accessible and flexible enough to allow employers to bring in temporary help when demand is high without causing a delay in hiring.

Some comments assert that we must provide ongoing education, training, and outreach for previously regulated firms, newly regulated firms, regulators that will be responsible for implementing the rules, and educators who will help farmers and facilities understand and manage the new requirements. Some comments assert that training is needed to educate farmers, the food industry, and State and local authorities as well.

(Response 177) All employees will need enough training to do their jobs and understand the importance of hygiene for food safety. The training offered does not need to be expensive (e.g., off-site training or off-the-shelf purchased training) and we expect that much of the training will be provided in-house by knowledgeable employees. As discussed in Response 2, the FSPCA is developing a preventive controls training curriculum. These training



materials will be available online, and we expect these training materials to be useful to small businesses to use for in-house training.

(Comment 178) Some comments ask us to continue to work with foreign governments on access to training and education to ensure that the industry as a whole is moving towards better advancements in food safety practices, no matter the size, channels of distribution, or geographic location.

(Response 178) As discussed in Response 717, we intend to work with the food industry, education organizations, USDA, the U.S. Agency for International Development, and foreign governments to develop tools and training programs to facilitate implementation of this rule.

(Comment 179) Some comments assert that the preventive controls qualified individual should perform the trainings. Some comments assert that the preventive controls qualified individual should be responsible for determining the appropriate frequency and scope of training for each facility and employee, and the records necessary to document that appropriate training has been conducted.

(Response 179) We decline these requests. Although we agree that the person delivering such training should be knowledgeable, we are providing flexibility for facilities to provide training as appropriate to the facility, including through on-line CGMP or other food safety courses.

(Comment 180) Some comments ask that this rule provide FDA (and those States under contract) the ability to require certification of industry managers and training of employees if serious operational hazards are found and management and staff are unable to

answer basic questions concerning hazards and controls in the facility.

(Response 180) We decline this request. We address each compliance situation on a case-by-case basis.

*B. Additional Requirements Applicable to Supervisory Personnel (Final § 117.4(c))*

We received no comments that disagreed with our proposal to retain the requirement in part 110 that responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel. We are correcting “all requirements of this subpart” to “all requirements of this part.” As a conforming change for consistency with the provisions of § 117.4(b), we are replacing the phrase “competent supervisory personnel” with the phrase “supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.”

**XI. Subpart A: Comments on Proposed § 117.5—Exemptions**

We proposed to establish a series of exemptions from the requirements for hazard analysis and risk-based preventive controls that would be established in subpart C, with modified requirements in some cases. We also proposed to redesignate § 110.19(a) (a pre-existing exemption from CGMP requirements applicable to establishments engaged solely in the harvesting, storage, or distribution of one or more RACs) as § 117.5(k) and to revise this exemption to adjust and clarify what activities fall within this exemption based on experience and changes in related areas of the law since issuance of the CGMP regulation.

Some comments support one or more of the proposed exemptions without change. For example, some comments note that the exemptions are specified in FSMA and, thus, reflect the intent of Congress. Some comments state that some exemptions (*i.e.*, those for products already subject to our HACCP regulations for seafood and juice, or to regulations for the control of microbiological hazards for LACF) make sense because they are risk-based. Other comments that support one or more of the proposed exemptions ask us to clarify particulars associated with these exemptions (*see, e.g.*, Comment 209, Comment 210, Comment 211, and Comment 212) or expand the scope of some of these exemptions (*see, e.g.*, Comment 185, Comment 196, Comment 197, Comment 208, and Comment 221). Other comments ask us to include additional exemptions in the rule (*see section XI.K*).

In the remainder of this section, we discuss comments that ask us to clarify the proposed exemptions or that disagree with, or suggest one or more changes to, the proposed exemptions. We also discuss comments that ask us to include additional exemptions in the rule. After considering these comments, we have revised the proposed exemptions as shown in table 12 with editorial and conforming changes as shown in table 52. A key conforming change that affects all proposed exemptions from the requirements of subpart C is that the final exemptions are from the requirements of subpart G, as well as subpart C. As discussed in section XLII, the final rule establishes the requirements for a supply-chain program in subpart G, rather than within subpart C as proposed.

TABLE 12—REVISIONS TO THE PROPOSED EXEMPTIONS

Section	Exemption	Modification
117.5(g) .....	From the requirements of subpart C for on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the specified low-risk packing or holding activity/food combinations.	<ul style="list-style-type: none"> <li>• Made changes consequential to the revised “farm” definition—<i>i.e.</i>, no longer identifying any packing or holding activities for any RACs.</li> <li>• Clarified that the modified requirements do not apply to on-farm packing or holding of food by a very small business if the only packing and holding activities subject to section 418 of the FD&amp;C Act that the business conducts are the listed low-risk packing or holding activity/food combinations.</li> <li>• Updated food categories consistent with the food categories included in table 1 in the section 103(c)(1)(C) RA.</li> <li>• Added low-risk packing or holding activity/food combinations as a result of an updated risk assessment.</li> <li>• Added a description of the food categories included in § 117.5(g) and (h).</li> </ul>

TABLE 12—REVISIONS TO THE PROPOSED EXEMPTIONS—Continued

Section	Exemption	Modification
117.5(h) .....	From the requirements of subpart C for on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the specified low-risk manufacturing/processing activity/food combinations.	<ul style="list-style-type: none"> <li>• Made changes consequential to the revised “farm” definition—<i>i.e.</i>:</li> <li>—No longer distinguish between manufacturing/processing activities conducted on a farm mixed-type facility’s own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility’s own RACs; and</li> <li>—Eliminated activities, conducted on others’ RACs, that would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding.</li> <li>• Clarified that the modified requirements do not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the FD&amp;C Act that the business conducts are the listed low-risk manufacturing/processing activity/food combinations.</li> <li>• Updated food categories consistent with the food categories included in table 1 in the section 103(c)(1)(C) RA.</li> <li>• Added low-risk manufacturing/processing activity/food combinations as a result of an updated risk assessment.</li> </ul>
117.5(k)(1)(iii) .....	From the requirements of subpart B for the holding and transportation of RACs.	Changed from an exemption for specific activities ( <i>i.e.</i> , holding and transportation of RACs) to establishments solely engaged in one or both of those activities.
117.5(k)(1)(v) .....	From the requirements of subpart B for certain activities conducted on nuts (without additional manufacturing/processing).	Changed from an exemption for specific activities to establishments solely engaged in those activities.

*A. General Comments on the Proposed Exemptions*

(Comment 181) Some comments ask us to provide the same flexibility for foreign small businesses as for domestic small businesses.

(Response 181) The exemptions apply to both foreign small businesses and domestic small businesses.

(Comment 182) Some comments note that proposed § 117.10(c) recommends, but would not require, that the responsible individual at a food establishment have a background of education, experience or a combination of both to provide a level of competence necessary to produce clean and safe food. These comments ask us to make this a requirement, rather than a recommendation, for the responsible individual at any facility that is exempt from the requirements for hazard analysis and risk-based preventive controls. These comments also ask us to require presentation of the training information to us before an exemption is granted.

(Response 182) We decline these requests. The statute does not require that we pre-qualify a facility for an exemption.

(Comment 183) Some comments ask us to clarify whether an establishment that is exempt from the requirements for hazard analysis and risk-based preventive controls in subpart C

remains subject to the CGMP requirements in subpart B.

(Response 183) An establishment that is exempt from the requirements for hazard analysis and risk-based preventive controls in subparts C and G remains subject to the CGMP requirements in subpart B, unless that establishment is exempt from subpart B under § 117.5(k) (which applies to: (1) Farms; (2) certain fishing vessels; (3) establishments solely engaged in the holding and/or transportation of one or more RACs; (4) activities of “farm mixed-type facilities” that fall within the definition of “farm”; and (5) establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing)).

*B. Proposed § 117.5(a)—Exemption Applicable to a Qualified Facility*

We proposed that subpart C would not apply to a qualified facility, except as provided by subpart E (Withdrawal of an Exemption Applicable to a Qualified Facility), and that qualified facilities would be subject to the modified requirements in § 117.201.

(Comment 184) Some comments support the proposed exemption for a qualified facility and assert that all farms should be eligible for this exemption until it is shown that food obtained from these farms makes people

sick. Other comments oppose this proposed exemption, asserting that it is not risk based and expressing concern that qualified facilities would cause significant food safety problems. Some comments ask us to strictly construct and narrowly apply the exemptions to as few businesses as possible.

Some comments do not agree that qualified facilities should be subject to modified requirements because even the modified requirements are burdensome. Some comments assert that qualified facilities having an average annual value of food sold during the previous three-year period of \$25,000 or less should be exempt from all requirements related to hazard analysis and risk-based preventive controls, including modified requirements.

(Response 184) The exemption for qualified facilities, including the criteria for being a qualified facility and the applicability of modified requirements, is expressly directed by section 418(l) of the FD&C Act. In defining “very small business” to mean a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee), we constructed this exemption to apply

to businesses that, collectively, produce less than 0.6 percent of the food supply (Ref. 38). In addition, as discussed in Response 151, most of these facilities will be subject to the CGMP requirements in subpart B.

(Comment 185) Some comments assert that a qualified facility should be exempt from the CGMP requirements of subpart B, as well as the requirements for hazard analysis and risk-based preventive controls in subpart C.

(Response 185) The exemption for qualified facilities is expressly directed by section 418(l) of the FD&C Act and is limited to an exemption from the requirements for hazard analysis and risk-based preventive controls in subparts C and G. The comments provide no basis for why new statutory requirements for hazard analysis and risk-based preventive controls should in any way impact the long-standing CGMPs requirements that apply to the manufacturing, packing, and holding of human food. CGMPs provide the basic requirements for ensuring production of safe and sanitary food. Following the CGMPs is essential to properly address public health risks from very small facilities that are provided an exemption from subparts C and G in order to minimize the burden on such facilities. (See also Response 221.)

(Comment 186) Some comments ask us to clarify how the exemption applies to diversified farms that produce both exempt and non-exempt products.

(Response 186) We assume that this comment is referring to a farm mixed-type facility that produces some products (such as juice or dietary supplements) that are exempt from the requirements for hazard analysis and risk-based preventive controls, as well as some products that are not exempt from these requirements. The exemption only applies to products that are not otherwise exempt from the requirements for hazard analysis and risk-based preventive controls. However, see the discussion in Response 157 with our response to comments requesting that we base the dollar threshold for the definition of very small business only on the annual monetary value of food covered by the preventive controls rule, rather than all human food; we declined that request.

(Comment 187) Some comments ask us to provide that a qualified facility may voluntarily choose to comply with the requirements for hazard analysis and risk-based preventive controls.

(Response 187) A qualified facility may voluntarily choose to comply with the requirements for hazard analysis and risk-based preventive controls

without a specific provision authorizing it to do so.

(Comment 188) Some comments ask us to specify in guidance that a qualified facility is not required to prepare and implement a food safety plan.

(Response 188) We intend to recommend in guidance how a qualified facility could comply with the modified requirements in § 117.201 without satisfying all of the requirements in subparts C and G.

*C. Proposed § 117.5(b) and (c)—Exemptions Applicable to Food Subject to HACCP Requirements for Fish and Fishery Products (21 CFR Part 123) or for Juice (21 CFR Part 120)*

We proposed that subpart C would not apply with respect to activities that are subject to part 123 (21 CFR part 123) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 with respect to such activities. We also proposed that subpart C would not apply with respect to activities that are subject to part 120 (21 CFR part 120) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 with respect to such activities. We requested comment on the criteria that should be used to determine whether a facility is in compliance with part 123 or part 120 (78 FR 3646 at 3704).

(Comment 189) Some comments ask us to clarify whether a seafood allergen that is identified as a hazard should be included in a seafood HACCP plan or in a facility's food safety plan. These comments also ask whether a food allergen that is identified as a hazard in juice subject to part 120 should be included in a juice HACCP plan or in a facility's food safety plan.

(Response 189) There is no specific requirement in the seafood HACCP regulation in part 123 that food allergen hazards be addressed in the seafood HACCP plan. However, Chapter 19 in our guidance entitled "Fish and Fishery Products Hazards and Controls Guidance (Fourth Edition)" includes recommendations for the control of undeclared food allergens (Ref. 42). The juice HACCP regulation in part 120 requires that a juice processor consider the presence of undeclared ingredients that may be food allergens as part of its hazard analysis, and several sections in our guidance entitled "Juice HACCP Hazards and Controls Guidance (First Edition)" include recommendations for the control of food allergens (Ref. 43). Both seafood processors and juice processors would also address allergen hazards through application of CGMPs.

Facilities that are exempt from the requirements of subparts C and G with respect to activities that are subject to part 120 or part 123 are not required to prepare and implement a food safety plan in addition to their HACCP plans.

(Comment 190) Some comments note that our HACCP regulations for juice and seafood do not require facilities subject to those regulations to address radiological hazards and ask how radiological hazards should be addressed for activities that are subject to part 120 or part 123.

(Response 190) A facility that conducts activities that are subject to part 120 or part 123 is not required to address radiological hazards in its HACCP plan if the facility is required to comply with, and is in compliance with, part 120 or part 123 with respect to such activities. However, under some circumstances radiological hazards might need to be considered. Moreover, the facility would be subject to the CGMP requirement that storage and transportation of food must be under conditions that will, among other things, protect against chemical (including radiological) contamination of food (§ 117.93).

(Comment 191) Some comments state that what is needed to assess compliance with the applicable HACCP regulation is evidence of compliance with each specific requirement of the regulation, such as compliance with requirements for a written hazard analysis and Sanitation Standard Operating Procedures (SSOPs). Other comments ask us to provide guidance to industry and the regulatory community regarding the criteria that will be used to determine when a facility is "in compliance with" part 120 or part 123. Some comments note that any determination of compliance with one of our HACCP regulations would be product specific, and that we would only be able to assess compliance on the inspected product, not all of the products being produced at the facility. Some comments ask us to establish a transparent process to follow when determining when to nullify an exemption applicable to food subject to HACCP in part 120 or part 123. These comments made specific suggestions for such a process, including through a HACCP inspection of a domestic facility or a review of a facility's HACCP plan and corresponding HACCP records for a foreign facility. These comments assert that FDA actions such as issuing inspectional observations, issuing a Warning Letter, or making an imported product subject to detention without physical examination, should not be the basis for determining non-compliance

because in such situations a facility would have an opportunity to respond to FDA with its approach to correcting problems.

Some comments assert that the key question for us to answer is when a situation will be so severe that it warrants requiring compliance with the human preventive controls rule rather than the applicable HACCP regulation. These comments raise questions about the practicality of requiring compliance with the human preventive controls rule for some products manufactured at a facility while continuing to require compliance with the applicable HACCP regulation for other products manufactured at that facility. These comments ask us to specify the added food safety protections that the human preventive controls rule can provide that cannot be obtained by compliance with the applicable HACCP regulation. These comments also ask us to consider the likelihood that a facility that cannot comply with the applicable HACCP regulation would be able to comply with the human preventive controls rule. Other comments ask whether we will modify existing guidance on compliance with applicable HACCP regulations to help facilities and inspectors understand what is needed for a facility to maintain its exemption.

Some comments assert that the statutory intent for compliance would be satisfied by enforcement actions (such as administrative detention, registration suspension, or mandatory recall) that will either ensure compliance with the applicable HACCP regulation, or prohibit that facility from distributing food.

(Response 191) We acknowledge the issues raised by these comments and agree that in many situations the appropriate action for us to take when a facility is out of compliance with an applicable HACCP regulation will be to employ existing enforcement tools to bring the facility into compliance with the applicable regulation. However, we also believe that there may be circumstances where an added food safety benefit could be achieved by requiring compliance with the human preventive controls rule when a facility does not comply with an applicable HACCP regulation. For example, the seafood HACCP regulation recommends—but does not require—that a seafood processor have and implement a written SSOP. In contrast, the human preventive controls rule requires that all preventive controls be written, and that preventive controls include, as appropriate to the facility and the food, sanitation controls, which include procedures, practices, and

processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards (§ 117.135(c)(3)). A seafood processing facility that has ongoing sanitation problems and contamination with, for example, an environmental pathogen, but does not have a written SSOP, may be better able to address its sanitation problems by a combination of written sanitation controls and verification of those sanitation controls through environmental monitoring (§ 117.165(a)(3)). Likewise, a juice processor that has ongoing problems with microbial contamination of fruit it receives for processing may be better able to address its supply of fruit by complying with the specific requirements of the human preventive controls rule for a supply-chain program (subpart G).

We expect that situations in which enforcement actions to ensure compliance with an applicable HACCP regulation are insufficient to correct problems, and lead to a facility losing its exemption from the requirements of subparts C and G, will be rare and will depend on very specific circumstances. Therefore, at this time we do not anticipate issuing guidance on when violations of one of our HACCP regulations would cause us to require compliance with subparts C and G.

(Comment 192) Some comments ask us to revise our HACCP regulations for seafood and juice to be consistent with subpart C to avoid the burden of having two systems within facilities that produce seafood or juice products, as well as other foods.

(Response 192) We decline this request. Our HACCP regulations are already consistent with—though not identical to—subpart C. Further, it is not clear that such facilities would need two separate systems, given the similarities in requirements and flexibility we have provided for implementing preventive controls. The food safety plan for the products not subject to the HACCP regulations is likely to be very similar to that for the foods subject to the HACCP regulations (which includes monitoring of SSOPs). To the extent that subparts C and G contain additional requirements, a facility is free to perform similar actions for its products produced under a HACCP regulation.

(Comment 193) Some comments ask us to exempt the production of fresh cider from the rule.

(Response 193) Fresh cider is juice. A facility that produces fresh cider is eligible for the exemption for products

subject to our HACCP regulation for juice.

*D. Proposed § 117.5(d)—Exemption Applicable to Food Subject to Part 113—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers*

We proposed that subpart C would not apply with respect to activities that are subject to part 113 at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 with respect to such activities. We also proposed that this exemption would apply only with respect to the microbiological hazards that are regulated under part 113. We requested comment on the criteria that should be used to determine whether a facility is in compliance with part 113 (78 FR 3646 at 3704).

(Comment 194) Some comments express concern that the partial exemption for products subject to part 113 could generate confusion for both regulators and regulated facilities. These comments also assert that the partial exemption for products subject to part 113 would generate duplicative recordkeeping requirements under the two rules.

(Response 194) We acknowledge the potential for confusion and expect any confusion to decrease over time as both regulators and facilities gain experience with the new requirements. We also expect that in most instances a facility that is subject to part 113, and that evaluates potential microbiological hazards as part of its hazard analysis, would conclude that the potential hazards are controlled by the targeted requirements of part 113 and conclude there are no microbiological hazards that require preventive controls to significantly minimize or prevent the hazards.

We disagree that the partial exemption for products subject to part 113 would generate duplicative recordkeeping requirements. The requirements of part 113 to control biological hazards are different from the requirements of subparts C and G to conduct a hazard evaluation for chemical and physical hazards, and implement preventive controls and associated preventive control management components to address significant chemical and physical hazards. Likewise, the records associated with the control of biological hazards under part 113 are not the same as the records associated with a hazard analysis, preventive controls, and associated preventive control management components for control of

chemical and physical hazards. However, to the extent that a facility appropriately determines that existing records required by part 113 can be used to demonstrate compliance with the requirements of subparts C and G, a facility may rely on those records (see § 117.330).

(Comment 195) Some comments ask us to provide guidance to industry and the regulatory community regarding the criteria that will be used to determine when a facility is “in compliance with” part 113.

(Response 195) We discuss similar comments regarding the exemptions for products subject to one of our HACCP regulations in Response 191. As an example, an LACF manufacturing facility that has ongoing problems controlling biological hazards may be better able to address biological hazards by preparing and implementing a written food safety plan. As with facilities subject to our HACCP regulations, we expect that situations in which enforcement actions to ensure compliance with part 113 are insufficient to correct problems, and lead to a facility losing its exemption from the requirements of subparts C and G, will be rare and will depend on very specific circumstances. Therefore, at this time we do not anticipate issuing guidance on when violations of part 113 could lead to this outcome.

*E. Proposed § 117.5(e)—Exemption Applicable to a Facility That Manufactures, Processes, Packages, or Holds a Dietary Supplement*

We proposed that subpart C would not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of part 111 (Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements) and section 761 (Serious Adverse Event Reporting for Dietary Supplements) of the FD&C Act. We requested comment on the criteria that should be used to determine whether a facility is in compliance with part 111 and section 761 of the FD&C Act (78 FR 3646 at 3705). As noted in table 52, we corrected the exemption to match the title of part 111—*i.e.*, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.”

(Comment 196) Some comments assert that the entire facility should be exempt from the requirements of subpart C if the facility implements the dietary supplement CGMP regulation

even if the facility also makes food products that are not dietary supplements. Some comments assert that the exemption applicable to the manufacturing, processing, packing, or holding of a dietary supplement should also apply to the manufacturing, processing, packing, or holding of a dietary ingredient if the facility chooses to follow the dietary supplement CGMP regulation.

(Response 196) The proposed exemption is directed by section 103(g) of FSMA. None of these comments explain how the desired expansion of the exemption is consistent with section 103(g), which limits the provision to “the manufacturing, processing, packing, or holding of a dietary supplement” (78 FR 3646 at 3705).

(Comment 197) Some comments ask us to revise the exemption applicable to dietary supplements to add that subparts B and F do not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of part 111. These comments assert that it would be illogical to subject the dietary supplement industry to industry-specific CGMPs (part 111), as well as a more general (and inherently less applicable) CGMP standard in part 117. These comments also assert that the intent of the CGMPs in part 117 is to regulate industries and industry segments that have not previously been regulated and that failing to acknowledge the regulations already applicable to dietary supplements would be duplicative, redundant, and provide no additional safety or public health protection.

(Response 197) As discussed in the final rule establishing the dietary supplement CGMP regulation, we included in part 111 the existing requirements in part 110 that we believe are common to dietary supplement manufacturing (72 FR 34752 at 34764, June 25, 2007). We recognized that there may be operations related to the manufacturing of dietary supplements for which certain provisions in part 110 (now largely subpart B of part 117) apply, but that we did not determine to be common to most dietary supplement manufacturing operations (*e.g.*, for dietary supplements that are dehydrated and rely on the control of moisture consistent with current § 110.80(b)(14) (proposed § 117.80(c)(14)). As was the case when we issued the final rule to establish dietary supplement CGMPs and continues to be the case now, a manufacturer would be required to comply with the CGMP regulations in subpart B of part 117 in addition to the

regulations in part 111, unless the regulations conflict. To the extent that the regulations conflict, the dietary supplement manufacturer would comply with the regulation in part 111.

(Comment 198) Some comments ask us to clarify how the exemption applies to foods, other than dietary supplements, that may be held in a facility that conducts activities in compliance with the dietary supplement CGMP regulation.

(Response 198) The exemption does not apply to foods, other than dietary supplements, that may be held in a facility that conducts activities in compliance with the dietary supplement CGMP regulation. The owner, operator, or agent in charge of a facility that produces both dietary supplements and foods that are not dietary supplements must comply with the requirements of this rule for hazard analysis and risk-based preventive controls, unless another exemption applies as specified in § 117.5.

(Comment 199) Some comments ask us to use information collected in the biennial food facility registration to help determine whether a facility is in compliance with part 111.

(Response 199) We decline this request. It would be the observations and findings from an inspection, rather than information in a facility’s registration, that could help us determine whether a facility is in compliance with part 111. Information collected during registration provides information on how we should inspect a facility, but has no bearing on whether the facility is complying with applicable regulations.

*F. Proposed § 117.5(f)—Exemption Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act*

We proposed that subpart C would not apply to activities of a facility that are subject to section 419 (Standards for Produce Safety) of the FD&C Act (21 U.S.C. 350h). We received no comments that disagreed with this proposal and are finalizing it as proposed.

*G. Proposed §§ 117.5(g) and (h)—Exemptions Applicable to On-Farm Low-Risk Activity/Food Combinations Conducted by a Small or Very Small Business*

As discussed in section VI.A, consistent with the statutory direction in section 103(c) of FSMA, including conducting a qualitative risk assessment, we proposed three exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very

small businesses (proposed §§ 117.5(g), (h)(1), and (h)(2)).

1. General Comments on the Proposed Exemptions Applicable to On-Farm Low-Risk Activity/Food Combinations Conducted by a Small or Very Small Business

(Comment 200) Some comments assert that conducting a low-risk activity/food combination should be sufficient to qualify any facility for exemption from subpart C, regardless of whether the activity is conducted on-farm or off-farm, or meets the economic threshold for a small or very small business.

(Response 200) The statute provides specific direction for those facilities that can qualify for this exemption. (See sections 418(l) and 418(o)(2) of the FD&C Act.) See also Response 184 and Response 222.

(Comment 201) Some comments ask why the activity/food combinations listed in proposed § 117.5(g) are not consistent with the activity/food combinations listed in proposed § 117.5(h). Some comments state that the exemptions for farming activities are confusing.

(Response 201) The items listed in § 117.5(g) only specify the food or food category (rather than an activity/food combination) because the activities addressed in § 117.5(g) are, in all cases, the same—*i.e.*, packing and holding activities. In contrast, the items listed in § 117.5(h) specify a particular activity (*e.g.*, coating, mixing) in addition to a food or food category (*e.g.*, peanuts and tree nuts) because there are multiple manufacturing/processing activities, each associated with a particular food or food category, listed in the provisions.

Although these exemptions are more complex than other exemptions (*e.g.*, because they are directed to specific activities conducted on specific foods or food categories), the final “farm” definition has simplified them to the extent practicable. For example, under the “farm” definition in the 2013 proposed preventive controls rule, whether an activity was packing or manufacturing/processing depended, in part, on whether the RACs being packed were the farm’s own RACs or others’ RACs. In contrast, under the “farm” definition established in this rule, packing RACs is a “packing” activity, regardless of ownership of the RACs being packed.

(Comment 202) Some comments note a distinction between the exemptions for on-farm low-risk activity/food combinations conducted by small and very small businesses and the exemption for qualified facilities.

Specifically, a farm mixed-type facility that only conducts low-risk activity/food combinations (such as making certain jams or syrups) would be exempt from the requirements of subpart C, whereas an off-farm qualified facility making those same jams and syrups, while exempt from the requirements of subpart C, would nonetheless be subject to modified requirements in § 117.201. These comments ask whether it would be better for a farm or farm mixed-type facility that satisfies criteria for a small or very small business, and also satisfies criteria for a qualified facility, to classify itself as a small or very small business or to classify itself as a qualified facility.

(Response 202) In light of the final “farm” definition, these comments no longer apply with respect to activities within the farm definition.

For activities conducted by a farm mixed-type facility, we acknowledge that the exemptions provided by § 117.5(g) and (h) for on-farm low-risk activity/food combinations are different from the exemption provided by § 117.5(a) for a qualified facility. A farm mixed-type facility that only conducts low-risk activity/food combinations listed in § 117.5(g) and (h) is fully exempt from the requirements of subparts C and G, and is not subject to the modified requirements in § 117.201, even if that farm mixed-type facility is also a very small business (and, thus, also is a qualified facility). To make this clear, we have revised proposed § 117.5(g) to specify that § 117.201 does not apply to on-farm packing or holding of food by a very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk packing or holding activity/food combinations. Likewise, we have revised proposed § 117.5(h) to specify that § 117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk manufacturing/processing activity/food combinations.

With these changes, a farm mixed-type facility that is a very small business and that only conducts the low-risk activity/food combinations listed in § 117.5(g) and/or (h) may find it advantageous to classify itself as a very small business eligible for the exemption in § 117.5(g) and/or (h) rather than as a qualified facility, which would be subject to the modified requirements in § 117.201.

(Comment 203) Some comments ask us to list activity/food combinations that

are not low-risk activity/food combinations, or that should have modified requirement rather than be exempt (*e.g.*, if the foods have been the subject of Class I recalls or outbreaks of foodborne illness).

(Response 203) We decline this request. With few exceptions, the exemptions are established by specifying the activities that are not subject to the requirements for hazard analysis and risk-based preventive controls, rather than the activities that are subject to these requirements. When an exemption does specify activities that are subject to certain requirements of the rule, the specified activities are a narrow exception (see § 117.5(k)). In the case of the exemptions for the low-risk activity/food combinations listed in § 117.5(g) and (h), the activity/food combinations that are subject to the requirements of subparts C and G are extensive and it is not feasible to identify and list all of them.

In developing the low-risk activity/food combinations that are exempt from the requirements, we conducted a qualitative risk assessment (Ref. 4) that considered whether manufacturing, processing, packing, or holding activities conducted on a farm mixed-type facility had been implicated in food that has been the subject of a Class I recall or outbreak of foodborne illness. However, whether specific types of food had been the subject of a Class I recall or outbreak of foodborne illness was only one factor we considered. For example, we also considered factors that impact the frequency and levels of contamination of the food (Ref. 4). For additional discussion, see the section 103(c)(1)(C) RA (Ref. 4).

(Comment 204) Some comments ask for a process to keep the list of low-risk activity/food combinations up to date, such as through guidance.

(Response 204) We decline this request. The exemptions established in this rule are binding, whereas any list of additional activity/food combinations established in a guidance document would not be binding. We established the list of activity/food combinations included in these exemptions through an extensive public process, including a request for comments on the section 103(c)(1)(C) draft RA. From this time forward, the process available to a person who wishes us to consider an additional activity/food combination is to submit a citizen petition in accordance with 21 CFR 10.30.

2. Proposed § 117.5(g)—Exemption Applicable to On-Farm Low-Risk Packing or Holding Activity/Food Combinations Conducted by a Small or Very Small Business

We proposed that subpart C would not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership. As a consequential change in light of the final “farm” definition, the final exemption no longer identifies any packing or holding activities for any RACs (whether the farm’s own RACs or others’ RACs), because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others’ RACs.

(Comment 205) Some comments ask us to expand the list of on-farm low-risk packing and holding activities to include packing and holding of food products not expressly covered by the proposed exemption. See the food products listed in table 13 and table 14.

(Response 205) We considered these comments within the context of the section 103(c)(1)(C) RA. Table 1 in the section 103(c)(1)(C) draft RA listed activity/food combinations that we identified as likely to be conducted by farm mixed-type facilities using broad food categories such as “grain” and “grain products.” In light of comments such as those described in Comment 205, table 1 in the final section

103(c)(1)(C) RA lists more types of food categories. The purpose of listing more types of food categories was to make it clearer when a particular food is encompassed within a particular activity/food combination. As one example, table 1 in the final section 103(c)(1)(C) RA lists food categories such as baked goods, milled grain products, and other grain products (e.g. dried pasta), in place of the original category “grain products.” As another example, table 1 in the section 103(c)(1)(C) RA lists the broad term “sap” and provides examples of different types of sap to make clear that activity/food combinations regarding sap are broader than “maple sap.”

We have revised the final exemption to list food categories consistent with the food categories included in table 1 in the section 103(c)(1)(C) RA and include those packing and holding activity/food combinations that the section 103(c)(1)(C) RA determines to be low-risk. For additional details about the outcome of the section 103(c)(1)(C) RA on the specific activity/food combinations described in the comments, see the section 103(c)(1)(C) RA (Ref. 4).

We also revised the proposed exemption to add two sets of information that we believe will be useful to a farm mixed-type facility when evaluating whether the farm’s packing activities satisfy the criteria for the exemption.

First, we have added a new provision (§ 117.5(g)(1)) explaining that the exemption in § 117.5(g) applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/

dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the “farm” definition in § 1.227. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

Second, we have added a provision (§ 117.5(g)(2)) describing the food categories listed in the exemption. For example, this provision explains that “milled grain products” include processed food products such as flour, bran, and cornmeal.

The first column in table 13 lists the food or food category that comments ask us to include in the exemption for on-farm, low-risk packing and holding activities. The second column lists the regulatory citation for the relevant exemption for on-farm packing and holding. Importantly, the full regulatory text of the exemption includes some limitations that were not specified in the comments, and table 13 should not be viewed as equating the requests of the comments with the final regulatory text of the exemption. For example, § 117.5(g)(2)(ix) specifies that the food category “baked goods” includes processed food products such as breads, brownies, cakes, cookies, and crackers, but does not include products that require time/temperature control for safety (such as cream-filled pastries). See § 117.5(g)(2) for a description of those food categories listed in the exemption for on-farm, low-risk packing and holding activity/food combinations in table 13.

TABLE 13—REQUESTED FOOD OR FOOD CATEGORY AND RELEVANT EXEMPTION FOR ON-FARM LOW-RISK PACKING AND HOLDING ACTIVITIES

Food or food category requested in the comments	Relevant regulatory section
<ul style="list-style-type: none"> <li>• Barley malt syrup .....</li> <li>• Barley malt extract .....</li> <li>• Other concentrated grain malt products in liquid or powder form.</li> </ul>	<ul style="list-style-type: none"> <li>§ 117.5(g)(3)(xix)—Sugar.</li> <li>§ 117.5(g)(3)(xx)—Syrups.</li> <li>§ 117.5(g)(3)(xxii)—Vinegar.</li> <li>§ 117.5(g)(3)(xxiii)—Any other processed food that does not require time/temperature control for safety.</li> </ul>
<ul style="list-style-type: none"> <li>• Birch sap and syrup .....</li> <li>• Cane syrup .....</li> <li>• Coconut sap and sugar.</li> <li>• Date sugar.</li> <li>• Palm sap and sugar.</li> <li>• Sorghum juice and syrup.</li> <li>• Other concentrated natural sweetener having a water activity lower than 0.85 and made with an adequate microbial reduction step.</li> </ul>	<ul style="list-style-type: none"> <li>§ 117.5(g)(3)(xix)—Sugar.</li> <li>§ 117.5(g)(3)(xx)—Syrups.</li> </ul>
<ul style="list-style-type: none"> <li>Chips .....</li> <li>• Crackers .....</li> <li>• Bread crumbs.</li> <li>• Dry bread.</li> </ul>	<ul style="list-style-type: none"> <li>§ 117.5(g)(3)(xiii)—Other fruit and vegetable products.</li> <li>§ 117.5(g)(3)(i)—Baked goods.</li> </ul>

TABLE 13—REQUESTED FOOD OR FOOD CATEGORY AND RELEVANT EXEMPTION FOR ON-FARM LOW-RISK PACKING AND HOLDING ACTIVITIES—Continued

Food or food category requested in the comments	Relevant regulatory section
Crude “dietary ingredient botanicals” in cut, chopped, or powdered form.	§ 117.5(g)(3)(xiii)—Other fruit and vegetable products.
• Dried cereal	§ 117.5(g)(3)(xv) Other herb and spice products.
• Dried pasta.	§ 117.5(g)(3)(xiv)—Other grain products.
Dried herbs and spices, chopped or ground	§ 117.5(g)(3)(xv)—Other herb and spice products.
Dry legume products (e.g., chickpea flour)	§ 117.5(g)(3)(xiii)—Other fruit and vegetable products.
Dry, unsulfited, fruits and vegetables in cut, chopped, sliced, shredded, or other form.	§ 117.5(g)(3)(xiii)—Other fruit and vegetable products.
Gums and resins	§ 117.5(g)(3)(vii)—Gums, latexes, and resins that are processed foods.
Herbal extracts (e.g., in solvents such as glycerin, alcohol and oil).	§ 117.5(g)(3)(xv)—Other herb and spice products.
• Honey infused with dried herbs or spices	§ 117.5(g)(3)(xv)—Other herb and spice products.
• Oil and/or vinegar infused with dried herbs or spices.	
Jerky	§ 117.5(g)(3)(vi)—Game meat jerky.
Molasses and treacle	§ 117.5(g)(3)(xi)—Molasses and treacle.
Potato starch	§ 117.5(g)(3)(xiii)—Other fruit and vegetable products.
Popcorn	§ 117.5(g)(3)(xiv)—Other grain products.
Salt, baking powder	§ 117.5(g)(3)(xxiii)—Any other processed food that does not require time/temperature control for safety.
Vitamins, minerals, and processed dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form.	§ 117.5(g)(3)(xxiii)—Any other processed food that does not require time/temperature control for safety.

In table 14, we list those foods or food categories, requested by comments, that are not included in the exemption for on-farm, low-risk packing and holding activities, and explain why.

TABLE 14—WHY CERTAIN REQUESTED FOOD CATEGORIES ARE NOT INCLUDED IN THE EXEMPTION FOR ON-FARM LOW-RISK PACKING AND HOLDING ACTIVITIES

Food or food group requested in the comments	Why the food or food group is not listed in the exemption
Barley malt and other grain malts	Malting increases the potential for a hazard, e.g., growth of microbial pathogens such as <i>Salmonella</i> , during the germination process. (However, the risk is mitigated when malting is done in conjunction with making sugar, syrups or vinegar.)
Crude “dietary ingredient botanicals” in whole, form	These are RACs, so packing and holding them is within the farm definition.
Dates (RACs)	These are RACs, so packing and holding them is within the farm definition
Dried intact herbs and spices	Although these are processed foods, packing and holding them is specifically included within the farm definition.
Dried legumes	Although these are processed foods, packing and holding them is specifically included within the farm definition.
Gums, resins, and exudates in solid, powdered, granular, or paste form.	Gums, resins and exudates (including latexes such as chicle) are RACs, so packing and holding them is within the “farm” definition. These products are made into processed foods in some cases, such as by boiling or cutting. The powdered, granular and paste forms from further processing are considered in the risk assessment as “any other processed food that does not require time/temperature control for safety.”

3. Proposed § 117.5(h)—Exemption Applicable to On-Farm Low-Risk Manufacturing/Processing Activity/Food Combinations Conducted by a Small or Very Small Business

We proposed that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are those listed in the proposed exemption. The proposed exemption specified those activity/food combinations that would be exempt when conducted on a farm mixed-type

facility’s own RACs and those activity/food combinations that would be exempt when conducted on food other than the farm mixed-type facility’s own RACs for distribution into commerce.

As a consequential change in light of the final “farm” definition, the final exemption no longer distinguishes between manufacturing/processing activities conducted on a farm mixed-type facility’s own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility’s own RACs. As another consequential change, the exemption has been revised to eliminate activities, conducted on others’ RACs,

which no longer are classified as manufacturing/processing and instead are classified as harvesting, packing, or holding. In addition, as discussed in Response 205 we have revised the final exemption to list food categories consistent with the food categories included in table 1 in the section 103(c)(1)(C) RA.

We also revised the proposed exemption to add two sets of information that we believe will be useful to a farm mixed-type facility when evaluating whether the farm’s manufacturing/processing activities satisfy the criteria for the exemption.



First, we have added a new provision (§ 117.5(h)(1)) explaining that the exemption in § 117.5(h) applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the “farm” definition in § 1.227. Drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the “farm” definition in § 1.227. In addition, treatment to manipulate the ripening of RACs (such as by treating produce with ethylene gas), and packaging and labeling the treated RACs, without additional manufacturing/processing, is within the “farm” definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the “farm” definition. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

Second, we have added a provision (§ 117.5(h)(2)) specifying that § 117.5(g)(2) describes the food categories listed in the exemption.

(Comment 206) Some comments ask us to include in the exemption a single list of low-risk manufacturing/processing activity/food combinations applicable to farm mixed-type facilities conducting activities on their own RACs and farm mixed-type facilities conducting activities on other’s RACs.

(Response 206) These comments no longer apply. As a consequence of the “farm” definition established by this rule, the exemption no longer distinguishes between manufacturing/processing activities conducted on a farm mixed-type facility’s own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility’s own RACs.

(Comment 207) Some comments ask us to include additional activity/food combinations in the exemption. See table 15 and table 16 for a list of the requested additional activity/food combinations.

(Response 207) We evaluated each of the requested activity/food combinations within the qualitative risk assessment (Ref. 4), unless the activity/food combination was out of scope of this rule (for example, if the requested activity/food combination was directed to animal food rather than human food). See table 15 and table 16 for the outcome of our evaluation of these requests, based on the findings of the section 103(c)(1)(C) RA as to whether the requested activity/food combination

satisfies the criteria in that risk assessment for a low-risk activity/food combination. When we determined through the section 103(c)(1)(C) RA that the requested activity/food combination did not satisfy the criteria for a low-risk activity/food combination, table 16 explains why. See § 117.5(g)(2) for a description of the food categories listed in the exemption for on-farm, low-risk manufacturing/processing activity/food combinations in table 15 and table 16.

The first column in table 15 lists the activity/food combination that comments ask us to include in the exemption for on-farm, low-risk manufacturing/processing activity/food combinations. The second column lists the regulatory citation for the relevant exemption for an on-farm manufacturing/processing activity/food combination. Importantly, the full regulatory text of the exemption includes some limitations that were not specified in the comments, and table 15 should not be viewed as equating the requests of the comments with the final regulatory text of the exemption. For example, § 117.5(g)(2)(ix) specifies that the food category “baked goods” includes processed food products such as breads, brownies, cakes, cookies, and crackers, but does not include products that require time/temperature control for safety (such as cream-filled pastries).

TABLE 15—REQUESTED ACTIVITY/FOOD COMBINATIONS AND RELEVANT EXEMPTION FOR ON-FARM LOW-RISK MANUFACTURING/PROCESSING ACTIVITIES

Activity/food combination requested in the comments	Regulatory section listing the exemption
Baking activities involving grain products .....	§ 117.5(h)(3)(ix)—Making baked goods from milled grain products (e.g., breads and cookies).
Chopping, coring, cutting, peeling, pitting, shredding, and slicing. .... • Crackers, dry bread, bread crumbs .....	§ 117.5(h)(3)(ii)—Chopping, coring, cutting, peeling, pitting, shredding, and slicing: • Baked goods • Other grain products • Gums/latexes/resins • Game meat jerky.
• Dry cereal, popcorn .....	
• Gums, resins and exudates .....	
• Jerky .....	
Cooking low-moisture foods with dry heat .....	§ 117.5(h)(3)(xxv)—Roasting and toasting baked goods.
Drying/dehydrating cut fruits and vegetables that are immediately moved into a drying process.	§ 117.5(h)(3)(iv)—Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2, and other herb and spice products (e.g., chopped fresh herbs, including tea).
• Distilling mint .....	§ 117.5(h)(3)(v)—Extracting (including by pressing, by distilling, and by solvent extraction) from:
• Extracting virgin olive oil .....	• Dried/dehydrated herb and spice products
• Extracting oils from seeds (e.g., sunflower seeds, flax seeds) .....	• Fresh herbs
• Making liquid botanical extracts from dry botanical raw material with solvents such as glycerin, ethanol, vinegar, honey.	• Fruits and vegetables • Grains • Other herb and spice products.
Grinding/milling/cracking/crushing: .....	§ 117.5(h)(3)(vii)—Grinding/milling/cracking/crushing:
• Crackers, dry bread, bread crumbs .....	• Baked goods
• Dry cereal, dry pasta, popcorn .....	• Other grain products
• Dry legumes .....	• Dried/dehydrated fruit and vegetable products.
Mixing .....	§ 117.5(h)(3)(xxii)—Mixing other herb and spice products.
• Honey infused with dried herbs or spices .....	
• Oil and/or vinegar infused with dried herbs or spices .....	
Making maple cream, maple sugar, and molded maple candy .....	§ 117.5(h)(3)(x)—Making candy.

TABLE 15—REQUESTED ACTIVITY/FOOD COMBINATIONS AND RELEVANT EXEMPTION FOR ON-FARM LOW-RISK MANUFACTURING/PROCESSING ACTIVITIES—Continued

Activity/food combination requested in the comments	Regulatory section listing the exemption
Making molasses and treacle from sugarcane and sugar beets ..... • Making apple syrup ..... • Making syrups from sorghum, rice ..... • Making syrups from malted barley ..... • Making syrups such as birch and walnut syrup .....	§ 117.5(h)(3)(xiv)—Making molasses and treacle. § 117.5(h)(3)(xix)—Making sugar and syrup from: • Fruits and vegetables • Grains • Other grain products • Saps.
Making vinegar, including infused and flavored vinegars .....	§ 117.5(h)(3)(xxi)—Making vinegar from fruits and vegetables, other fruit and vegetable products, and other grain products.
Processing tea .....	§ 117.5(h)(3)(xxii)—Mixing other herb and spice products. § 117.5(h)(3)(iv)—Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2, and other herb and spice products (e.g., chopped fresh herbs, including tea).

TABLE 16—WHY CERTAIN REQUESTED ACTIVITY/FOOD COMBINATIONS ARE NOT INCLUDED IN THE EXEMPTION FOR ON-FARM LOW-RISK MANUFACTURING/PROCESSING ACTIVITIES

Food or food group requested in the comments	Why the food or food group is not listed in the exemption
Acidifying, pickling, and fermenting low-acid fruits and vegetables made in compliance with CGMPs.	Acidifying, pickling, and fermenting activities control microbial hazards and, thus, are not low-risk activities.
Cucumbers, garlic scapes, peppers, and other low-acid foods that are preserved.	The production of low-acid processed foods must control the microbial hazard <i>C. botulinum</i> and, thus, is not a low-risk activity.
Drying/dehydrating tea leaves (e.g., by withering) .....	Drying/dehydrating tea leaves is within the “farm” definition.
Fermentation of vegetables .....	Fermenting activities control microbial hazards and, thus, are not low-risk activities.
Food processing conducted in compliance with relevant State regulation.	It is the risk associated with the activity/food combination, not the regulatory oversight by a State, that is relevant of this exemption.
Freezing fruit juices .....	Fruit juices are outside the scope of the RA based on the statutory framework of FSMA.
Low-acid fruits and vegetables manufactured in compliance with CGMPs under the FD&C Act.	The production of low-acid processed foods must control the microbial hazard <i>C. botulinum</i> and, thus, is not a low-risk activity.
Making pickles and salsa .....	The processes for making pickles and salsa must control microbial hazards and, thus, are not low-risk activities.
Roasting grains for animal feed .....	This activity involves the production of animal food, which is subject to the animal preventive controls rule rather than the human preventive controls rule.

*H. Proposed § 117.5(i)—Exemptions Related to Alcoholic Beverages*

Section 116 of FSMA (21 U.S.C. 2206) (Alcohol-Related Facilities) provides a rule of construction for certain facilities engaged in the manufacturing, processing, packing, or holding of alcoholic beverages and other food. In the proposed human preventive controls rule, we discussed our interpretation of section 116 of FSMA and requested comment on our interpretation. Based on our interpretation, we proposed that subpart C would not apply with respect to alcoholic beverages at facilities meeting two specified conditions (78 FR 3646 at 3707 to 3709). We also proposed that subpart C would not apply with respect to food other than alcoholic beverages at facilities described in the exemption, provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility.

(Comment 208) Some comments ask us to include the production of spent grains, distillers’ grains, grape pomace, and other by-products of the manufacturing process within the alcohol exemption. These comments argue that the mere act of separating and disposing of those by-products by sale or otherwise should not trigger an obligation to meet the requirements of subpart C.

(Response 208) The exemption established under the rule of construction in section 116 of FSMA applies to alcoholic beverages, not to any other food (see section 116(c) of FSMA (21 U.S.C. 2206(c)), and we have revised the exemption to make the statutory applicability clearer (see table 52 and the regulatory text of § 117.5(i)). As previously discussed (79 FR 58524 at 58558), the by-products described in these comments appear to be products that would be used in food for animals rather than in human food, and we addressed these by-products in the 2014

supplemental animal preventive controls notice (79 FR 58476 at 58487–58489). (See also the discussion in section L regarding the specific CGMP provisions that will apply to these foods.)

*I. Proposed § 117.5(j)—Exemption Applicable to Facilities Solely Engaged in Storage of Raw Agricultural Commodities Other Than Fruits and Vegetables Intended for Further Distribution or Processing*

We proposed that subpart C would not apply to facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. In the following paragraphs, we discuss comments that ask us to clarify how the proposed exemption would apply to specific circumstances.

(Comment 209) Some comments ask whether this proposed exemption (proposed § 117.5(j)) would apply to facilities such as peanut buying points or bean elevators and assert that such

commodities are analogous to grains and the activities conducted at such facilities are analogous to those performed by grain elevators.

(Response 209) We classify peanuts and beans (such as kidney beans, lima beans, and pinto beans) within the category of “fruits and vegetables”; we classify soybeans as grain (see the discussion of fruits and vegetables, 78 FR 3646 at 3690 and proposed §§ 112.1 and 112.2 in the proposed produce safety rule). The exemption for facilities solely engaged in storage of RACs intended for further distribution or processing does not apply to facilities that store fruit and vegetable RACs and, thus, does not apply to facilities such as peanut buying points and bean elevators. As discussed in Response 25, we have revised the “farm” definition to provide that an operation devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition as a secondary activities farm, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. With this revision, some operations dedicated to holding RACs, including fruit and vegetable RACs, will be within the “farm” definition.

Peanut buying points and bean elevators that do not meet the revised farm definition are storing RACs that are “fruits and vegetables” and do not meet the criteria for exemption under § 117.5(j). However, we would not expect such facilities to need an extensive food safety plan. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

(Comment 210) Some comments refer to our statement that there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable RACs intended for further distribution or processing to the requirements of subpart C (78 FR 3646 at 3709) and assert that the same conclusion applies to those portions of oilseed processing facilities that are devoted solely to RAC storage. According to these comments, in the overwhelming majority of cases the inclusion of a separate RAC storage area in the same building as the oilseed processing area will not introduce additional risk either to the processing

area or to the operations that take place there and that storage areas, whether standing alone as a separate facility or incorporated into a larger processing facility, store RACs safely. These comments ask us to recognize that storage activities may include grain drying to standardize moisture levels and preserve product quality. These comments also ask us to expand the exemption in § 117.5(j) to also apply to distinct and physically separate storage areas that are used solely for storage of RACs (other than fruits and vegetables) intended for further distribution or processing.

(Response 210) The activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs. In the 2014 supplemental human preventive controls notice, we explained that facilities that conduct operations similar to those conducted at grain elevators and silos, such as some facilities that hold oilseeds, may satisfy the criteria for exemption if activities other than storage are performed as a practical necessity for the distribution of RACs (see 79 FR 58524 at 58537 and the definition of “holding” in § 117.3). Examples of holding activities include drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (see § 117.3). Thus, the specific example of drying grains to standardize moisture levels and preserve product quality would fall within the definition of holding as a practical necessity for the distribution of RACs. A facility that stores oilseeds, and dries them as a practical necessity for the distribution of RACs, would be covered by the exemption in § 117.5(j).

However, we decline the request to modify the exemption in § 117.5(j) to also apply to distinct and physically separate storage areas that are used solely for storage of RACs (other than fruits and vegetables) intended for further distribution or processing. To the extent that the comments are asking us to do so to provide for facilities that conduct activities as a practical necessity for the distribution of RACs to be eligible for the exemption, doing so is not necessary in light of the definition of holding. To the extent that the comments are asking us to do so to provide for facilities that conduct manufacturing/processing activities in addition to holding activities, we disagree that doing so would be consistent with the statutory direction in FSMA. As previously discussed, section 418(m) of the FD&C Act provides in relevant part that we may by regulation exempt or modify the

requirements for compliance under section 418 of the FD&C Act with respect to facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (78 FR 3646 at 3709). The plain meaning of “solely” is only, completely, entirely; without another or others; singly; alone (Ref. 44). Facilities that conduct manufacturing/processing activities in addition to holding activities are not “solely” engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. See also Response 233 regarding a similar request regarding the applicability of the requirements for hazard analysis and risk-based preventive controls to a facility solely engaged in the storage of unexposed packaged food.

*J. Proposed § 117.5(k)—Exemption Applicable to Farms, Fishing Vessels, Activities of “Farm Mixed-Type Facilities” Within the Definition of “Farm,” the Holding or Transportation of One or More Raw Agricultural Commodities, and Specified Activities Conducted on Specified Raw Agricultural Commodities*

We proposed to redesignate § 110.19(a) as proposed § 117.5(k) and revise the exemption that had been in § 110.19(a) to provide that subpart B would not apply to: (1) Farms; (2) fishing vessels that are not required to register as a food facility; (3) the holding or transportation of one or more RACs; (4) activities of “farm mixed-type facilities” that fall within the definition of “farm”; and (5) hulling, shelling, and drying nuts (without manufacturing/processing, such as roasting nuts).

(Comment 211) Some comments ask us to clarify whether the proposed exemption for the holding or transportation of one or more RACs (proposed § 117.5(k)) would apply to any food establishment, or only apply to farms and farm mixed-type facilities.

(Response 211) The exemption applies to any food establishment.

(Comment 212) Some comments ask us to clarify that CGMP requirements (such as requirements for the plant design to permit the taking of adequate precautions to protect food in outdoor bulk vessels (§ 117.20(b)(3)) and requirements for warehousing and distribution (§ 117.93) do not apply to the bulk outdoor storage of RACs for further processing.

(Response 212) We are returning to the long-standing approach that the exemption applies to establishments “solely engaged” in specific activities. Under the exemption we are

establishing in § 117.5(k)(1)(iii), those activities are holding and/or transportation of RACs. Under the exemption we are establishing in § 117.5(k)(1)(v), those activities are hulling, shelling, drying, packing, and/or holding nuts. We explain why in the following paragraphs.

These comments appear to interpret the proposed exemption in a way that goes beyond the long-standing “RAC exemption” in § 110.19 and is inconsistent with our intent in updating § 110.19 to adjust and clarify what activities fall within this exemption based on experience and changes in related areas of the law since issuance of this exemption from the CGMPs (78 FR 3646 at 3710). The suggestion of these comments—*i.e.*, that CGMPs should not apply to the holding of RACs in a facility that manufactures, processes, or packs RACs—would not make sense in some circumstances and would create difficulties for establishments (in determining how to comply with the CGMP requirements) and for regulators (in determining how to enforce the CGMP requirements). For example, it does not make sense for the part of a facility that holds RACs prior to processing to be exempt and the parts of the facility that are processing the RACs and storing them after processing to be covered. Likewise, it does not make sense for part of a transportation vehicle to be covered and part to be exempt.

By revising these two proposed exemptions that derive from the “RAC exemption” so that they apply only to establishments “solely engaged” in the storage and/or transportation of RACs, and to establishments “solely engaged” in the hulling, shelling, drying, packing, and/or holding of nuts, we are providing for a predictable framework for interpreting exemptions for facilities “solely engaged” in other activities. For example, as discussed in Comment 209, comments ask us to expand the exemption (in § 117.5(j)) from the requirements for hazard analysis and risk-based preventive controls for facilities that are “solely engaged” in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing to also apply to distinct and physically separate storage areas that are used solely for storage of such RACs. In our response, we noted that facilities that conduct manufacturing/processing activities in addition to holding activities are not “solely engaged” in the storage of such RACs (see Response 209). In addition, as discussed in Comment 233, comments ask us to apply the exemption (in § 117.7) from the requirements for

hazard analysis and risk-based preventive controls for facilities that are “solely engaged” in the storage of unexposed packaged food to storage areas of facilities that also engage in food processing activities—*e.g.*, for distributors that are engaged in limited food processing, such as cutting vegetables or packing ready-to-eat foods. In our response, we noted that such distributors are not “solely” engaged in the storage of unexposed packaged food (see Response 233).

The questions raised by these comments led us to reexamine the reasons we gave, in the 2013 proposed human preventive controls rule and the 2014 supplemental human preventive controls notice, for describing these exemption in terms of the activities conducted without specifying that the establishment is “solely engaged” in conducting these activities. For example, in the 2013 proposed human preventive controls rule we explained our assumption that if activities subject to the CGMPs take place in the same establishment, compliance with the CGMPs with respect to those activities should provide necessary protection. The comments led us to question that assumption. For example, with respect to the question posed by the comments about the outdoor bulk storage of RACs for further processing, it is not clear how conducting subsequent activities on the RACs in accordance with the CGMP requirements would protect the RACs during outdoor bulk storage. As discussed more fully in Response 660, processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination. RACs stored in bulk outdoors before being processed into fresh-cut produce must be stored in clean containers or vessels such that these do not contribute to contamination of the produce before it is processed. In addition, as already noted in this response, in interpreting the exemptions from subparts C and G for facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (§ 117.5(j)) and for facilities solely engaged in the storage of unexposed packaged food (§ 117.7), we do not consider that the exemption for these “holding” activities applies when holding is part of other operations conducted by the facility. For example, the exemption in § 117.7 would not apply to a packaged food warehouse of a processing facility, even if the warehouse only stores unexposed packaged food.

In the 2013 proposed human preventive controls rule we tentatively concluded that it would be reasonable

to revise the RAC exemption in § 110.19 so that it would exempt the specifically identified activities when performed on RACs, regardless of whether the establishment that conducts those activities also conducts other activities that do not qualify for the exemption, in part because the exemptions in section 418(j)(1) applied to “activities” (*i.e.*, covered by parts 120, 123, and 113) (see 78 FR 3646 at 3710). However, section 418(j)(1) is premised on the existence of similar mandatory requirements for those specific foods. In contrast, there are no requirements similar to subpart B in some situations that would be exempt under an exemption broadly directed to the activities of holding and transportation. For example, there would be no other requirements similar to subpart B (*e.g.*, for pest control) applicable to an off-farm establishment that stores apples in a controlled atmosphere storage facility or to an establishment that stores harvested dry beans. We now believe that a better comparison is to other exemptions in FSMA, such as the exemption in section 103(c)(1)(D)(i) of FSMA for facilities engaged only in specific types of on-farm manufacturing, processing, packing or holding activities, and the exemption in section 418(m) of the FD&C Act for facilities solely engaged in storage of RACs (other than fruits and vegetables) intended for further distribution or processing. It is reasonable to infer that one reason for the use of “solely” in the statutory provisions in section 103(c)(1)(D)(i) of FSMA and in section 418(m) of the FD&C Act is to avoid some of the problems we have discussed in this response.

In the 2013 proposed human preventive controls rule, we stated our belief that activities should be regulated the same way regardless of whether activities subject to the CGMP requirements take place in same establishment. However, as with the exemptions in section 103(c)(1)(D)(i) of FSMA and section 418(m) of the FD&C Act, this is a situation where context matters. RACs that are the sole food in a warehouse are different from RACs being held in a manufacturing operation. As already noted in this response and as discussed more fully in Response 660, processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination, and produce being stored before processing into fresh-cut produce must be protected against contamination while being stored.

The exemptions we are establishing in this rule for establishments solely engaged in the storage and/or

transportation of RACs, and for establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts), remain consistent with our announced intent to adjust and clarify what activities fall within this exemption based, in part, on changes in related areas of the law since this exemption from the CGMP requirements was first issued. As discussed in section IV, we have made a number of changes to the “farm” definition, including changes that provide for an operation devoted to harvesting, packing, and/or holding of RACs to be a “farm” (*i.e.*, a “secondary activities farm”) (and, thus, be exempt from the CGMP requirements under § 117.5(k)(1)(i) even though the operation does not grow RACs (see § 117.3). With this revised “farm” definition, some establishments that had relied on the “RAC exemption” in § 110.19 to be exempt from CGMP requirements as establishments solely engaged in the “storage” of RACs, or because they were solely engaged in the harvesting (such as hulling and shelling) and storage (which includes drying) of nuts, will be exempt from the CGMP requirements because they are a “farm.” As a result, there are fewer operations that need to rely on exemptions that are an outgrowth of the long-standing RAC exemption in § 110.19.

#### *K. Comments Requesting Additional Exemptions*

##### 1. Introduction

(Comment 213) We received comments requesting several additional exemptions from the requirements for hazard analysis and risk-based preventive controls in subpart C, the CGMP requirements of subpart B, or both. See the remainder of section XI.K for a description of the specific requests.

(Response 213) Each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to recent estimates from the Centers for Disease Control and Prevention (CDC) (Ref. 45). This is a significant public health burden that is largely preventable. We believe that improvements to our CGMP regulations, coupled with implementation of FSMA’s directives to focus more on preventing food safety problems than on reacting to problems after they occur, can play an important role in reducing foodborne illness (other than foodborne illnesses that are the result of improper food handling practices in the home and food service settings, which would not be addressed by this rule). We did not

propose any exemptions or exceptions from the requirements of subpart C other than those contained in section 103 of FSMA (78 FR 3646 at 3657). Likewise, we did not propose any additional exemptions from the CGMP requirements other than to adjust and clarify what activities fall within a long-standing exemption related to RACs based on experience and changes in related areas of the law since issuance of the CGMP regulation (78 FR 3646 at 3709–3711).

In the remainder of section XI.K, we respond to the specific requests for additional exemptions from the requirements of subparts C and G for hazard analysis and risk-based preventive controls. None of these specific requests describe (or otherwise provide) evidence demonstrating that the regulatory framework associated with the request would address all of the requirements of subparts C and G. Therefore, we have declined all of these requests. In some cases, a facility that is subject to other Federal, State, or local regulations that have some of the same requirements as subparts C and G will not have to repeat the same activity and will be able to use any existing records to demonstrate compliance and supplement those actions and records as necessary to demonstrate compliance with the remaining requirements of subparts C and G (see, *e.g.*, 79 FR 58524 at 58542, Response 215, Response 216, Response 219, and the discussion of § 117.330 in section XLI.G). In one case (for facilities subject to the PMO; see Response 214), we have extended the date for compliance with the requirements of subparts C and G in light of comments expressing an intent to revise the current requirements of a Federal/State cooperative program to incorporate the requirements of this rule. In other cases, a facility may determine and document through its hazard analysis that no preventive controls are necessary to prevent its food products from being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (see, *e.g.*, Response 222, Response 226, Response 229, and the discussion of § 117.130 in section XXV). Such facilities, although not exempt, will have a reduced burden to comply with the rule, if the outcome of their hazard analysis is that there are no hazards requiring preventive controls.

Likewise, in the remainder of section XI.K we respond to the specific requests for additional exemptions from the CGMP requirements of subpart B. None of these requests provide a basis for why the long-standing CGMP provisions that establish basic requirements for the

manufacturing, processing, packing, and holding of food to prevent adulteration should no longer apply to a particular type of food establishment and, thus, we have declined these requests.

##### 2. Facilities That Comply With the Pasteurized Milk Ordinance

(Comment 214) Some comments discuss facilities that comply with the Grade “A” PMO and are regulated under the National Conference on Interstate Milk Shipments (NCIMS) system (PMO facilities). NCIMS has been part of a cooperative program among the U.S. Public Health Service/FDA, the States and the dairy industry since 1950. Procedures for Governing the Cooperative Program of the NCIMS include procedures establishing milk sanitation standards, rating procedures, sampling procedures, laboratory procedures, laboratory evaluation and sample collector procedures. As previously discussed (78 FR 3646 at 3662), the PMO is a model regulation published and recommended by the U.S. Public Health Service/FDA for voluntary adoption by State dairy regulatory agencies to regulate the production, processing, storage and distribution of Grade “A” milk and milk products to help prevent milkborne disease. Appendix K—HACCP Program of the PMO—describes a voluntary, NCIMS HACCP Program alternative to the traditional inspection system. A milk plant, receiving station or transfer station may not participate in the voluntary NCIMS HACCP Program unless the regulatory agency responsible for the oversight of the facility agrees to participate with the dairy plant(s), receiving station(s) and transfer station(s) in the NCIMS HACCP Program. Currently all 50 States, the District of Columbia, and Puerto Rico have adopted the PMO by reference or have codified the PMO or similar provisions in State regulations. At its biennial conferences, the NCIMS considers changes and modifications to the Grade “A” PMO to further enhance the safety of Grade “A” milk and milk products, including the administrative and technical details on how to obtain satisfactory compliance. Changes ultimately accepted by NCIMS voting delegates (representatives from States and territories) are forwarded to FDA for concurrence before they become effective.

Some comments recommend that we make full use of the existing milk safety system of State regulatory oversight for Grade “A” milk and milk products provided through the NCIMS and the food safety requirements of the PMO. Some comments assert that we are

exceeding our authority by requiring PMO-regulated facilities to comply with both the PMO and the requirements of FSMA for hazard analysis and risk-based preventive controls.

Some comments ask us to exempt PMO-regulated facilities (or the PMO-regulated part of a PMO facility that also produces food products not covered by the PMO) from the requirements of the rule for hazard analysis and risk-based preventive controls, or to otherwise determine that facilities operating in compliance with the PMO are also in compliance with those requirements. These comments suggest we could, as an interim step if we find it necessary, stay the application of these requirements to PMO-regulated facilities and work with the NCIMS cooperative program to enact any modifications to the PMO as may be needed to warrant an exemption or comparability determination. The comments characterize these changes as “minor.”

Some comments ask for clarification as to whether the human preventive controls rule would preempt the PMO if there are any conflicts or duplications between the human preventive controls rule and the PMO. Some comments ask us to explain our position concerning the interstate movement of milk and milk products and imported milk if the final rule does not recognize that PMO-regulated facilities are also in compliance with the requirements of the human preventive controls rule for hazard analysis and risk-based preventive controls. These comments ask: (1) Whether the final rule will become the de facto standard or the standard enforced by the FDA for the movement of milk in interstate commerce and for imported milk; (2) how the final rule will affect States that have adopted the PMO as their law/regulation for the production and processing of products such as fluid milk products and cottage cheese; and (3) how a final rule that does not recognize the PMO and the products made under the PMO will affect other Federal rules, policy, procedures, or practices that require compliance with the PMO.

(Response 214) We agree that we should make use of the existing system of State regulatory oversight for Grade “A” milk and milk products provided through the NCIMS and the food safety requirements of the PMO. The NCIMS program has been effective from a regulatory standpoint, and has likely had a significant public health impact in reducing the incidence of foodborne illness attributable to milk and milk products. FDA is committed to the mission of the NCIMS and ensuring the

continuance of an effective milk safety system with State regulatory oversight. However, the PMO does not address all of the requirements of subparts C and G, such as requirements relevant to the potential presence of environmental pathogens in the food processing environment (see, e.g., §§ 117.130(c)(1)(ii) and 117.150(a)(1)(iii)(B)). Such provisions could help to prevent food safety problems from the consumption of food produced by PMO facilities and play an important role in reducing foodborne illness. For example, in 2007, contamination of a PMO-regulated facility with the environmental pathogen *L. monocytogenes* was the cause of three deaths via listeriosis (Ref. 46). As another example, there have been large-scale recalls as a result of contamination of dried milk with the environmental pathogen *Salmonella* (Ref. 47).

In addition, the NCIMS HACCP Program is a voluntary program and, as of March 17, 2015, had been utilized by only 11 of approximately 625 PMO facilities (Ref. 48). Further, the current NCIMS HACCP Program does not address all of the requirements of subparts C and G, such as environmental monitoring as a verification of sanitation controls for environmental pathogens and a supply-chain program for non-dairy ingredients (Ref. 49). The PMO also does not address food allergen controls, which are appropriate for those Grade “A” facilities that also handle food containing allergens other than milk. The comments do not provide a basis for why we should exempt PMO facilities from the rule in light of the differences between the requirements of this rule and the requirements of the PMO.

NCIMS has initiated work to modify the PMO and that work is expected to include all of the requirements in a final human preventive controls rule. FDA has committed resources to work with the appropriate NCIMS Committees to make the necessary changes. However, the NCIMS process will not be complete in time for PMO facilities to meet the first two compliance dates for this rule (i.e., September 19, 2016 for businesses other than small and very small businesses, and September 18, 2017 for small businesses), because the next scheduled Conference following the publication of this final rule would be April 2017. Therefore, to make use of the existing system of State regulatory oversight for Grade “A” milk and milk products provided through the NCIMS and the food safety requirements of the PMO, we are extending the compliance

date for PMO-regulated facilities to comply with the requirements of subparts C and G to September 17, 2018. Doing so is consistent with the request of comments asking us to “stay” the application of the requirements for hazard analysis and risk-based preventive controls to PMO-regulated facilities and work with the NCIMS cooperative program to effect the necessary modifications to the PMO so that it will include all of the requirements in the human preventive controls rule. The extended compliance date is not equivalent to an exemption. Regardless of whether the PMO is modified to include the requirements of a final human preventive controls rule by the extended compliance date, PMO facilities must comply with the human preventive controls rule on September 17, 2018.

The extended compliance date also is responsive to comments that identified complex implementation issues concerning the interstate movement of milk and milk products and imported milk. If the requirements of this rule for hazard analysis and risk-based preventive controls are incorporated into the PMO by the compliance date, such implementation issues will be moot, because a facility that complies with the revised PMO would also comply with this rule. As the compliance date approaches, it will be clearer as to whether any or all of the necessary revisions to the PMO will be in place by the compliance date for PMO facilities. If it appears that these revisions will not be in place by the compliance date for PMO facilities, we will take steps to address implementation issues specific to this Federal/State cooperative program.

In establishing a compliance date of September 17, 2018 for PMO facilities, we considered: (1) The extent of revisions that must be made to incorporate the requirements of this rule for hazard analysis and risk-based preventive controls into the PMO; (2) the process to revise the PMO; and (3) the date at which the necessary revisions to the PMO could begin to be made. We discuss each of these considerations in the following paragraphs.

We disagree that the necessary revisions to incorporate the requirements of this rule for hazard analysis and risk-based preventive controls into the PMO are “minor.” There are gaps between the requirements of this rule and the current required and voluntary provisions of the PMO (Ref. 49), and gaps such as provisions directed to environmental

monitoring, supply-chain controls, and food allergen controls are not “minor.”

With respect to process, NCIMS considers changes and modifications to the Grade “A” PMO at its biennial conferences, and proposals with the necessary changes must be voted on at such a biennial meeting. The next scheduled biennial conference is in the spring of 2017. Although it may be possible for NCIMS to convene a special conference in 2016 for the purpose of voting on proposals to revise the PMO to make it comply with the requirements of this rule, practicalities such as the availability of funds for a special conference could interfere with any plans for a special conference. In addition, given that we do not view the necessary changes as “minor,” it could take more than one round of proposals for revising the PMO before a proposal receives the votes necessary to be adopted. Because the provisions of this rule will not be established until the date of publication of this final rule, any preliminary drafts of proposals to modify the PMO (*e.g.*, to incorporate the provisions that we proposed in the 2014 supplemental preventive controls notice) before today’s date may need revision to reflect the final provisions of the rule.

In light of all these considerations, we are establishing September 17, 2018 as the date for PMO facilities to comply with the requirements for hazard analysis and risk-based preventive controls in part 117, subparts C and G. The compliance date for PMO facilities to comply with the CGMP requirements of subpart B is also September 17, 2018, and PMO facilities will continue to comply with part 110 until that date. Under NCIMS procedures, changes agreed to by the voting delegates at the 2017 NCIMS conference (and to which FDA concurs) would be effective within one year of the electronic publication of the NCIMS documents; or by official notification by FDA to the States and the dairy industry of “Actions from the 2017 NCIMS Conference;” or by a previously determined effective date (*e.g.*, September 17, 2018). We believe that the date of September 17, 2018 appropriately balances the need to realize the benefits of FSMA’s requirements for hazard analysis and risk-based preventive controls with the practicalities associated with revising the PMO to incorporate the requirements of this rule.

### 3. Facilities That Have an Established HACCP Program

(Comment 215) Some comments ask us to recognize operations that have an established HACCP Program

implemented by a trained individual as meeting the requirements of the human preventive controls rule. Some of these comments note that the NCIMS HACCP Program describes a voluntary, NCIMS HACCP Program alternative to the traditional inspection system. Other comments discuss the EU Dairy HACCP Program and assert that the preventive controls system mandated by FSMA is a HACCP-like system but is not as robust as the EU Dairy HACCP Program. Other comments ask us to support and recognize industry-driven, mandatory programs that afford the same level of public health protection as the human preventive controls rule.

Other comments note that facilities such as pizza manufacturing facilities are “dual jurisdiction” facilities, regulated and inspected by both FDA and USDA’s Food Safety and Inspection Service (FSIS). These comments assert that such facilities already are operating under FSIS-approved HACCP plans, and their HACCP plans cover FDA-regulated products, as well as FSIS-regulated products. These comments acknowledge that there are differences between FSIS’ HACCP regulation and FDA’s proposed requirements for hazard analysis and risk-based preventive controls but nonetheless assert that requiring dual jurisdiction facilities to operate under two different food safety plans would result in unnecessary duplication of effort and confusion.

(Response 215) Whether a particular HACCP program implemented by a trained individual would satisfy the requirements of the human preventive controls rule will depend on whether the particular HACCP program satisfies all of the requirements of the rule. (See Response 213.) For operations that have implemented HACCP programs that are generally similar to the provisions of part 117, the burden of complying should be minimal in light of the provisions of § 117.330, which provides for use of existing records. As an example, if a facility has an existing HACCP plan (or multiple HACCP plans for different types of foods), supported by certain prerequisite programs that include food safety controls, the facility would not need to duplicate or re-write its existing HACCP plans or prerequisite programs, as long as the existing HACCP plans and prerequisite programs contain all of the required information and satisfy the requirements of subpart F, or are supplemented as necessary to include all of the required information and satisfy the requirements of subpart F (see § 117.330(a)). Because the rule also provides that the required information does not need to be kept in one set of records, a facility may

supplement existing records associated with its HACCP plans and prerequisite programs with other required components of a food safety plan (such as recall plan and, when applicable, a supply-chain program and written verification procedures for environmental monitoring) (see § 117.330(b)). Moreover, the rule provides additional flexibility for a facility that relies on both existing records and newly established records to keep the records either separately or combined (see § 117.330(b)).

The flexibility provided by the provisions for use of existing records also enables a facility to comply with the requirement (in § 117.310) for the owner, operator, or agent in charge of a facility to sign and date the facility’s food safety plan, even when components of the food safety plan are kept separately. For example, when the food safety plan consists of one or more existing HACCP plans, one or more prerequisite programs that include food safety controls, a recall plan, a written supply-chain program, written verification procedures such as environmental monitoring, and any other components required by the rule, one approach for signing and dating the food safety plan could be to collect all these documents in a single location (*e.g.*, a binder or folder) with a cover page containing the signature of the owner, operator, or agent in charge of the facility and the date on which the cover page was signed. However, because the food safety plan also could be a set of documents kept in different locations within the facility, a facility could sign and date a list of the relevant documents (*e.g.*, as in a Table of Contents). (See also the discussion in Response 369 that a food safety plan may be prepared as a set of documents kept in different locations within the facility (*e.g.*, based on where they will be used)).

### 4. Facilities That Are Subject to Requirements for Acidified Foods

(Comment 216) Some comments ask us to exempt (or partially exempt) facilities that produce acidified foods from the requirements of subpart C, because acidified foods are subject to the specific food safety regulation in part 114 (21 CFR part 114) in addition to the CGMP requirements in subpart B. If we do not do so, these comments ask us to clarify whether a scheduled process established for an acidified food would be accepted as a process that had been validated as a preventive control for a microbiological hazard. Some of these comments mention specific acidified food products, such as salsa.

Other comments ask us to withdraw part 114 and regulate acidified foods under part 117 to avoid confusion, and then consider acidification as a preventive control.

(Response 216) We agree that the specific CGMP requirements already established in part 114 play a key role in the safe production of acidified foods, but disagree that it would be appropriate to exempt facilities that are subject to part 114 from the requirements of subparts C and G. As the comments suggest, the long-standing requirements of part 114 could function as a type of preventive control.

However, part 114 does not address all of the requirements of subparts C and G, such as the requirement to address chemical and physical hazards.

We also disagree that we should withdraw part 114 and simply consider acidification as a preventive control under subparts C and G. The long-standing requirements of part 114 provide many details that do not fit within the framework of this rule, and we do not believe that it is in the best interest of public health to simply eliminate those details.

A processor of acidified foods can consider its current scheduled processes, established in accordance with part 114, when conducting the hazard analysis required by this rule (§ 117.130). A processor of acidified foods could, through its hazard analysis, determine and document that the microbiological hazards associated with its products are addressed by preventive controls in its scheduled processes established under part 114. To the extent that the processor considers an existing scheduled process to be a preventive control as that term is defined in this rule, the processor would establish and implement preventive control management components (*i.e.*, monitoring, corrective actions and corrections, and verification (including validation)) as appropriate to ensure the effectiveness of that preventive control, taking into account the nature of the preventive control. Again, a processor of acidified foods can consider its current procedures, established in accordance with part 114, when determining what preventive control management components to establish and implement. For example, a facility that previously validated a scheduled process can rely on its existing validation records and would not need to repeat the validation or make a new record. Processes issued by a process authority for acidified foods are generally accepted as validated processes. As another example, a facility can consider its current procedures for

complying with the requirements of part 114, including frequent pH testing and recording of results, to exercise sufficient control so that the finished equilibrium pH values for acidified foods are not higher than 4.6 (§ 114.80(a)(2)), and to address deviations from scheduled processes (§ 114.89). A facility that produces acidified foods could demonstrate compliance with the requirements of subparts C and G of this rule by relying on the records it is currently required to establish and maintain (§ 114.100), as applicable, supplemented as necessary (see § 117.330).

(Comment 217) Some comments ask whether a qualified facility with activities that are subject to part 114 (Acidified Foods) would be exempt from the requirements of Subpart C.

(Response 217) A qualified facility is exempt from the requirements of subparts C and G, and instead subject to the modified requirements in § 117.201, for all foods that it produces, including acidified foods.

#### 5. Egg Facilities

(Comment 218) Some comments ask us to exempt shell egg facilities that are also regulated by USDA and by State shell egg grading programs from the requirements of both subpart B and subpart C or at least recognize these establishments as meeting the requirements for subpart B and Subpart C without further routine FDA inspection. Some comments ask us to exempt shell egg establishments subject to part 118 (21 CFR part 118) (Production, Storage, And Transportation Of Shell Eggs) from the requirements of subpart C because part 118 already requires shell egg establishments to take specific, concrete, steps to prevent the hazard *Salmonella* from contaminating eggs on the farm and from further growth during storage and transportation.

(Response 218) Shell eggs are RACs. The on-farm production of shell eggs is exempt from both the CGMP requirements in subpart B (see the exemption for farms in § 117.5(k)(1)(i)) and from the requirements for hazard analysis and risk-based preventive controls in subparts C and G (because a “farm” is exempt from the requirement to register as a food facility). Likewise, the packing of shell eggs by egg packinghouses that are within the “farm” definition established during this rulemaking are exempt from both the CGMP requirements in subpart B and the requirements for hazard analysis and risk-based preventive controls in subparts C and G, (see Response 25).

Establishments that are solely engaged in the holding or transportation of shell eggs are exempt from the CGMP requirements in subpart B (see the exemption for establishments solely engaged in the holding or transportation of one or more RACs in § 117.5(k)(1)(iii)). Facilities that are required to register, but are solely engaged in the storage of shell eggs intended for further distribution or processing, are exempt from the requirements for hazard analysis and risk-based preventive controls in subparts C and G (see the exemption in § 117.5(j)).

Shell egg processing facilities that are regulated exclusively, throughout the entire facility, by USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are exempt from the section 415 registration regulations and, thus, are not subject to the requirements of this rule for hazard analysis and risk-based preventive controls (subparts C and G).

#### 6. Facilities That Produce Infant Formula

(Comment 219) Some comments ask us to exempt the production of infant formula from the requirements of subpart C after we issue a final rule establishing requirements for CGMPs and quality control procedures for infant formula.

(Response 219) We issued an interim final rule entitled “Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula” on February 10, 2014 (79 FR 7934) and a final rule (the infant formula rule) adopting, with some modifications, that interim final rule on June 10, 2014 (79 FR 33057).

We agree that the requirements of the infant formula rule play a key role in the safe production of infant formula, but disagree that it would be appropriate to exempt facilities that are subject to the infant formula rule from the requirements of subparts C and G. The infant formula rule does not address all of the requirements of subparts C and G, such as requirements relevant to the potential presence of environmental pathogens in the food processing environment (see, *e.g.*, §§ 117.130(c)(1)(ii) and 117.150(a)(1)(ii)(B)). As with products such as acidified foods (see Response 216), a manufacturer of infant formula could demonstrate compliance with the requirements of subparts C and G of this rule by relying on the records it is currently required to establish and maintain (§ 106.100), as applicable,



supplemented as necessary (see § 117.330).

#### 7. Small Businesses

(Comment 220) Some comments ask us to provide more exemptions for small farms and small facilities.

(Response 220) We decline this request. As discussed in Response 213, the exemptions we are establishing are those provided by section 103 of FSMA. Small farm that only conduct activities within the “farm” definition are not subject to the human preventive controls rule. Small farms that also conduct activities outside the “farm” definition (such as manufacturing jams or jellies) (and, thus, are farm mixed-type facilities) are eligible for an exemption if the only such activities they conduct are the low-risk activity/food combinations specified in the exemptions in § 117.5(g) and (h). Small farms that are subject to this rule as farm mixed-type facilities, and other small businesses, will have an extra year to comply with the rule. As discussed in Response 222, the new requirements for hazard analysis and risk-based preventive controls are flexible, and the preventive controls (if any) that a facility would establish and implement would depend on the outcome of the facility’s hazard analysis and therefore would be tailored to the operation. These aspects of this rulemaking provide ample flexibility to small businesses.

#### 8. Exemptions Based on Risk

(Comment 221) Some comments ask us to exempt facilities identified as conducting low-risk activities from the CGMP requirements.

(Response 221) We decline this request. The umbrella CGMPs that we are establishing in subpart B are long-standing provisions that establish basic requirements for the manufacturing, processing, packing, and holding of food to prevent adulteration. For example, food that is exposed must be protected against contamination from the plant’s grounds, the design and construction of the plant, and sanitary operations regardless of whether the uncontaminated food could be “high-risk” or “low-risk”; contamination introduced during the production of food can adulterate any food. In addition, these umbrella CGMPs are not “one-size-fits-all” in that many provisions provide flexibility to tailor specific practices to the nature of the food and the activities being conducted. For example, many provisions establish a performance standard in which the measures taken must be “adequate” to comply with the rule, where adequate is

defined as that which is needed to accomplish the intended purpose in keeping with good public health practice. As another example, provisions directed to raw materials require that they be washed or cleaned “as necessary” to remove soil or other contamination (see § 117.80(b)(1)). Moreover, some comments point out that one strength of the long-standing CGMPs is their applicability to the broad spectrum of food manufacturing, from the manufacture of processed products and packaging of fresh produce to production of food additives and GRAS substances (see section VIII). (As already noted, some packaging of fresh produce (e.g., packaging of RACs on a farm) is not subject to the CGMPs.)

(Comment 222) Some comments assert that we should not base the requirements for hazard analysis and risk-based preventive controls on the status of a business as a facility that is required to register under the section 415 registration regulations if there is no risk from consumption of food produced by that business. Some comments assert that a food safety plan should only be required for high-risk processing facilities because adhering to CGMPs is sufficient for low-risk facilities. Some comments assert a food safety plan should be required for large businesses, but not for small and medium-size businesses, including small businesses that manufacture low-risk foods that are sterilized before being eaten and already undergo a 48-point inspection twice a year.

Some comments ask us to adopt a commodity-specific approach to the exemptions and to only apply the requirements for hazard analysis and risk-based preventive controls to RACs that fall within the five highest-risk commodity groups and to any other specific commodities that we determine pose a comparable risk based on outbreak history and the commodity’s characteristics.

Other comments note that some States provide “exemptions” for “non-potentially-hazardous foods.” These comments assert that there should be national agreement on what such foods are and, if such foods are truly low risk, there should not be onerous requirements regardless of the size of the business.

(Response 222) We decline these requests to establish additional exemptions based on risk, other than the exemptions for on-farm low-risk activity/food combinations provided by section 103(c)(1)(D) of FSMA (§ 117.5(g) and (h)). The applicability of the requirements of the human preventive controls rule to facilities that are

required to register is required by the statute (see the definition of facility in section 418(o)(2) of the FD&C Act). Section 418(h) of the FD&C Act requires that a facility prepare and implement a food safety plan, unless an exemption applies. Neither FSMA nor this rule establishes a broad exemption for “low-risk” facilities, including “low-risk” facilities that are regularly inspected by State, local, or tribal government agencies. As discussed in Response 213, the exemptions we are establishing are those specifically authorized by the statute.

The new requirements for hazard analysis and risk-based preventive controls are not “one-size-fits-all,” and facilities that are subject to the rule would consider the risk presented by the products as part of their hazard evaluation. (See § 117.130(c)(1)(i), which requires that the hazard analysis include an evaluation of identified known or reasonably foreseeable hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.) Although each facility subject to the rule must prepare and implement a food safety plan, the preventive controls that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility’s hazard analysis (§§ 117.130 and 117.135(c)). In addition, the preventive control management components (*i.e.*, monitoring, corrective actions and corrections, and verification) that a facility would establish and implement for its preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system (§ 117.140(a)). A facility that appropriately determines through its hazard analysis that no preventive controls are necessary to prevent its food products from being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act would document that determination in its written hazard analysis but would not need to establish preventive controls and associated preventive control management components for its products. A facility that is a very small business as that term is defined in this rule is exempt from the requirements of subparts C and G, including the requirement to prepare and implement a food safety plan, and is instead subject to the modified requirements in § 117.201.

We expect that there will be many circumstances in which a facility appropriately determines that certain biological, chemical, or physical hazards are not hazards requiring a preventive control that must be addressed in the food safety plan. There are several types of food products for which a facility may determine that there are no hazards requiring a preventive control. Such products could include, but are not limited to: many crackers, most bread, dried pasta, many cookies, many types of candy (hard candy, fudge, maple candy, taffy and toffee), honey, molasses, sugar, syrup, soft drinks, and jams, jellies, and preserves from acid fruits.

#### 9. Hullers/Shellers

(Comment 223) Some comments ask us to clarify whether an operation solely engaged in hulling/shelling would qualify for the exemption from the requirements for hazard analysis and risk-based preventive controls for facilities that solely are engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (§ 117.5(j)). Other comments ask us to clarify whether an operation that is solely engaged in hulling/shelling and, thus, is exempt from the CGMP requirements of subpart B would also be exempt from the requirements for hazard analysis and risk-based preventive controls in subpart C. Some of these comments assert that it seems contrary to the principles of HACCP that a facility that is not required to implement CGMPs (which is a foundation of HACCP) would still need to develop a food safety plan. Some comments assert that requiring these operations to apply HACCP standards to what is an extension of harvesting is overkill, because the consumer is ultimately protected by processes at the handler (processor) level. Other comments assert that our clarification that operations that hull/shell/dry nuts are exempt from the CGMP requirements recognizes that hulling/shelling activities are low risk and do not alter the status of a RAC. Because the requirements for hazard analysis and risk-based preventive controls will be applied by those receiving product from the huller/sheller, it does not seem appropriate for an operation that is explicitly exempt from CGMP requirements to be required to conduct a hazard analysis, implement controls, conduct monitoring, etc.

(Response 223) Under the revised “farm” definition, some hulling/shelling operations will be within the “farm” definition (*i.e.*, if the primary production farm(s) that grows, harvests,

and/or raises the majority of the nuts owns, or jointly owns, a majority interest in the hulling/shelling operation). Because hulling/shelling is a harvesting activity, not a holding activity, those hulling/shelling operations that are not within the “farm” definition are not eligible for the exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (§ 117.5(j)). As discussed in Response 222, there is no exemption for “low-risk operations.” However, a facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

#### 10. Fruit and Vegetable RACs

(Comment 224) Some comments ask us to clarify the two exemptions applicable to RACs—*i.e.*, the exemption from CGMP requirements for the holding or transportation of one or more RACs (§ 117.5(k)) and the exemption from the requirements for hazard analysis and risk-based preventive controls for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (§ 117.5(j)). These comments ask whether an off-farm holding facility that strictly deals with fruit and vegetable RACs would be exempt from subpart B, but not subpart C.

Some comments assert that operations that pack RACs other than fruits and vegetables intended for further distribution or processing should be exempt from both CGMP requirements and requirements for hazard analysis and risk-based preventive controls. These comments ask us to expand the exemption from CGMP requirements for the holding or transportation of one or more RACs to include the packing of RACs (other than fruits and vegetables). These comments also ask us to include packing RACs in the exemption from subpart C for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing.

(Response 224) Under the revised “farm” definition, some operations that pack RACs will be within the “farm” definition (*i.e.*, if the farms that grow or raise the majority of the RACs own, or jointly own, a majority interest in the packing operation). Packing operations that are within the “farm” definition are exempt from the CGMP requirements (§ 117.5(k)(1)). However, the packing of

RACs is not otherwise exempt from either the CGMP requirements or the requirements for hazard analysis and risk-based preventive controls. As discussed in Response 221, the umbrella CGMPs that we are establishing in subpart B are long-standing provisions that establish basic requirements for the manufacturing, processing, packing, and holding of food to prevent adulteration.

Packing operations that are within the “farm” definition are exempt from the requirements for hazard analysis and risk-based preventive controls (because “farms” are exempt from the section 415 registration requirements for “facilities”). As discussed more fully in Response 222, the new requirements for hazard analysis and risk-based preventive controls are not “one-size-fits-all.” Although each facility subject to the rule must prepare and implement a food safety plan, the preventive controls that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility’s hazard analysis. In addition, the preventive control management components that a facility would establish and implement for its preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system.

#### 11. Enclosed Outdoor Vessels

(Comment 225) Some comments ask us to exempt enclosed outdoor vessels from the specific CGMP provisions (such as requirements for the plant design to permit the taking of adequate precautions to protect food in outdoor bulk vessels (§ 117.20(b)(3)) and requirements for warehousing and distribution (§ 117.93)) if they are properly “risk assessed” and covered by appropriate procedures for preventing contamination, and system verification is implemented.

(Response 225) We decline this request. The long-standing CGMP requirements are comprehensive, interrelated provisions intended to prevent the adulteration of food. Specifying particular provisions that would not apply if a food establishment appropriately implements other provisions would be contrary to this comprehensive approach to food safety, in addition to being both impractical and difficult to administer. If a food establishment has appropriately determined that its procedures for preventing contamination adequately address the requirements for the safe storage of food in enclosed outdoor

vessels, it should have no difficulty demonstrating that during inspection.

#### 12. Supermarket Distribution Centers

(Comment 226) Some comments ask us to exempt supermarket distribution centers from the requirements of subpart C and instead require them to have written CGMPs. If this request is not accepted, then these comments ask us to either exempt supermarket distribution centers from the requirements of subpart C for those packaged foods not exposed to the environment (with modified requirements for unexposed, refrigerated, packaged TCS foods), or specify that there are no significant hazards for such a facility to address in a food safety plan.

(Response 226) A supermarket distribution center must register as a food facility because it holds food for human consumption and does not satisfy any of the criteria for entities that are not required to register (see § 1.226). As discussed in Response 222, the preventive controls that a facility would establish and implement would depend on the facility, the food, and the outcome of the facility's hazard analysis, and any preventive control management components associated with a facility's preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. In the case of a facility that is a supermarket distribution center, the facility would, as part of its evaluation, determine whether any preventive controls are necessary for unexposed, non-refrigerated packaged foods. The facility might determine that the modified requirements in § 117.206 for unexposed, refrigerated, packaged TCS foods are appropriate to apply to such foods that it holds. If so, the facility could establish its food safety plan by building on the provisions established in § 117.206.

#### 13. Local and Regional Facilities Such as Kitchen Incubators, Food Hubs, and Grower Marketing Cooperatives

(Comment 227) Some comments ask us to provide flexibility to local and regional facilities that do not qualify for an exemption from subpart C (e.g., "kitchen incubators" and farm mixed-type facilities that are subject to State or local laws). Some comments ask us to exempt (or partially exempt) food hubs, grower marketing cooperatives, "produce auctions," and similar entities. Some comments ask us not to cover facilities with less than \$25,000 in annual sales (similar to a provision

being considered under the 2013 proposed produce safety rule) or to establish a higher sales limit (i.e., \$100,000) applicable to both the human preventive controls rule and the produce safety rule.

(Response 227) We decline the requests to exempt (or partially exempt) the business models described in these comments. (See Response 213.) None of these requests describe or provide evidence that the regulatory framework associated with the business model would address all of the requirements of subparts C and G. Many of the types of facilities listed have multiple business models that conduct different types of activities. For example, USDA defines a regional food hub as "a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand." (Ref. 50). Some food hubs have facilities at which they conduct activities, including dry and cold storage, grading, packing, labeling, and light processing (trimming, cutting, and freezing), whereas other food hubs never physically handle the product sold but instead rely on farmers and contract trucking firms to provide aggregation and transportation services (Ref. 50). Some food hubs have a farm-to-business model (e.g., selling to food cooperatives, grocery stores, institutional foodservice companies, and restaurants), while others have a farm-to-consumer model (i.e., selling directly to the consumer, e.g., through a CSA), and some are hybrids that do both (Ref. 50). Some food hubs combine produce distribution with food processing operations (shared commercial processing space, or "incubator kitchens"). Thus, some of these operations could be exempt. For example, some of these operations may fall within the revised "farm" definition (e.g., if the farms that grow or raise the majority of the RACs own, or jointly own, a majority interest in a food hub or a grower marketing cooperative and the food hub or grower marketing cooperative does not conduct any activities outside of the "farm" definition). Other operations could be exempt if they fall within the definition of "retail food establishment" (see Response 4). With respect to produce auction houses, to the extent that these operations are simply a location for buyers and sellers to meet and to sell and transfer produce and the food is not stored, we do not consider such facilities to be holding food and would

not expect them to register; therefore these operations would not be subject to the requirements of subparts C and G for hazard analysis and risk-based preventive controls.

We also decline the request not to cover facilities with less than \$25,000 or \$100,000 in annual sales. (See the discussion in Response 220, in which we declined the request to provide more exemptions for small farm mixed-type facilities and other small facilities). However, if a local or regional facility such as those described in the comments is a very small business, the facility would be subject to modified requirements (§ 117.201) rather than to the full requirements for hazard analysis and risk-based preventive controls. When such an operation is not a farm, a retail food establishment, or a very small business, the preventive controls that a facility would establish and implement would depend on the facility, the food, and the outcome of the facility's hazard analysis, and any preventive control management components associated with a facility's preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. (See Response 222.)

#### 14. Production of Raw Sugar

(Comment 228) Some comments ask us to exempt the production of raw sugar that is destined for refining from the requirements in subpart C for hazard analysis and risk-based preventive controls.

(Response 228) Making sugar from sugarcane or sugar beets is a low-risk activity/food combination (see § 117.5(h)), and the statutory exemption in § 117.5(h) would apply to a small or very small business that makes sugar on-farm if the only other activities it conducts outside the farm definition are the low-risk activity/food combinations in § 117.5(g) and (h).

We decline the request to extend this exemption to a small or very small business that makes sugar off-farm or to a business that is not a small or very small business (see Response 213). As discussed in Response 222, the preventive controls that such businesses would establish and implement would depend on the facility, the food, and the outcome of the facility's hazard analysis, and any preventive control management components associated with a facility's preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account

the nature of the preventive control and its role in the facility's food safety system. An off-farm facility that makes sugar from sugarcane or sugar beets can consider the findings of the section 103(c)(1)(C) RA (*i.e.*, that this is a low-risk activity/food combination) in determining whether there are any hazards requiring a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

15. Biological Hazards in Olive Oil

(Comment 229) Some comments ask us to establish an exemption for the consideration of biological hazards such as *Salmonella* and pathogenic *E. coli* in olive oil.

(Response 229) We decline this request. The rule requires the facility to conduct a hazard analysis to determine hazards requiring a preventive control. If the facility appropriately determines through its hazard analysis that biological hazards such as *Salmonella* and pathogenic *E. coli* are not hazards requiring a preventive control in its product, then these hazards would not be addressed in the facility's food safety plan.

We expect that there will be many circumstances in which a facility appropriately determines that certain

biological, chemical, or physical hazards are not hazards requiring a preventive control that must be addressed in the food safety plan. The provisions of the rule that allow a facility to appropriately determine that a particular hazard is not a hazard requiring a preventive control in certain food products are not equivalent to an exemption from the rule. For example, a facility that appropriately determines that there are no hazards requiring a preventive control associated with its food products must document that determination in its written hazard analysis (§ 117.130(a)(2)); however, no preventive controls, including supplier verification activities, and associated management components would be required in such a situation. As discussed in Response 222, there are several types of food products for which a facility may determine that there are no hazards requiring a preventive control.

**XII. Subpart A: Comments on Proposed § 117.7—Applicability of Part 117 to a Facility Solely Engaged in the Storage of Unexposed Packaged Food**

We proposed that subpart C would not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 117.7(a)). We also proposed that a facility solely engaged in the storage of packaged food that is not exposed to the environment would be subject to the modified requirements that would be

established in § 117.206 of subpart D (proposed § 117.7(b)).

Some comments support these proposed provisions without change. For example, one comment expresses the view that the safety of these products would be ensured during the manufacturing process by companies that comply with the stringent requirements of the proposed rule, and no new hazards will be introduced to the food at these facilities. Other comments that support the proposed provisions ask us to clarify some aspects of the provisions (*see, e.g.*, Comment 230) or to clarify how the provisions will apply in particular circumstances (*see, e.g.*, Comment 231 and Comment 232). Other comments that support the proposed provisions ask us to broaden them (*see, e.g.*, Comment 233, Comment 234, and Comment 235).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 17, with editorial and conforming changes as shown in table 52. A key conforming change that affects § 117.7 is that the final exemption is from the requirements of subpart G, as well as subpart C. As discussed in section XLII, the final rule establishes the requirements for a supply-chain program in subpart G, rather than within subpart C as proposed.

TABLE 17— REVISIONS TO THE PROPOSED APPLICABILITY OF SUBPARTS C AND D TO A FACILITY SOLELY ENGAGED IN THE STORAGE OF UNEXPOSED PACKAGED FOOD

Section	Description	Revision
117.7(b) .....	Applicability of subpart D.	Clarification that subpart D only applies to those unexposed packaged foods that require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(Comment 230) Some comments ask us to clarify the interplay between the proposed exemption (proposed § 117.7) and the proposed modified requirements (proposed § 117.206) to better reflect that the modified requirements would apply only to TCS foods. Some comments ask us to clarify that if a facility stores both TCS food and non-TCS food (*i.e.*, unexposed packaged food that does not require time/temperature control for safety), then the modified requirements only apply for the portion of the facility that holds the TCS foods.

(Response 230) We have revised § 117.7(b) to clarify that a facility solely engaged in the storage of unexposed

packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 117.206 of subpart D for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(Comment 231) Some comments ask us to revise the regulatory text to be explicit that frozen unexposed packaged food is not a TCS food subject to modified requirements.

(Response 231) We decline this request. In the 2013 proposed human preventive controls rule, we tentatively concluded that it would be rare for a frozen food to be a TCS food (78 FR 3646 at 3774), and we affirm that conclusion in this document. However, specifying in the regulatory text that a frozen food is not a TCS food would require us to conclude that a frozen food would “never” (rather than “rarely”) be a TCS food, and we lack information to support “never.”

(Comment 232) Some comments assert that a hazard analysis of the risks associated with storage of produce in vented crates would reveal no significant hazards and, thus, that even

if we do not agree that produce packaged in vented crates satisfies the criterion “not exposed to the environment,” we should exercise enforcement discretion for produce packaged in vented crates.

(Response 232) As discussed in Response 170, produce stored in vented crates is not “unexposed packaged food.” Although environmental exposure to produce packed in vented crates would be less than environmental exposure to produce packed in open crates, a vented crate can subject produce to contamination. Thus, we disagree that we should not enforce the provisions of the rule for such produce. A facility that stores produce packed in vented crates must conduct a hazard analysis and evaluate whether there are any hazards requiring a preventive control. However, as discussed in Response 222, the preventive controls that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility’s hazard analysis, and any preventive control management components associated with a facility’s preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control associated with its food products would document that determination in its written hazard analysis (§ 117.130(a)(2)) but would not need to establish preventive controls and associated preventive control management components for its products.

(Comment 233) Some comments ask us to apply the exemption to storage areas of facilities that also engage in food processing activities—*e.g.*, for distributors that are engaged in limited food processing, such as cutting vegetables or packing RTE foods. These comments assert that the intent of the term “solely” is to make clear that a facility that conducts an activity subject to the exemption does not escape responsibility for complying with the requirements for hazard analysis and risk-based preventive controls when conducting activities that are not exempt. In the comment’s example, a facility that cuts vegetables or packs RTE foods would prepare and implement a food safety plan for cutting vegetables and packing RTE foods, but would not conduct a hazard analysis to determine whether there are significant hazards for storing unexposed packaged food.

(Response 233) We disagree with the comment’s interpretation of the term “solely.” The plain meaning of “solely” is only, completely, entirely; without another or others; singly; alone (Ref. 44). The facility described in the comment is not “solely” engaged in the storage of unexposed packaged food.

Such a facility must conduct a hazard analysis that addresses all activities conducted by the facility. As discussed in Response 222, the preventive controls that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility’s hazard analysis, and any preventive control management components associated with a facility’s preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system. A facility that stores unexposed packaged food that is not a TCS food could, for example, determine that no preventive controls and associated management components would be necessary for those foods. A facility that stores unexposed refrigerated packaged TCS food could, for example, determine that preventive controls and management components patterned after the modified requirements in § 117.206 are adequate to address hazards requiring a preventive control associated with that food.

(Comment 234) Some comments ask us to allow a facility to designate a storage area as a separate facility for purposes of compliance with the requirements for hazard analysis and risk-based preventive controls. In the comments’ view, an area solely engaged in the storage of unexposed packaged food could fall within the exemption in § 117.7 even though other areas would be subject to the requirements for hazard analysis and risk-based preventive controls.

Some comments contrast our proposed approach to applying the statutory provision for facilities “solely engaged in . . . storage” with our proposed approach to applying section 418 of the FD&C Act to farm mixed-type facilities and facilities that conduct activities subject to one of our HACCP regulations. These comments point out that, for farm mixed-type facilities, we determined that section 418 applies only with respect to the activities that trigger registration (78 FR 3646 at 3705). Likewise, these comments point out that for facilities that conduct activities subject to our HACCP regulations for seafood or juice, we determined that the facilities can be exempt from the

requirements of section 418 with respect to the activities subject to those regulations but not with respect to other activities (78 FR 3646 at 3704).

(Response 234) We disagree that a designated storage area in an establishment that conducts manufacturing, processing, or packing in addition to storage can fall within the exemption for facilities “solely engaged in . . . storage.” The statute provides authority for us to exempt or modify the requirements for compliance with respect to “facilities” that are solely engaged in the storage of packaged foods that are not exposed to the environment (section 418(m) of the FD&C Act). The statute defines “facility” as a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act (section 418(o)(2) of the FD&C Act). The section 415 registration regulations define facility as “any establishment, structure, or structures under one ownership at one general physical location . . .” The comment’s interpretation that we could view “areas” of registered facilities to be “facilities that are solely engaged in . . . the storage of packaged foods that are not exposed to the environment” is inconsistent with the statutory and regulatory framework under sections 415 and 418 of the FD&C Act.

See also the discussion in Response 233 regarding how a facility that both stores unexposed packaged food and conducts activities such as food processing or packing could address the requirements for hazard analysis and risk-based preventive controls for the storage activities conducted by the facility.

(Comment 235) Some comments ask us to consider an alternative to the exemption for unexposed packaged foods when a facility conducts manufacturing, processing, packing, or holding activities in addition to storing unexposed packaged food. Specifically, these comments ask us to recognize that the minimal risks of storing unexposed packaged foods can be addressed through a combination of compliance with the modified requirements for TCS foods (if applicable) and the CGMPs in subpart B and state that doing so would be consistent with our discussion in the 2013 proposed human preventive controls rule.

(Response 235) These comments appear to suggest the outcome of a facility’s hazard analysis for storing unexposed packaged food—*i.e.*, that the only hazards requiring a preventive control are the potential for growth of pathogens in refrigerated unexposed packaged foods and that the preventive controls and preventive control

management components specified in the modified requirements for TCS food are adequate to address such hazards. It is the responsibility of the facility's preventive controls qualified individual to identify the hazards requiring a preventive control associated with the facility and the food it stores, as well as the appropriate preventive controls and preventive control management components. However, we agree that in some cases the approach suggested in these comments would be appropriate.

(Comment 236) Some comments assert that it is difficult to identify TCS foods and that the benefits of undertaking that work are unclear when existing CGMP requirements protect public health. These comments ask us to work with industry and professional organizations to develop guidance on when the modified requirements apply. Other comments ask us to specify that specific foods such as yogurt are not TCS foods and provide scientific information to support their request.

(Response 236) This document does not include guidance on whether specific foods, such as yogurt, are TCS foods. Information on whether specific foods are TCS foods is already widely available—e.g., in Annex 3, Chapter 1 (Purpose and Definitions) of the Food Code (Ref. 51) and in a report prepared for us under contract by the Institute of

Food Technologists (Ref. 52). A facility solely engaged in storage of unexposed packaged food can consult the Food Code or work with the manufacturer of the food to identify TCS food. Alternatively, such a facility could simply treat any refrigerated food as a TCS food.

Although we agree with comments that in general yogurt would not be a TCS food, whether a particular yogurt is a TCS food would depend on what is added to the yogurt. For example, in 1989 an outbreak of foodborne botulism in the United Kingdom from the consumption of yogurt containing added hazelnut conserve (puree) caused 27 illnesses and one death (Ref. 53). The hazelnut puree had not been adequately processed to prevent toxin production by *C. botulinum*. Even though this particular outbreak was not related to the question of whether yogurt is a TCS food, it demonstrates the importance of having a preventive controls qualified individual consider all hazards associated with a product to determine whether there are hazards requiring a preventive control, including temperature control.

**XIII. Subpart B: Comments on Proposed § 117.10—Personnel**

We proposed to re-establish the provisions of § 110.10 in new § 117.10

with some revisions to modernize them. Some comments agree with one or more of these proposed provisions without change. For example, some comments state that the proposed provisions for disease control are already widely practiced across the produce industry and are part of most food safety guidance and standards. Some comments that support the proposed revisions suggest alternative or additional regulatory text (see, e.g., Comment 243 and Comment 244) or ask us to clarify how we will interpret the revised provision (see, e.g., Comment 239). Other comments that support provisions that we proposed to re-establish in part 117 without change ask us to revise or clarify those provisions (see, e.g., Comment 237, Comment 238, Comment 240, and Comment 241).

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we proposed to re-establish in § 117.10 with no changes. After considering these comments, we have revised the proposed provisions as shown in table 18, with editorial and conforming changes as shown in table 52.

TABLE 18—PERSONNEL PROVISIONS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.10—Management Responsibility .....	No .....	Yes .....	Yes.
§ 117.10(a)—Disease Control .....	No .....	Yes .....	Yes.
§ 117.10(b)—Cleanliness .....	Yes .....	No .....	No.
§ 117.10(b)(1)—Outer Garments .....	Yes .....	Yes .....	No.
§ 117.10(b)(2)—Personal Cleanliness .....	No .....	No .....	No.
§ 117.10(b)(3)—Washing Hands .....	No .....	No .....	No.
§ 117.10(b)(4)—Unsecured Jewelry and Other Objects .....	Yes .....	Yes .....	No.
§ 117.10(b)(5)—Gloves .....	Yes .....	Yes .....	No.
§ 117.10(b)(6)—Hair Restraints .....	No .....	No .....	No.
§ 117.10(b)(7)—Clothing and Other Personal Belongings .....	Yes .....	Yes .....	No.
§ 117.10(b)(8)—Eating Food, Drinking Beverages, and Using Tobacco .....	Yes .....	Yes .....	Yes.
§ 117.10(b)(9)—Any Other Necessary Precautions .....	Yes .....	Yes .....	No.
§ 117.10(c)—Education and Training .....	Yes .....	Yes .....	Shifted to § 117.4 as a requirement rather than a recommendation.
§ 117.10(d)—Supervision .....	Yes .....	No .....	Shifted to § 117.4.

*A. Management Responsibility for Requirements Applicable to Personnel*

We proposed no revisions to the requirement that plant management must take all reasonable measures and precautions to ensure compliance with the provisions for disease control, cleanliness, and training.

(Comment 237) Some comments ask us to remove “all” because it is too extreme and prescriptive. These comments ask us to instead specify that the intended measures and precautions must be “adequate.”

(Response 237) We have revised the regulatory text to delete “all.” We

disagree that the term “all” in this long-standing provision is too extreme and prescriptive, but find that the term “all” is not necessary to communicate the intent of the requirement. We decline the request to add “adequate.” The intent of the requirement is to communicate our expectation that these

measures and precautions are reasonable. Other, more specific provisions that management must address specify that particular measures and precautions must be “adequate” (see § 117.10(b)(2), (3), and (4)).

*B. Proposed § 117.10(a)—Disease Control*

We proposed no revisions to the requirement that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.

(Comment 238) Some comments ask us to provide flexibility to not exclude from operations personnel who have an open lesion (such as boils, sores or any other infected wounds) that is covered completely using appropriate first aid materials.

(Response 238) We have revised the regulatory text to reflect flexibility such as that provided in FDA’s Food Code (Ref. 51). Under the Food Code, workers need not be excluded if an open lesion on hands and wrists, or on exposed portions of arms, is protected by an impermeable cover, and workers need not be excluded if an open lesion on other parts of the body is covered by a dry, durable, tight-fitting bandage.

*C. Proposed § 117.10(b)—Cleanliness*

1. Proposed § 117.10(b)(1)—Outer Garments

We proposed that the methods for maintaining cleanliness include wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.

(Comment 239) Some comments ask us to clarify whether the newly proposed requirement to prevent allergen cross-contact would require a line worker to change outer garments when switching between individual food-production lines if separate major allergens are present on the food production lines.

(Response 239) The provision does not prescribe the specific methods by which wearing outer garments must

protect against allergen cross-contact and, thus, the establishment has flexibility to take appropriate steps to satisfy the requirements in the context of the establishment and the food it produces. Requiring a line worker to change outer garments when switching between individual food-production lines could be an appropriate precaution for some establishments. When a facility that is subject to the requirements for hazard analysis and risk-based preventive controls determines that it is necessary to require a line worker to change outer garments to prevent allergen cross-contact between food-production lines, the facility could decide to establish such a procedure as a food allergen control under § 117.135(c)(2).

2. Proposed § 117.10(b)(4)—Unsecured Jewelry and Other Objects

We proposed to require that the methods for maintaining cleanliness include removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(Comment 240) Some comments ask us to modify the requirements to provide that they only apply as appropriate to each operation and recommend that jewelry be removed when the company’s hazard analysis determines that it is a hazard. These comments acknowledge that jewelry is a physical hazard in some instances, but assert that objects such as jewelry are not a physical hazard for operations conducted on many medium- to large-sized RACs (e.g., melons, apples, oranges, potatoes).

(Response 240) We decline this request. We included this long-standing provision of the umbrella CGMPs during our last revision of the food CGMPs based on public comments during that rulemaking (51 FR 22458 at 22463). The provision provides flexibility for an establishment to do what is appropriate in the context of its own operations—e.g., by limiting some requirements to “unsecured” jewelry and by providing options to cover hand jewelry during periods in which food is manipulated by hand. Although a facility could decide to also establish preventive controls for jewelry as a physical hazard following a hazard analysis, such

preventive controls would be distinct from the more general CGMP requirements in this provision.

3. Proposed § 117.10(b)(5)—Gloves

We proposed that the methods for maintaining cleanliness include maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. We also proposed to delete a recommendation that gloves should be of an impermeable material. Although some comments ask us to retain this nonbinding recommendation, as discussed in Response 67 we are deleting those non-binding recommendations of part 110 that we are not establishing as requirements.

4. Proposed § 117.10(b)(7)—Clothing and Other Personal Belongings

We proposed to require that the methods for maintaining cleanliness include storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(Comment 241) Some comments ask us to specify that the requirements only apply to “extra” clothing. These comments express concern that the requirement otherwise might be interpreted to mean that no personal clothing is allowed in these areas (e.g., that employees are permitted to wear only company-issued uniforms).

(Response 241) We decline this request. This long-standing provision of the umbrella GMPs has been in place for decades. The comments do not provide any examples of how we have interpreted this provision in the past to mean that employees must wear company-issued uniforms.

5. Proposed § 117.10(b)(8)—Eating Food, Drinking Beverages, and Using Tobacco

We proposed to require that the methods for maintaining cleanliness include confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, drinking beverages, or using tobacco.

(Comment 242) Some comments note that the provision would no longer require that chewing gum be confined to areas other than where food may be exposed or where equipment or utensils are washed. These comments ask us whether this omission was intentional, or whether we are simply considering that requirements applicable to “chewing gum” are covered by those for “eating food.” Some comments state that it would not be immediately obvious to many laypersons as to whether the chewing of gum is included in “eating food.”

(Response 242) We agree that removing the phrase “chewing gum” from this provision could make it unclear that this long-standing requirement regarding chewing gum still applies and we have revised the proposed regulatory text to retain the express requirement regarding chewing gum. As the comments point out, the statute includes chewing gum in its definition of “food” (see section 201(f) of the FD&C Act). However, in this long-standing provision, the term “chewing gum” is used to mean “the act of chewing” rather than to refer to the gum itself.

(Comment 243) Some comments regarding processes conducted on RACs ask us to modify the regulatory text to distinguish “drinking beverages” from “drinking water.” These comments note that this provision is of concern to their industry because drinking water needs to be readily available to workers.

(Response 243) We decline this request. We acknowledge that workers may need ready access to drinking water when conducting activities on RACs, particularly in an environment that is largely outdoors (such as in an off-farm packinghouse that has a roof but is otherwise largely unenclosed). However, this provision does not apply to on-farm activities such as harvesting of RACs. During packing activities

covered by this rule, workers must move away from the packing operations to get a drink. The establishment can make drinking water available in a designated area that is nearby, and provide multiple designated areas when appropriate to make drinking water readily available to all workers.

6. Proposed § 117.10(b)(9)—Any Other Necessary Precautions

We proposed that the methods for maintaining cleanliness include taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.

(Comment 244) Some comments ask us to specify that the provision applies to “medicines or other products” applied to the skin.

(Response 244) We decline this request. The comment does not explain what “other products” applied to the skin are not already covered by “cosmetics” and “medicines.” For example, powders and lotions applied as “make-up” generally would be cosmetics and products such as

sunscreen generally are classified as over-the-counter medicines.

**XIV. Subpart B: Comments on Proposed § 117.20—Plant and Grounds**

We proposed to re-establish the provisions of § 110.20 in new § 117.20 with some revisions to modernize them. Some comments agree with one or more of these proposed revisions without change. Some comments that support the proposed revisions suggest alternative or additional regulatory text (see, e.g., Comment 251 and Comment 256) or ask us to clarify how we will interpret the revised provision (see, e.g., Comment 253). Other comments that support provisions that we proposed to re-establish in part 117 without change ask us to revise or clarify those provisions (see, e.g., Comment 246, Comment 247, Comment 248, Comment 250, and Comment 254).

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we proposed to re-establish in § 117.20 with no changes. After considering these comments, we have revised the proposed provisions as shown in table 19, with editorial and conforming changes as shown in table 52.

TABLE 19—PROVISIONS FOR PLANT AND GROUNDS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.20(a)—Grounds	No	Yes	No.
§ 117.20(a)(1)—Equipment, Litter, Waste, Weeds, and Grass	No	Yes	No.
§ 117.20(a)(2)—Roads, Yards, and Parking Lots	No	No	No.
§ 117.20(a)(3)—Draining Areas	No	No	No.
§ 117.20(a)(4)—Operating Systems for Waste Treatment and Disposal	No	Yes	Yes.
§ 117.20(a)(5)—Grounds Not Under the Operator’s Control	Yes	Yes	Yes.
§ 117.20(b)—Plant Construction and Design	Yes	Yes	No.
§ 117.20(b)(1)—Space for Equipment and Materials	No	Yes	Yes.
§ 117.20(b)(2)—Food Safety Controls, Operating Practices, or Design	Yes	Yes	Yes.
§ 117.20(b)(3)—Outdoor Bulk Vessels	Yes	Yes	Yes.
§ 117.20(b)(4)—Plant Construction	Yes	No	No.
§ 117.20(b)(5)—Lighting	No	Yes	Yes.
§ 117.20(b)(6)—Ventilation	Yes	Yes	Yes.
§ 117.20(b)(7)—Screening or Other Protection	No	Yes	No.

**A. Proposed § 117.20(a)—Grounds**

**1. Proposed § 117.20(a)—Management Responsibility for Maintaining Grounds**

We proposed no revisions to the requirement that the grounds about a food plant under the control of the operator must be kept in a condition

that will protect against the contamination of food.

(Comment 245) Some comments ask us to specify that the requirements do not apply to test/pilot kitchens.

(Response 245) We decline this request. An establishment must have control of the grounds under its control regardless of the specific food or amount

of food being produced, because litter, waste, weeds, and grass can all attract and harbor pests, and the first step for pest control in the plant is to avoid attracting pests.



## 2. Proposed § 117.20(a)(1)—Equipment, Litter, Waste, Weeds, and Grass

We proposed no revisions to the requirement that the methods for adequate maintenance of grounds include properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(Comment 246) Some comments ask us to specify “immediately adjacent to” rather than “the immediate vicinity.” These comments also ask us to provide guidance on the importance of pollinator habitat so that inspectors will view such areas within the greater context of the farm and not immediately see that the farm is out of compliance.

(Response 246) We decline the request to modify the regulatory text of this long-standing provision. We note that a “farm” is not subject to the CGMP requirements of subpart B (see § 117.5(k)). We do not see that the suggested modification would provide any specific information to investigators who are inspecting a food establishment (such as a farm mixed-type facility or packing shed) that has pollinator habitat near plant buildings or structures. We expect that investigators will adapt their inspection programs to account for such circumstances and food establishments will take steps to prevent weeds or grass in a pollinator habitat from leading to problems with pests in the plant.

## 3. Proposed § 117.20(a)(4)—Operating Systems for Waste Treatment and Disposal

We proposed no revisions to the requirement that the methods for adequate maintenance of grounds must include operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator’s control and not maintained in the manner described in § 117.20(a)(1) through (a)(3), care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(Comment 247) Some comments assert that the term “adequate” has been added to this provision and is ambiguous when used to describe the way in which “operating systems for waste treatment and disposal” must be managed, even though that term is defined in the rule. These comments ask us to clarify what constitutes

“adequate” for the purpose of this provision, such as whether it requires compliance with local plumbing codes.

(Response 247) The term “adequate” has been in § 110.20(a) and (a)(4) since 1986 (51 FR 22477). This long-standing provision addresses matters under FDA’s jurisdiction rather than local plumbing codes. An example of waste disposal under FDA’s jurisdiction is an operating system for water disposal. Such an operating system would be inadequate if it allowed water to accumulate on the facility grounds and become an attractant for pests.

(Comment 248) Some comments ask us to clarify how the requirements in § 117.20(a) would apply to potential problems associated with neighboring grounds. Other comments note that we proposed to address potential problems with neighboring grounds within the final sentence of this provision (proposed § 117.20(a)(4)) and suggest editorial changes to more clearly identify the requirements regarding grounds under the control of a neighboring entity.

(Response 248) These provisions do not require an establishment to take action on its neighbor’s property to protect against contamination, but do require an establishment to be aware of any problems that may affect its own grounds. For example, if a neighbor’s grass is long, the establishment is not required to mow the neighbor’s grass, but if the long grass in the neighbor’s property provides a breeding ground for pests, the establishment needs to be aware of this potential for contamination and may need to take mitigating actions (e.g., enhanced pest control in the bordering areas).

We have clarified the proposed requirements by redesignating the final sentence of proposed § 117.20(a)(4) as § 117.20(a)(5) and specifying that the requirements of newly designated § 117.20(a)(5) apply if the plant grounds are bordered by grounds not under the operator’s control and not maintained in the manner described in § 117.20(a)(1) through (a)(4) (rather than in § 117.20(a)(1) through (a)(3)).

## B. Proposed § 117.20(b)—Plant Construction and Design

### 1. Proposed § 117.20(b)—Suitability of Plant Construction and Design

We proposed that the plant buildings and structure must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).

(Comment 249) Some comments ask us to specify that the requirements for suitability of plant construction and design apply only where the potential for contamination exists.

(Response 249) We decline this request. A plant requires suitable construction and design regardless of the specific potential for contamination at any particular location in the plant. Each of the seven more specific provisions governed by § 117.20(b) adds the context that the requirements are directed to what is “adequate” (e.g., adequate space, adequate precautions, and adequate cleaning). The defined term “adequate” provides context that the purpose of the requirements for plant construction and design are related to public health.

### 2. Proposed § 117.20(b)(1)—Placement of Equipment and Storage of Materials

We proposed no revisions to the requirement that the plant must provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(Comment 250) Some comments assert that the phrase “maintenance of sanitary operations” is unclear because it does not clearly communicate that maintenance of equipment and the facility is necessary for the production of safe food. These comments ask us to revise the provision to specify that the plant must provide sufficient space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(Response 250) We agree that the suggested revision adds clarity and have modified the provision as requested. The revised requirement is consistent with the governing paragraph in § 117.20(b), which clearly addresses both maintenance and sanitary operations.

### 3. Proposed § 117.20(b)(2)—Reduce Potential for Contamination and Allergen Cross-Contact Through Adequate Food Safety Controls and Operating Practices or Effective Design

We proposed that the plant must permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact. The potential for cross-contact and contamination may be reduced by adequate food safety controls and operating practices or effective design,

including the separation of operations in which cross-contact and contamination are likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, or other effective means.

(Comment 251) Some comments ask us to specify both air flow systems and dust control systems as examples of separation of operations in which allergen cross-contact and contamination are likely to occur.

(Response 251) We agree that both air flow systems and dust control systems are appropriate examples of separation of operations and have added these examples as requested.

#### 4. Proposed § 117.20(b)(3)—Food in Outdoor Bulk Vessels

We proposed that the plant must permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including using protective coverings, controlling areas over and around the vessels to eliminate harborage for pests, checking on a regular basis for pests and pest infestation, and skimming fermentation vessels.

(Comment 252) Some comments express concern about applying these provisions to the transport of large RACs such as watermelons and assert that there would be no food safety advantage to doing so after the RACs had spent the growing season in an uncovered environment.

(Response 252) The comments are mistaken about these requirements, which relate to installed bulk vessels such as outdoor tanks, silos, etc. Moreover, this section addresses the construction and design of the plant, not transportation. To make this clearer, we have revised the provision to specify that it applies to “installed outdoor bulk vessels.”

(Comment 253) Some comments ask us to clarify that the requirements do not apply to open containers of RACs that are subject to further processing. Other comments assert that lugs, totes, corrugated bins, and harvest containers used to hold fruit are not bulk vessels that are subject to the provision. The comments explain that these containers are designed and built to be open at the top, with air holes on the sides and bottom that provide an adequate air flow to the fruit.

(Response 253) The requirement applies to installed bulk vessels, not containers (including lugs, totes, corrugated bins, and harvest containers generally) that are delivered to a food establishment for packing or processing. (See discussion in Response 252.) Thus,

the provision does not preclude the use of such containers. Although the provision specifies the use of protective coverings, it does so only as an example of an effective means of precautions to protect food held in outdoor vessels. Other specified examples of precautions to protect food held in outdoor bulk vessels include controlling areas over and around the vessels to eliminate harborage for pests, and checking on a regular basis for pests and pest infestation. Such measures to protect against pests are appropriate when food such as fruit is held in outdoor containers. (See also Response 327.)

We agree that the measures taken by the establishment are those applicable to public health protection. To make this clearer, we have revised the provision to refer to “adequate precautions” rather than “proper precautions,” because the defined term “adequate” focuses on public health.

#### 5. Proposed § 117.20(b)(5)—Lighting

We proposed no revisions to the requirement that the plant must provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(Comment 254) Some comments ask us to add that the plant must provide adequate lighting in areas where food is packed and to substitute the term “shatter-resistant” for the term “safety-type.”

(Response 254) We have revised the provision to specify that it applies to areas in the plant where food is examined, manufactured, processed, packed, or held. Doing so makes the terms in this provision consistent with terms used throughout the CGMPs (78 FR 3646 at 3692). We also have substituted the term “shatter-resistant” for the term “safety-type.” “Shatter-resistant” is a more modern term describing the safety features that are specified in the provision.

#### 6. Proposed § 117.20(b)(6)—Ventilation

We proposed that a plant must provide adequate ventilation or control equipment to minimize odors and vapors in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food-contact surfaces and for cross-contact.

(Comment 255) Some comments ask us to specify “where necessary” to modify “adequate.”

(Response 255) We decline this request because “where necessary” is captured by “is needed” in the long-standing definition of “adequate.”

(Comment 256) Some comments ask us to specify that the provision requires minimizing dust and that the applicable areas include areas where dust could cause allergen cross-contact.

(Response 256) We agree that it is important to minimize dust (e.g., dust from milk powder that could be a source of allergen cross-contact) and have modified the provision as requested.

#### 7. Proposed § 117.20(b)(7)—Screening

We proposed no revisions to the requirement that the plant must provide, where necessary, adequate screening or other protection against pests.

(Comment 257) Some comments ask us to add examples of adequate screening, such as by window screens, door sweeps, gap sealant, or other appropriate measures.

(Response 257) We decline this request. Although the examples suggested by the comment appear to be acceptable, examples of screening are not necessary in this long-standing requirement.

### XV. Subpart B: Comments on Proposed § 117.35—Sanitary Operations

We proposed to re-establish the provisions of § 110.35 in new § 117.35 with some revisions to modernize them. Some comments agree with one or more of these proposed provisions without change. Some comments that support the proposed revisions suggest alternative or additional regulatory text (see, e.g., Comment 258, Comment 261, Comment 263, Comment 269, Comment 272, and Comment 273) or ask us to clarify how we will interpret the revised provision (see, e.g., Comment 260, Comment 267, Comment 268, and Comment 270). We also proposed to delete current § 110.35(d)(5) (requirements for sanitizing agents) because it would be redundant with another proposed provision (proposed § 117.35(b)(1)). We received no comments that disagreed with this proposed deletion and are not re-establishing current § 110.35(d)(5) in part 117.

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions. After considering these comments, we have revised the proposed provisions as

shown in table 20, with editorial and conforming changes as shown in table 52.

TABLE 20—PROVISIONS FOR SANITARY OPERATIONS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.35(a)—General Maintenance .....	Yes .....	Yes .....	Yes.
§ 117.35(b)(1)—Substances Used in Cleaning and Sanitizing .....	Yes .....	Yes .....	Yes.
§ 117.35(b)(2)—Storage of Toxic Materials .....	Yes .....	Yes .....	No.
§ 117.35(c)—Pest Control .....	Yes .....	Yes .....	Yes.
§ 117.35(d)—Sanitation of Food-Contact Surfaces .....	Yes .....	Yes .....	No.
§ 117.35(d)(1)—Food-Contact Surfaces Used for Manufacturing/Processing or Holding .....	Yes .....	Yes .....	Yes.
§ 117.35(d)(2)—Wet Cleaning .....	Yes .....	Yes .....	Yes.
§ 117.35(d)(3)—Single-Service Articles .....	Yes .....	Yes .....	Yes.
§ 117.35(e)—Sanitation of Non-Food-Contact Surfaces .....	Yes .....	Yes .....	Yes.
§ 117.35(f)—Storage and Handling of Cleaned Portable Equipment and Utensils .....	Yes .....	Yes .....	No.

*A. Proposed § 117.35(a)—General Maintenance*

We proposed that buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food packaging materials.

(Comment 258) Some comments ask us to specify that buildings, fixtures, and other physical facilities of the plant must be maintained in a “clean” condition in addition to a “sanitary” condition.

(Response 258) We have revised the requirement as requested. Doing so is consistent with other provisions of subpart B that specify clean and sanitary conditions (e.g., the personnel cleanliness provisions in § 117.10(b)(4) and (5)), including the requirements for sanitary operations (see the requirements for substances used in cleaning and sanitizing in § 117.35(b)(1) and the requirements for sanitation of food-contact surfaces in § 117.35(d)).

(Comment 259) Some comments ask us to qualify the level of sanitation required for different areas of the plant because the degree of sanitation required for a warehouse or utility room is different from the degree of sanitation required for a processing room.

(Response 259) We decline this request. The requirement is a long-standing provision that has been used in this context for decades. The comments do not provide any examples of how we have interpreted this provision in the past in a manner that does not

acknowledge the appropriate degree of sanitation required in different areas of a plant. Importantly, however, the fact that the degree of sanitation may be different does not mean that it could be appropriate, for example, for pests to be present in areas, like utility rooms, that may not need the same degree of sanitation as a processing room.

(Comment 260) Some comments assert that by its nature, the operations of some facilities generate dust and debris. For example, although equipment such as conveyors and screens used for hulling and shelling almonds can be cleaned before use, as soon as operations begin dust will accumulate on the surfaces of the equipment. Some comments ask us to clarify that the intent of the CGMP requirements for sanitary operations is to ensure that equipment is clean prior to use, with the understanding that once operations commence, dust will accumulate and that the presence of this type of dust and debris does not necessarily mean that sanitation is not being regularly conducted.

(Response 260) We agree that the intent of the CGMP requirements for sanitary operations is to ensure that equipment is clean prior to use. However, the fact that dust and debris can accumulate during some production operations does not excuse the establishment from taking appropriate steps to prevent food from becoming contaminated. The timing and extent of such steps would depend on the nature of the food and the production operation.

*B. Proposed § 117.35(b)—Substances Used in Cleaning and Sanitizing; Storage of Toxic Materials*

1. Proposed § 117.35(b)(1)—Cleaning Compounds and Sanitizing Agents

We proposed that cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. We also proposed that mechanisms to comply with provisions related to cleaning compounds and sanitizing agents must be safe and effective and provided examples of ways to achieve such compliance (78 FR 3646 at 3721). Only the toxic materials listed in this provision may be used or stored in a plant where food is processed or exposed.

(Comment 261) Some comments ask us to specify that “Cleaning and sanitizing agents used on food-contact surfaces must contain only ingredients which are generally recognized as safe or are approved in § 178.1010 for use in cleaning and sanitizing food-contact surfaces” because this information will be useful to processors who may be unaware of the specific kinds of substances approved for food-contact surfaces. Other comments ask us to specify that residual levels of cleaning and sanitizing agents which are generally recognized as safe or are approved for use on food-contact surfaces are permissible.

(Response 261) We decline these requests. Requirements such as those applicable to substances added to food or substances used in cleaning and sanitizing food-contact surfaces are available elsewhere in our regulations and it is neither practical nor necessary

to use the CGMP requirements of part 117 as a means to communicate some or all of these other requirements. For example, the manufacturer of a food product must also comply with food labeling regulations ranging from declaration of ingredients (§ 101.4) to health claims (part 101, subpart E).

## 2. Proposed § 117.35(b)(2)— Identification and Storage of Toxic Materials

We proposed that toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. We also proposed to remove a recommendation for following all relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of toxic cleaning compounds, sanitizing agents, and pesticides.

(Comment 262) Some comments ask us to specify that we require that the compounds, agents, and pesticides be used according to the manufacturer's instructions.

(Response 262) We decline this request. Such a recommendation is more properly addressed by the applicable Federal, State, and local government agencies. See the discussion at 78 FR 3646 at 3721.

## C. Proposed § 117.35(c)—Pest Control

We proposed that pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(Comment 263) Some comments ask us to specify “pest-detection” dogs in addition to guard and guide dogs because the use of animals to detect pests is widespread in the professional pest management industry for concealed and difficult to find pests. Comments assert that like guard and guide dogs, detection dogs are well trained and should be permissible in areas of the plant where the presence of the dog is unlikely to result in contamination of

the food, food-contact surfaces or food-packaging materials.

Other comments ask us to specify that pests must not be allowed in any area of a food plant “where appropriate” or “where the potential for contamination exists.” Other comments assert that animals should be excluded from all areas that are used by production or packaging employees or that communicate with food processing, packing, or storage areas. Some comments ask us to clarify whether this provision includes administrative offices, cafeterias, and other rooms that are not directly involved in the processing, packing, or holding of food because the provision applies to “any area of a food plant.”

(Response 263) We have revised the regulatory text to account for “pest-detection dogs.” However, we have not otherwise modified the regulatory text of this long-standing provision as a result of these comments. Areas of the food plant (such as a cafeteria) that are not directly involved with production may nonetheless be a source of contamination (e.g., if there are pests in that area). We have long provided that specified types of dogs may be allowed in some areas of a plant provided that the presence of the dogs is unlikely to result in contamination, and the comments provide no basis for why this qualified exception is no longer appropriate.

(Comment 264) Some comments ask us to specify that insecticides and rodenticides are types of pesticides and that the use of these substances is permitted in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) label precautions and restrictions.

(Response 264) We have revised the regulatory text to specify the “use of pesticides” rather than the “use of insecticides and rodenticides” to use the broader term “pesticides.” We also modified the regulatory text to clarify that the restrictions on use of pesticides is when the pesticides are used “to control pests.” We made this modification because we are aware that some food processing processes (such as fumigating almonds) involve treating food with substances that are classified as “pesticides.” Without this modification, the provision could mistakenly appear to prevent establishments from conducting such processes.

We decline to modify the text to account for FIFRA label precautions and restrictions. See (Response 262).

(Comment 265) Some comments express concern that the phrases “must not be allowed” and “exclude” suggest

that it is always possible to prevent all types of pests. Some comments assert that it is not always possible to prevent all types of pests, especially on farms and in areas where pests are prevalent because of the presence of conditions over which the food manufacturer has no control. Some comments assert that a food establishment should be required to take all reasonable measures to exclude pests, but an outright “exclude” is unrealistic.

(Response 265) The requirements apply to activities conducted in a plant and do not apply to activities that are within the “farm” definition, such as harvesting RACs and on-farm packing of RACs. We disagree that effective measures cannot be taken to exclude pests from a plant that is fully enclosed. When a plant is only partially enclosed (e.g., a partially enclosed area that processes seafood taken off a fishing vessel, or a partially enclosed building on an off-farm establishment that packs RACs), we would interpret the provision in a manner consistent with the provisions of previous guidance, such as our 2005 “Guide to Produce Farm Investigations” and the final provisions of the produce safety rule. We are not modifying the requirement to incorporate this interpretation because pest control in buildings that are only partially enclosed will be a concern for only a small percentage of establishments subject to subpart B.

## D. Proposed § 117.35(d)—Sanitation of Food-Contact Surfaces

We proposed that all food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

(Comment 266) Some comments ask us to specify that all food-contact surfaces must also be sanitized.

(Response 266) We decline this request. These long-standing requirements identify specific circumstances when food-contact surfaces must be sanitized (see § 117.35(d)(2), which specifies circumstances when food-contact surfaces must be sanitized when used in wet processing operations). The comment provided no basis for why food-contact surfaces must be sanitized when they will be used in manufacturing/processing or holding low-moisture food or why food-contact surfaces must be sanitized when used in wet processing operations other than the circumstances specified in § 117.35(d)(2). There are some situations in which food-contact surfaces do not need to be sanitized. For example, raw

materials and other ingredients for processing may be held in clean containers prior to processing with steps lethal to microorganisms; sanitizing such containers is not necessary for the production of safe food.

(Comment 267) Some comments ask us to clarify that we are not requiring an absolutely allergen-free environment, but rather that the expectation is that the manufacturer will take steps to identify potential sources of allergen cross-contact and implement preventive measures. Some comments ask us to also clarify that dedicated lines or equipment are not required for effective preventive control of food allergens. Some comments discuss practical difficulties that arise when balancing the need to control microorganisms such as *Salmonella* in chocolate and low-moisture confectionary products (through procedures such as dry cleaning) with the control of allergens (which may be controlled better when wet cleaning procedures are used).

(Response 267) See also the discussion of food allergen controls in Response 429. This rule does not establish a particular standard for preventing allergen cross-contact. In general, when we do establish a standard we avoid “absolute” standards such as the “absolutely allergen-free” standard mentioned by the comment. Likewise, the rule does not require the use of dedicated lines or equipment for effective prevention of allergen cross-contact. As the comments suggest, the intent of the requirement is for the manufacturer to take steps to identify potential sources of allergen cross-contact and implement preventive measures.

(Comment 268) Some comments ask us to clarify that the use of advisory label statements is appropriate when allergen cross-contact has been reduced to the greatest extent possible, but cannot be eliminated with certainty.

(Response 268) See Response 434 for a discussion about the use of advisory label statements.

*E. Proposed § 117.35(d)(1)—Food-Contact Surfaces Used for Manufacturing/Processing or Holding*

We proposed that food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(Comment 269) Some comments ask us to specify “packing” for clarity and completeness.

(Response 269) We have revised the provision to specify that it applies to food-contact surfaces used for manufacturing, processing, packing, or holding low-moisture food. Doing so makes the terms in this provision consistent with terms used throughout the CGMPs (78 FR 3646 at 3692).

(Comment 270) Some comments ask us to clarify that the proposed requirement to maintain food-contact surfaces in a sanitary condition is not a requirement to sanitize all product contact surfaces. These comments also ask us to specifically allow the continued use of cleaning methods based on a risk assessment, including dry cleaning with no sanitizing step. Some comments ask us to clarify that “sanitary condition” is not synonymous with “sanitized” from an antimicrobial standpoint.

(Response 270) See Response 266. This provision does not require that all product contact surfaces be sanitized and, thus, it is not necessary to specify that dry cleaning methods with no sanitizing step are acceptable in certain circumstances. We do not consider “sanitary condition” to be synonymous with “sanitized.” We consider “sanitary condition” to be a state of cleanliness. Terms such as “sanitize” and “sanitizing” are associated with the reduction of microorganisms.

(Comment 271) Some comments ask us to specify different requirements for food-contact surfaces used during different stages of manufacturing/processing or holding. These comments explain that the provision does not accommodate initial processing steps prior to moisture removal where food-contact surfaces will be exposed to moist (non-dry) conditions. These comments also explain that the provision also does not recognize that food-contact surfaces may not appear to be “sanitary” when raw materials handled at initial processing steps have not yet undergone subsequent processes designed to eliminate microorganisms of public health concern. Some comments ask us to specify that food-contact surfaces only need to be clean and sanitary “before use and after any interruption during which the food-contact surfaces may have become contaminated.” Comments also ask us to specify that “finished product low-moisture food-contact surfaces must be maintained in a clean, dry, and sanitary condition.”

(Response 271) We decline these requests. This long-standing provision has been used in this context for decades. The full requirements for sanitation of food-contact surfaces (§ 117.35(d), (d)(1), and (d)(2)) address

both processing of low-moisture foods and wet processing. It is not practical to describe all variations of complex manufacturing scenarios that may involve both wet processing and low-moisture foods. Instead, we expect both industry and regulators to appropriately apply the specific requirements associated with the sanitary condition of food-contact surfaces during such complex manufacturing scenarios. The comments do not provide any examples of how we have interpreted this provision in the past in a way that does not accommodate manufacturing processes such as those it describes.

(Comment 272) Some comments ask us to specify that food-contact surfaces used for manufacturing/processing or holding low-moisture food be in a clean, dry, sanitary condition “prior to use or the start of production” instead of “at time of use” to more accurately reflect the reality of food processing. Some comments express concern that properly cleaned and sanitized food-contact surfaces begin to accumulate small dust particles on the surface of conveyors, sizing screens, and other equipment surfaces as soon as operations commence. These comments assert that it is unrealistic to keep the equipment in a clean, dry, sanitary condition during the entire operation.

(Response 272) We have revised the regulatory text to specify that the requirement applies “before use.” We agree that “before use” more accurately describes the intent of the requirement.

*F. Proposed § 117.35(d)(2)—Wet Cleaning*

We proposed that in wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(Comment 273) Some comments ask us to specify that this requirement applies when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, not only when both conditions are satisfied.

(Response 273) We have revised the regulatory text to specify “necessary to protect against allergen cross-contact or the introduction of microorganisms into food.”

*G. Proposed § 117.35(d)(3)—Single-Service Articles*

We proposed that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials. We also requested comment on whether to require, rather than recommend, that single-service articles be stored in appropriate containers (78 FR 3646 at 3721).

(Comment 274) Comments are mixed regarding whether to require, rather than recommend, that single-service articles be stored in appropriate containers. Some comments ask us to keep this provision as a recommendation, whereas other comments ask us to change this recommendation to a requirement. One comment asking us to retain the provision as a recommendation asserts that these practices have never resulted in a food safety risk.

Other comments ask us to specify that “single-service articles must be handled in a manner that protects against allergen cross-contact and contamination of food.” These comments assert that the proposed use of “must” and “appropriate” in the same sentence will lead to inconsistency in determining what is “appropriate” for each individual situation. In addition, the comments assert that the common definition of “handling” encompasses “appropriate storage, dispensing, usage, and disposal.”

(Response 274) We have decided to establish this provision as a requirement rather than as a recommendation. Articles used in the manufacturing, processing, packing, or holding of food must not cause allergen cross-contact or contamination of food, food-contact surfaces, or food-packaging materials, regardless of whether the articles are single-service or would be used multiple times.

We have revised the regulatory text to accept some, but not all, of the suggestions in these comments. We deleted “in appropriate containers” so as not to prescribe a specific mechanism for complying with the requirement. We also deleted “dispensed” and “used” because we agree that these terms are captured by the term “handled.” We have not deleted “stored” because other provisions of these long-standing CGMPs refer to both storage and handling (see § 117.35(f)) and, thus, we

have not previously considered that the term “handling” includes “storage” in this context. See the regulatory text for the final provision containing all of these modifications.

*H. Proposed § 117.35(e)—Sanitation of Non-Food-Contact Surfaces*

We proposed that non-food-contact surfaces of equipment used in the operation of a food plant should be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials. We also requested comment on whether to establish these recommendations as requirements (78 FR 3646 at 3722).

(Comment 275) Some comments ask us to change this recommendation to a requirement to prevent the creation of insanitary conditions and the adulteration of product.

(Response 275) We have revised the regulatory text to establish this recommendation as a requirement.

(Comment 276) Some comments assert that it is impractical to sanitize all non-food-contact surfaces in a farm mixed-type facility and that this provision should only apply to those areas where a RAC is being transformed into a processed food.

(Response 276) These comments appear to misinterpret the proposed provision, which does not require sanitizing any non-food-contact surfaces, but rather requires cleaning the non-food-contact surfaces of equipment. (See also Response 278.)

(Comment 277) Some comments ask us to specify that this provision applies to non-food-contact surfaces of equipment used “where food is exposed or in the food production sections.”

(Response 277) We decline these requests. The provision clearly addresses equipment used in the operation of a food plant, which includes food storage in addition to food production. Non-food-contact surfaces can become harborage for environmental pathogens (Ref. 55). Specifying that non-food-contact surfaces be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination provides flexibility for industry and regulators to interpret this long-standing provision as appropriate to the establishment and the food being processed.

(Comment 278) Some comments ask us to specify that non-food-contact surfaces be sanitized or “sanitized where appropriate.” Other comments assert that sanitizing of high touch areas in the non-processing areas of a food

facility will help prevent transmission of public health pathogens into food processing areas. Some comments assert that sanitizing non-food-contact surfaces could also assist with minimizing risks from possible pathogen transfer to food-contact surfaces.

(Response 278) We decline these requests. We acknowledge that there could be some benefit to sanitizing non-food-contact surfaces with substances that would reduce pathogens but disagree that treating non-food-contact surfaces with substances that would reduce pathogens is necessary if the surfaces are kept clean. The provision does not preclude an establishment from sanitizing non-food-contact surfaces in addition to cleaning them, if the establishment determines that doing so is necessary or prudent for its operations. See also Response 125.

(Comment 279) Some comments ask us not to designate the frequency for cleaning of non-food-contact surfaces because doing so would create an unnecessary burden for smaller facilities.

(Response 279) The provision does not specify the frequency for cleaning of non-food-contact surfaces. Instead, it specifies that the surfaces be cleaned “as frequently as necessary.”

*I. Proposed § 117.35(f)—Storage and Handling of Cleaned Portable Equipment and Utensils*

We proposed that cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination. We also requested comment on whether to establish this provision as a requirement rather than a recommendation (78 FR 3646 at 3722).

(Comment 280) Comments are mixed regarding whether to require, rather than recommend, provisions for cleaned and sanitized portable equipment with food-contact surfaces and utensils. Some comments ask us to keep this provision a recommendation, whereas other comments ask us to change this recommendation to a requirement. Some comments agree that it is important that these food-contact surfaces are clean and sanitary when used, but because storage of equipment and utensils could be for an extended period of time, the comments ask us to specify that this requirement applies before the subsequent use of the equipment and utensils.

(Response 280) The intent of the provision is to emphasize that equipment that is cleaned and sanitized at one location has the potential to

become contaminated or be subject to allergen cross-contact before or during movement to a location in which the equipment is used. Examples of such equipment are portable mixing kettles, tables, and slicers. We are establishing the provision as a requirement because of the importance of ensuring that food-contact surfaces are clean and sanitary at time of use.

(Comment 281) Some comments assert that the manner in which this equipment is stored includes the location and therefore such wording is redundant. These comments ask us to modify the language to remove “location.”

(Response 281) We acknowledge that “manner” in which the equipment is stored could be interpreted to include “location” but disagree that this interpretation would be universal. The storage location can affect the potential for the equipment to become contaminated or subject to allergen cross-contact, and we are retaining it in the rule.

(Comment 282) Some comments state that they support the proposed revision for “all new equipment installations being away from the wall,” but request a waiver for equipment installed before this rule is issued. These comments ask for a clear definition of “portable

equipment” because some large, stationary pieces of equipment may have wheels.

(Response 282) The provision is directed to the storage of equipment that does not remain stationary in a given establishment, regardless of whether the equipment is designed in such a way so that it could readily be moved in that establishment or another establishment. These comments appear to misinterpret the proposed provision, which does not specify that equipment be installed away from a wall. (See also Response 296.)

(Comment 283) Some comments ask us to clarify this provision to adapt industry practices for transport of watermelons because it is unrealistic and impractical to clean the carpet or replace the cardboard lining the harvest buses that transport watermelons on a regular basis. Other comments ask that the use of wooden totes to transport nuts from the field to the wash and dryer operators remains an option for this industry.

(Response 283) These comments appear to have misinterpreted this provision, which relates to the storage and handling of cleaned portable equipment and utensils used within an establishment rather than to vehicles or

equipment used to transport food to a location other than the establishment.

**XVI. Subpart B: Comments on Proposed § 117.37—Sanitary Facilities and Controls**

We proposed to re-establish the provisions of § 110.37 in new § 117.37 with some revisions to modernize them. Some comments agree with one or more of these proposed provisions without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 285 and Comment 286). Other comments that support the proposed provisions ask us to revise or clarify current provisions that we proposed to re-establish in part 117 without change (see, e.g., Comment 290).

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we proposed to re-establish in § 117.37 with no changes. After considering these comments, we have revised the proposed provisions as shown in table 21, with editorial and conforming changes as shown in table 52.

TABLE 21—PROVISIONS FOR SANITARY FACILITIES AND CONTROLS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.37(a)—Water Supply .....	Yes .....	Yes .....	No.
§ 117.37(b)—Plumbing .....	No .....	No .....	No.
§ 117.37 (b)(1), (2), and (3) .....	No .....	No .....	No.
§ 117.37(b)(4)—Adequate floor drainage .....	No .....	Yes .....	No.
§ 117.37(b)(5)—Backflow .....	Yes .....	No .....	No.
§ 117.37(c)— Sewage Disposal .....	No .....	Yes .....	Yes.
§ 117.37(d)—Toilet Facilities .....	Yes .....	Yes .....	No.
§ 117.37(e)—Hand-Washing Facilities .....	Yes .....	Yes .....	No.
§ 117.37(f) —Rubbish and Offal Disposal .....	Yes .....	No .....	No.

*A. Proposed § 117.37(a)—Water Supply*

We proposed that the water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(Comment 284) Some comments express concern that because the provision does not define specific microbial limits, it is possible that a packer or processor that is subject to the CGMPs for human food could have more flexibility in interpreting and following water quality expectations than a farm that will be subject to the produce safety rule.

(Response 284) We expect that most facilities subject to this rule will have access to a public water supply that would not, under the provisions of the proposed produce safety rule, require testing to demonstrate that it complies

with defined microbial standards. When facilities that pack or process produce subject to the produce safety rule use untreated ground water or surface water to wash produce, the measures described in the proposed produce safety rule are appropriate measures to demonstrate that water used in packing and processing of produce is safe and of adequate sanitary quality when the produce does not undergo any processing to reduce pathogens.

(Comment 285) Some comments ask us to modify the requirement that water must be safe and of adequate sanitary quality by specifying that the standard

for water quality is “as defined in 40 CFR part 141.” These comments also ask us to specify that compliance with this requirement may be verified by any effective means, such as examination of the supplier’s specifications or test reports; purchase of the water under a supplier’s guarantee or certification; or analyzing the water.

(Response 285) We decline these requests. The CGMP provisions apply to diverse establishments, including some establishments that do not have access to water that satisfies the drinking water requirements of 40 CFR part 141. For example, seafood processing vessels may need to use seawater to clean areas of the ship used for food processing. This long-standing provision has been in place since the umbrella CGMPs were first established and the comments do not provide any examples of food safety problems that would have been addressed by the proposed change. Moreover, the CGMP Working Group report (Ref. 3) did not identify the water quality standard as something that needed to be changed.

(Comment 286) Some comments ask us to specify that running water be provided only “at appropriate locations.”

(Response 286) We decline this request. We agree that running water must be provided only “at appropriate locations.” However, in the context of this provision “appropriate locations” means “in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities” as has been specified for decades.

#### B. Proposed § 117.37(b)—Plumbing

We proposed that plumbing must be of adequate size and design and adequately installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the plant;
- (2) properly convey sewage and liquid disposable waste from the plant;
- (3) avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition;
- (4) provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
- (5) provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(Comment 287) Some comments assert that requirements for adequate floor drainage are overly prescriptive

and do not allow for any standing water subsequent to washing and sanitizing activities.

(Response 287) This provision does not prohibit standing water—*e.g.*, during vegetable or other wet processing operations. However, floors should provide for drainage, *e.g.*, be sloped towards drains, and standing water should be minimized to the extent possible to reduce the potential for contamination of food and food-contact surfaces. This is a long-standing provision and the comment does not provide any information as to how this has been interpreted in the past to not allow for standing water during processing or subsequent to washing and sanitizing activities.

#### C. Proposed § 117.37(c)—Sewage Disposal

We proposed that sewage disposal must be made into an adequate sewerage system or disposed of through other adequate means.

(Comment 288) Some comments ask us to specify that sewage “must be disposed.”

(Response 288) We have revised the regulatory text to consistently use the verb “dispose” rather than to use a noun (*i.e.*, “disposal”) in the first clause.

#### D. Proposed § 117.37(d)—Toilet Facilities

We proposed to replace the existing CGMP requirements for toilets (*i.e.*, that each plant provide its employees with adequate, readily accessible toilet facilities, along with recommendations for how to comply with these requirements) with a requirement that each plant must provide its employees with adequate, readily accessible toilet facilities. We proposed that toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact, or food-packaging materials. We also proposed to delete the guidance on how to comply with the requirements.

(Comment 289) Some comments ask us to retain the guidance we proposed to delete. Some comments ask us to retain some of the guidance and make some of it optional to allow for flexibility based on the design of the facility. Some comments provide specific editorial suggestions to include the guidance in this provision.

(Response 289) We decline these requests. As noted in the final rule establishing CGMPs for dietary supplements (72 FR 34752 at 34817), it is unnecessary to require specific features because an establishment may be able to achieve compliance through

other means better suited to its operations.

#### E. Proposed § 117.37(e)—Hand-Washing Facilities

We proposed to replace the existing CGMP requirements for hand-washing facilities (*i.e.*, that hand-washing facilities must be adequate and convenient and be furnished with running water at a suitable temperature, along with recommendations for how to comply with these requirements) with a requirement that each plant must provide hand-washing facilities designed to ensure that an employee’s hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. We also proposed to delete the guidance on how to comply with the requirements.

(Comment 290) Some comments ask us to clarify the meaning of “suitable temperature” in this provision.

(Response 290) By “suitable temperature,” we mean a temperature that does not discourage employees from adequately washing hands, or from washing hands at all, because the water is either too cold or too hot.

(Comment 291) Some comments ask that we specify that hot water should be provided so that this provision is more consistent with similar rules for most State and local jurisdictions that interpret “suitable temperature” as “hot.” Some comments ask whether we are deleting a current requirement for hot water to be provided at a hand-wash station.

(Response 291) We are not deleting a current requirement for hot water to be provided at a hand-wash station. The comments may be mistaking our CGMP requirements with the provisions of our Food Code, which specify that a hand-washing sink shall be equipped to provide water at a temperature of at least 38 degrees C (110 degrees F) through a mixing valve or combination faucet (See section 5–202.12 of the Food Code) (Ref. 51).

We decline the request to modify the regulatory text so that it requires that “hot water” be provided. This long-standing requirement for a “suitable temperature,” without specifying a requirement for “hot water,” means that the water should be neither too hot nor too cold to discourage personnel from washing their hands. We continue to believe that it is not necessary to specify a particular temperature or to use the subjective term “hot.”



**XVII. Subpart B: Comments on Proposed § 117.40—Equipment and Utensils**

We proposed to re-establish the provisions of § 110.40 in new § 117.40 with some revisions to modernize them. Some comments agree with one or more of these proposed provisions without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 301, Comment 305, and Comment 307) or ask us to clarify

how we will interpret the provision (see, e.g., Comment 308). Other comments that support the proposed provisions ask us to revise or clarify current provisions that we proposed to re-establish in part 117 without change (see, e.g., Comment 292, Comment 300, and Comment 310).

We also proposed to reorganize provisions found in current § 110.40(a) by creating paragraph designations (a)(1) through (a)(6) with associated editorial changes. We received no comments that disagreed with this proposed

redesignation and are finalizing it as proposed.

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we proposed to re-establish in § 117.40 with no changes. After considering these comments, we have revised the proposed provisions as shown in table 22, with editorial and conforming changes as shown in table 52.

TABLE 22—PROVISIONS FOR EQUIPMENT AND UTENSILS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.40(a)(1)—Design of Plant Equipment and Utensils .....	No .....	Yes .....	No.
§ 117.40(a)(2)—Design Construction, and Use of Equipment and Utensils .....	No .....	Yes .....	Yes.
§ 117.40(a)(3)—Installation and Maintenance of Equipment .....	Yes .....	Yes .....	Yes.
§ 117.40(a)(4)—Corrosion-Resistant Food-Contact Surfaces .....	No .....	Yes .....	No.
§ 117.40(a)(5)—Food-Contact Surfaces and Nontoxic Materials .....	No .....	Yes .....	Yes.
§ 117.40(a)(6)—Maintenance of Food-Contact Surfaces .....	Yes .....	Yes .....	No.
§ 117.40(b)—Seams on Food-Contact Surfaces .....	Yes .....	Yes .....	No.
§ 117.40(c)—Construction of Equipment .....	No .....	Yes .....	Yes.
§ 117.40(d)—Holding, Conveying, and Manufacturing Systems .....	No .....	Yes .....	Yes.
§ 117.40(e)—Freezer and Cold Storage Compartments .....	Yes .....	Yes .....	No.
§ 117.40(f)—Accurate and Precise Instruments and Controls .....	Yes .....	Yes .....	No.
§ 117.40(g)—Compressed Air or Other Gases .....	No .....	Yes .....	No.

*A. Proposed § 117.40(a)—Design, Construction, Use, Installation, and Maintenance of Equipment and Utensils*

1. Proposed § 117.40(a)(1)—Design of Plant Equipment and Utensils

We proposed no revisions to the requirement that all plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained.

(Comment 292) Some comments ask us to specify that this provision only applies to equipment and utensils used for, or in connection with, food manufacturing, processing, packing, or holding and appropriate to the stage of production it is used in. These comments assert that “all plant equipment and utensils” is too broad and that the requirements for cleanliness of the equipment and utensils differ at various stages of production. Other comments ask us to specify “as needed to protect against allergen cross-contact and contamination.”

(Response 292) We agree that it is not necessary to apply the provision to all plant equipment and utensils, regardless of what the equipment is and whether it has any role in the production of food. For example, we agree that it is not

necessary to apply the requirement to equipment such as welding equipment used in an establishment’s machine shop. Accordingly, we have made the following modifications to the provision: (1) Specify that the provision applies to all plant equipment and utensils “used in manufacturing, processing, packing, or holding food”; (2) specify that equipment and utensils must be “adequately” maintained, rather than “properly” maintained, to emphasize the public health goal of the requirement; and (3) specify that the purpose of the requirement is to protect against allergen cross-contact and contamination.

2. Proposed § 117.40(a)(2)—Design, Construction, and Use of Equipment and Utensils

We proposed no revisions to the requirement that the design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(Comment 293) Some comments suggest editorial changes to the provision to improve clarity.

(Response 293) We agree that the suggested changes improve the clarity of

the provision and have incorporated them into the regulatory text.

3. Proposed § 117.40(a)(3)—Installation and Maintenance of Equipment

We requested comment on whether to establish the current recommendation that all equipment be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces as a requirement (78 FR 3646 at 3723).

(Comment 294) Some comments assert that we should establish this recommendation as a requirement in light of recent findings of the pathogen *L. monocytogenes* in environmental swab samples taken from food processing plants.

(Response 294) We agree with these comments that an additional reason to establish this recommendation as a requirement, in addition to the reasons we provided in the 2013 proposed preventive controls rule (78 FR 3646 at 3728), is that it could facilitate cleaning for environmental pathogens. We have revised the regulatory text to change “should” to “must.”

(Comment 295) Some comments suggest that we make editorial changes, for clarity and completeness, to read “so as to facilitate the cleaning and maintenance” rather than “so installed

and maintained as to facilitate the cleaning.”

(Response 295) We agree that the suggested changes improve the clarity of the provision and have incorporated them into the regulatory text.

(Comment 296) Some comments support the proposed revision for “all new equipment installations being away from the wall,” but ask that we provide a waiver for equipment that has been installed prior to the issuance of this rulemaking.

(Response 296) These comments appear to misinterpret the proposed provision, which does not specify that equipment be installed away from a wall. The requirement is to install equipment so as to facilitate both cleaning and maintenance. This provision has been a long-standing recommendation. Moreover, if the existing equipment is installed in a way that it cannot be cleaned, it would not have been in compliance with existing CGMP requirements for the design and construction of the plant (§ 110.20). For example, the current CGMPs have long required that the design and construction of the plant must provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food (§ 110.20(a)(1)).

#### 4. Proposed § 117.40(a)(4)—Corrosion-Resistant Food-Contact Surfaces

We proposed no revisions to the requirement that food-contact surfaces must be corrosion-resistant when in contact with food.

(Comment 297) Some comments ask us to specify that the requirement only applies where appropriate for food safety. Other comments ask us to specify that the food-contact surfaces be corrosion-resistant as appropriate to the type of food and other substances with which they come in contact.

(Response 297) We decline these requests. We disagree with the implication that the condition of some food-contact surfaces would not be relevant to food safety. We also disagree that it would be acceptable for some food products to be in contact with surfaces susceptible to corrosion, regardless of the nature of the food product.

#### 5. Proposed § 117.40(a)(5)—Food-Contact Surfaces and Nontoxic Materials

We proposed no revisions to the requirement that food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of

food, and, if applicable, cleaning compounds and sanitizing agents.

(Comment 298) Some comments assert that food-contact surfaces or utensils could be dedicated to allergens only or non-allergens only.

(Response 298) We agree that dedicating food-contact surfaces and utensils is one way to comply with various requirements of this rule to prevent allergen cross-contact, but disagree that we should require this particular mechanism to prevent allergen cross-contact. Other mechanisms can prevent allergen cross-contact, such as adequately cleaning equipment and surfaces between uses.

(Comment 299) Some comments ask us to specify that food-contact surfaces must be made of food-grade materials and suitably durable.

(Response 299) We decline these requests. Food-grade materials must be non-toxic. The comment provides no examples of circumstances in which the long-standing criterion of “nontoxic” is inadequate. We agree that “suitably durable” could be interpreted to capture the general intent of the current text that specifies “designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents,” but disagree that this interpretation would be universal and are retaining the long-standing regulatory text.

(Comment 300) Some comments ask us to specify that food-contact surfaces must be designed to withstand cleaning procedures.

(Response 300) We have revised the regulatory text to include cleaning procedures. For example, food-contact surfaces must be designed to withstand the actions of scrubbing utensils that could scratch or pit the equipment, creating cracks and crevices that could be difficult to clean and lead to a niche where environmental pathogens could lodge and potentially contaminate food produced using the equipment.

#### 6. Proposed § 117.40(a)(6)—Maintenance of Food-Contact Surfaces

We proposed that food-contact surfaces must be maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives. As an inadvertent error, we specified that this requirement would be designated as § 117.40(a)(5); we intended to specify that it be designated § 117.40(a)(6).

(Comment 301) Some comments ask us to specify that this requirement also applies to equipment and utensils but does not apply to single-use items.

(Response 301) We decline these requests. As proposed, the requirement applies to all food-contact surfaces, including those on equipment and utensils; it is not necessary to separately specify that the requirement applies to equipment and utensils. We are not specifying that single-use food-contact surfaces do not need to be maintained. Using equipment or utensils that have single-use food-contact surfaces may be one way to satisfy the requirements of the provision, although single use items may still need to be protected from allergen cross-contact and from contamination, *e.g.*, by protective packaging.

(Comment 302) Some comments ask us to require that the surfaces also be appropriately cleaned and sanitized.

(Response 302) We decline this request. Cleaning and sanitizing of food-contact surfaces is covered by § 117.35(d) and does not need to be repeated here.

(Comment 303) Some comments ask us to strike the phrase “including unlawful indirect food additives.” These comments assert that the wording would be equally effective without the phrase and that striking it would result in a stronger and more absolute requirement.

(Response 303) We decline this request. Although some persons might realize that the provision requires them to protect against unlawful indirect food additives, such an interpretation may not be universal.

#### B. Proposed § 117.40(b)—Seams on Food-Contact Surfaces

We proposed that seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms and cross-contact.

(Comment 304) Some comments assert that this provision should not apply to all establishments—*e.g.*, that it seems directed towards bakeries but inapplicable to establishments that pack produce.

(Response 304) The provision requires an establishment to minimize accumulation of food particles, dirt, and organic matter in seams on food-contact surfaces to minimize the opportunity for growth of microorganisms and allergen cross-contact and provides flexibility for how to comply with the requirement (*i.e.*, through smoothly bonded seams or through maintenance). Minimizing the accumulation of food particles, dirt, and organic matter in seams on food-contact surfaces is appropriate for all establishments that produce food.

*C. Proposed § 117.40(c)—Construction of Equipment*

We proposed that equipment that is in the manufacturing or food-handling area and that does not come into contact with food must be so constructed that it can be kept in a clean condition.

(Comment 305) Some comments ask us to specify “areas where food is manufactured, processed, or packed” and clarify that the equipment must be constructed so that it can be kept “appropriately clean and sanitary.”

(Response 305) We have revised the provision to specify that it applies to areas in the plant where food is manufactured, processed, packed, or held. Doing so makes the terms in this provision consistent with terms used throughout the CGMPs (78 FR 3646 at 3692). Consistent with (Response 258, we also have modified the provision to specify that the equipment must be constructed so that it can be kept “clean and sanitary.”

(Comment 306) Some comments ask us to consider inserting technical language to address systems used for sanitizing in food processing environments to ensure they meet generally accepted design principles for food grade equipment. Some comments ask us to specify that the equipment must be constructed of materials that will not get corroded by cleaning chemicals and that welded joints must be of non-corrosive materials and “dressed” to eliminate porous surfaces and occlusions.

(Response 306) We decline these requests. It is not necessary to specify every type of equipment that could be used in a food processing environment or every situation that must be addressed to satisfy the specific requirements of this provision and the more general requirements of § 117.40(a).

*D. Proposed § 117.40(d)—Holding, Conveying, and Manufacturing Systems*

We proposed no revisions to the requirement that holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(Comment 307) Some comments ask us to specify that these systems also need to be maintained in an appropriately clean condition in addition to a sanitary condition.

(Response 307) Consistent with Response 258, we have revised the provision to specify that the equipment must be constructed so that it can be kept “clean and sanitary.”

*E. Proposed § 117.40(e)—Freezer and Cold Storage Compartments*

We proposed that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment. We also proposed to delete the recommendation that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(Comment 308) Some comments ask us to clarify that this requirement is only for foods that require temperature control for food safety, and does not apply to any intact fruits or vegetables that are only held at specific temperatures for quality and shelf-life purposes. Some comments ask us to change this requirement to a recommendation for the same reason. Some comments assert that temperature control for intact fruits and vegetables is likely not always necessary or even desirable (e.g., to avoid chill damage).

(Response 308) We decline this request. The requirement applies to refrigerated storage when the establishment has placed food in a refrigerated storage compartment, whether for food safety or for food quality (e.g., to prevent the growth of spoilage microorganisms). The provision, which is an existing requirement in § 110.40, does not specify which foods must be refrigerated or what the refrigeration temperature must be. However, once the establishment has determined that refrigerated storage is appropriate, either for food safety or food quality, it is appropriate to require that the establishment have evidence that it is refrigerating the food as it has decided to do.

*F. Proposed § 117.40(f)—Accurate and Precise Instruments and Controls*

We proposed that instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(Comment 309) Some comments ask us to specify “calibrated” for clarity, accuracy, and completeness. Some comments assert that proper calibration of such equipment is essential to ensure food safety, and does not entail so large a cost as to preclude even small companies from compliance.

(Response 309) We decline this request. The request of this comment is already addressed by our proposal to revise this long-standing provision to require that these types of instruments be accurate, as well as precise. As discussed in Comment 519 and Response 519, some types of instruments generally are subject to accuracy checks rather than to calibration.

*G. Proposed § 117.40(g)—Compressed Air or Other Gases*

We proposed no revisions to the requirement that compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

(Comment 310) Some comments ask us to specify that compressed air or other gases must be “filtered or otherwise treated” for clarity.

(Response 310) We decline this request. We agree that filtration is a common treatment to prevent contamination, but disagree that it is necessary to modify this long-standing requirement to add this particular example of a treatment to prevent contamination with unlawful indirect food additives. As written, the provision provides flexibility for an establishment to determine the appropriate treatment for compressed air or other gases in a manner that works best for its plant.

(Comment 311) Some comments ask us to strike the phrase “with unlawful indirect food additives.” These comments assert that the wording would be equally effective without the phrase and that striking it would result in a stronger and more absolute requirement.

(Response 311) We decline this request. Although some persons might realize that the provision requires them to protect against unlawful indirect food additives, such an interpretation may not be universal.

**XVIII. Subpart B: Comments on Proposed § 117.80(a)—General Processes and Controls**

We proposed to re-establish the provisions of § 110.80 in new § 117.80(a) with some revisions to modernize them and with some

redesignations. Some comments support one or more of these proposed provisions without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 316) or ask us to clarify how we will interpret the provision (see, e.g.,

Comment 317). Other comments that support the proposed provisions ask us to revise or clarify current provisions that we proposed to re-establish in part 117 without change (see, e.g., Comment 312 and Comment 320).  
 In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree

with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we did not propose to revise. After considering these comments, we have revised the proposed provisions as shown in table 23, with editorial and conforming changes as shown in table 52.

TABLE 23—PROVISIONS FOR GENERAL PROCESSES AND CONTROLS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.80(a)(1)—Adequate sanitation principles .....	No .....	Yes .....	No.
§ 117.80(a)(2)—Quality control operations .....	No .....	Yes .....	No.
§ 117.80(a)(3)—Supervising overall sanitation .....	No .....	Yes .....	No.
§ 117.80(a)(4)—Production procedures .....	Yes .....	Yes .....	Yes.
§ 117.80(a)(5)—Chemical, microbial, or extraneous-material testing procedures ..	Yes .....	Yes .....	No.
§ 117.80(a)(6)—Contaminated food .....	No .....	Yes .....	No.

*A. Proposed § 117.80(a)(1)—Adequate Sanitation Principles*

We proposed no revisions to the requirements of current § 110.80 (proposed § 117.80(a)(1)) that all operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) be conducted in accordance with adequate sanitation principles.

(Comment 312) Some comments ask us to clarify “adequate sanitation principles.” Some of these comments express concern that facilities receiving raw produce that will be further cleaned or processed will be unable to meet this requirement and assert that this requirement will not provide additional public health benefits.

(Response 312) These comments fail to explain how we have interpreted the provision in a way that has been problematic such that clarification is necessary. The term “adequate” is a long-standing term that we defined in its current form when we first established the umbrella CGMPs in 1969 (34 FR 6977 at 6978). Furthermore, during a previous rulemaking to revise the umbrella CGMPs and establish current § 110.80 we explained that the phrase “adequate sanitation principles” must be broad so that industry can easily adapt sanitation principles to its existing procedures (51 FR 22458 at 22461).

(Comment 313) Some comments ask us to specify that operations be conducted in accordance with adequate sanitation principles “specific to the operation” to provide for extended time intervals between sanitation procedures. These comments explain that in the case

of low-moisture almonds, sanitation intervals may be extended in order to minimize addition of water into the facility.

(Response 313) We decline this request. By specifying that sanitation principles must be “adequate,” the provision already provides flexibility such as that requested by these comments. In addition, the rule does not specify any time intervals for conducting sanitation operations and, thus, the provision needs no qualification to provide flexibility for an establishment to adopt a frequency of sanitation procedures consistent with its operations.

*B. Proposed § 117.80(a)(2)—Quality Control Operations*

We proposed no revisions to the requirements of current § 110.80 (proposed § 117.80(a)(2)) that appropriate quality control operations be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(Comment 314) Some comments assert that specifying that food-packaging materials must be “safe and suitable” is confusing because the definition for “safe and suitable” at § 130.3(d) defines the phrase with respect to ingredients.

(Response 314) The requirement is a long-standing provision that has been used in this context for decades. When we first proposed this provision during a previous rulemaking to revise the umbrella CGMPs, we included this exact phrase and did not receive any comments regarding its use (44 FR 33238 at 33246). Furthermore, as

evidence that industry commonly understands the use of the term “suitable” in the context of CGMP requirements in addition to requirements applicable to ingredients used in standardized foods, we note that we substituted the term “suitable” for “fit” in another provision (§ 110.80(a)(1)) in response to comments from industry stating that “suitable” was a more familiar term than “fit” (51 FR 22458 at 22470).

*C. Proposed § 117.80(a)(3)—Supervision of Overall Sanitation*

We proposed no revisions to the requirements of current § 110.80 (proposed § 117.80(a)(3)) that overall sanitation of the plant be under the supervision of one or more competent individuals assigned responsibility for this function.

(Comment 315) Some comments ask us to revise this provision to specify that it applies to overall cleaning of the plant, as well as overall sanitation of the plant.

(Response 315) We decline this request. Sanitation is a general term that already encompasses cleaning (and, as appropriate, sanitizing).

*D. Proposed § 117.80(a)(4)—Production Procedures*

We proposed that all reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.

(Comment 316) Some comments assert that the phrase “all reasonable precautions” is too extreme and prescriptive and suggest that “adequate” would be more appropriate than “all” to

describe the intended measures and precautions.

(Response 316) We agree that “adequate” is more appropriate than “all” and have substituted the word “adequate” for “all reasonable” in the final rule.

*E. Proposed § 117.80(a)(5)—Chemical, Microbial, or Extrinsic-Material Testing Procedures*

We proposed that chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.

(Comment 317) Some comments ask whether the word “must” in the provision means that testing will always be required, including for food allergens. Other comments assert that testing should only be used when there is reason to suspect a specific problem has occurred and when methods are available.

(Response 317) Testing is not always required. The provision provides flexibility for an establishment to test when appropriate, such as when a facility determines that it is necessary to use rapid ATP (adenosine triphosphate) swabs as an indicator of microbial or food residue contamination to verify cleaning of a line prior to running a different product (Ref. 56). Facilities commonly conduct tests on food for microorganisms that indicate sanitation failures, such as testing for total plate count, generic *E. coli*, total coliforms, etc. (Ref. 57). When the number of such organisms exceeds expectation, sanitation or other failures are suspected and the facility can take actions to determine the source of the problem.

(Comment 318) Some comments oppose any implication that food manufacturers are required to develop test methods or analytical standards, or search out methods that are not readily available, for this or any other purpose.

(Response 318) The provision does not require food manufacturers to develop test methods or analytical standards, or search out methods that are not readily available.

(Comment 319) Some comments suggest that testing as part of an environmental monitoring program should be risk-based and include allergens, but should not be required for finished product.

(Response 319) The provision does not use the term “environmental monitoring,” which is a term that has come to be associated with monitoring

for environmental pathogens rather than for other substances that may contaminate the food processing environment. Likewise, the provision does not establish requirements for environmental monitoring for finished product. As discussed in Response 317, the provision provides flexibility for an establishment to test when testing is appropriate, such as when the facility determines testing would be useful to verify adherence to CGMPs or when there is a problem such as allergen cross-contact.

*F. Proposed § 117.80(a)(6)—Contaminated Food*

We proposed no revisions to the requirements of current § 110.80 (proposed § 117.80(a)(6)) that all food that has become contaminated to the extent that it is adulterated be rejected, or if permissible, treated or processed to eliminate the contamination.

(Comment 320) Some comments assert that the use of the phrase “if permissible” is vague and confusing and should be replaced by a statement of precisely what is impermissible.

(Response 320) We acknowledge that the phrase “if permissible” does not communicate the circumstances under which it is permissible to treat or process a food to eliminate contamination. Rather than add such circumstances to the rule, we have replaced the phrase “if permissible” with “if appropriate.” In the following paragraphs, we discuss examples of when treatment or processing to eliminate contamination would or would not be appropriate.

Some RACs, such as cocoa beans, can become adulterated with insects or filth but may be fumigated or cleaned in accordance with an application for reconditioning submitted to FDA to bring the product into compliance. Acid or acidified canned goods with microbial contamination due to a container defect may be reconditioned by sorting out the defective containers to ensure that containers released into commerce are intact and the product is not contaminated. Tree nuts with signs of mold growth can be reconditioned using methods that separate the moldy nuts from those that are not contaminated. Tree nuts found to be contaminated with *Salmonella* may be treated by processes such as steam or propylene oxide when such treatments have been validated to provide an adequate reduction of *Salmonella*. A heat-treated food contaminated from the environment, such as a heat-treated,

dried protein product, can sometimes be rehydrated, and a food establishment could repeat the processing to reduce pathogens. Other products, such as many types of produce, are not normally processed to reduce pathogens, and product quality may be impacted by such treatments. Even though processing techniques such as irradiation have the potential to reduce pathogens, irradiation is a food additive that requires approval. For example, as of January 15, 2015, irradiation had been approved for control of foodborne pathogens and extension of shelf-life in fresh iceberg lettuce and fresh spinach, but not in other fresh leafy greens. Using irradiation for a purpose that has not been approved (such as for the irradiation of fresh leafy greens other than fresh iceberg lettuce and fresh spinach) would render the food adulterated under section 402(a)(2)(C)(i) of the FD&C Act and, thus, it would not be appropriate to treat or process fresh leafy greens other than fresh iceberg lettuce and fresh spinach using irradiation.

**XIX. Subpart B: Comments on Proposed § 117.80(b)—Processes and Controls for Raw Materials and Other Ingredients**

We proposed to re-establish the provisions of § 110.80(a) in new § 117.80(b) with some revisions to modernize them. Some comments support one or more of these proposed provisions without change. For example, some comments support a new provision that would require raw materials and ingredients that are food allergens, and rework that contains food allergens, to be identified and held in a manner that prevents allergen cross-contact. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 324, Comment 325, Comment 328, and Comment 329) or ask us to clarify how we will interpret the provision (see, e.g., Comment 323 and Comment 327).

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we did not propose to revise. After considering these comments, we have revised the proposed provisions as shown in table 24, with editorial and conforming changes as shown in table 52.

TABLE 24—PROVISIONS FOR PROCESSES AND CONTROLS FOR RAW MATERIALS AND OTHER INGREDIENTS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.80(b)(1)—Inspection, storage, and handling of raw materials and other ingredients.	Yes .....	Yes .....	Yes.
§ 117.80(b)(2)—Levels of microorganisms in raw materials and other ingredients	Yes .....	Yes .....	No.
§ 117.80(b)(3)—Natural toxins in raw materials and other ingredients .....	Yes .....	Yes .....	No.
§ 117.80(b)(4)—Pests, undesirable microorganisms, and extraneous material in raw materials and other ingredients.	Yes .....	Yes .....	No.
§ 117.80(b)(5)—Holding raw materials, other ingredients, and rework in bulk .....	Yes .....	Yes .....	No.
§ 117.80(b)(6)—Frozen raw materials and other ingredients .....	No .....	No .....	No.
§ 117.80(b)(7)—Liquid and dry raw materials and other ingredients .....	Yes .....	Yes .....	No.
§ 117.80(b)(8)—Raw materials and other ingredients that are food allergens .....	Yes .....	Yes .....	No.

*A. Proposed § 117.80(b)(1)—Inspection, Segregation and Handling of Raw Materials and Other Ingredients*

We proposed that raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross-contact.

We also proposed to continue to recommend that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration. However, we also requested comment on whether to establish this recommendation as a requirement (78 FR 3646 at 3724).

(Comment 321) Some comments express concern about revising current § 110.80(a)(1) to require, rather than recommend, that containers and carriers of raw materials be inspected on receipt. Some comments focus on practical problems associated with inspecting bins containing RACs such as produce. These comments explain that produce bins received by a packing establishment are too large to be handled directly and instead are delivered by a fork lift followed by automated travel through the establishment.

(Response 321) We agree that circumstances such as those described in these comments make it appropriate to continue to recommend, but not

require, that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to allergen cross-contact, contamination, or deterioration. Therefore, we are not re-establishing this nonbinding recommendation as a requirement. Instead, as discussed in Response 67, we have deleted this non-binding provision from the rule.

*B. Proposed § 117.80(b)(2)—Levels of Microorganisms in Raw Materials and Other Ingredients*

We proposed that raw materials and ingredients must either not contain levels of microorganisms that may render the food injurious to health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated. We also proposed to delete guidance regarding how to comply with this requirement.

(Comment 322) Some comments ask us to supply the list of microorganisms that may render the food injurious to the health of humans. Some comments assert that we would have to establish acceptable pathogen concentration limits in order for industry to comply with this provision.

(Response 322) We are not providing a list of microorganisms that may render the food injurious to the health of humans. CGMPs establish procedural requirements, not declarations of foods that are adulterated. It is not necessary for us to establish acceptable pathogen concentration limits in order for industry to comply with this provision. Moreover, several Compliance Policy Guides (CPGs) provide guidance to our investigators about agency policies that apply when food is contaminated with microorganisms, and these CPGs are available to industry (Ref. 58) (Ref. 59) (Ref. 60) (Ref. 61) (Ref. 62).

(Comment 323) Some comments express concern about the requirement for pasteurization, explaining that fresh produce cannot be pasteurized.

(Response 323) The proposed provision would not require pasteurization of products such as produce. The proposed provision clearly states that pasteurization or other treatment is only required when raw materials and other ingredients contain levels of microorganisms that may render the food injurious to health of humans. However, when products such as produce contain levels of microorganisms that may render the food injurious to health of humans, and the products cannot be pasteurized or otherwise treated so that they no longer contain levels that would cause the product to be adulterated, other provisions require that the product be rejected and disposed of in a manner that protects against the contamination of other food (see, e.g., §§ 117.80(a)(6) and 117.80(c)(9)).

(Comment 324) Some comments assert that this requirement is overly broad and should only apply to RTE food. These comments express the view that we should not focus on the issue of microbiological contamination in foods that are early in the supply chain (other than produce that will be consumed without adequate processing or cooking). Some comments suggest adding a statement to be provided in commercial documentation accompanying the sale of produce not covered by the proposed produce safety rule to alert potential purchasers to the hazard that may exist and allow them to determine whether the food offered for sale is suitable for their particular needs or whether the food requires commercial formulation, processing, or both to adequately reduce microorganisms.

(Response 324) It is not necessary to narrow this requirement to RTE food to

provide for use of raw materials and other ingredients that are early in the supply chain. The requirement already clearly provides for pasteurization or other treatment during manufacturing operations so that the processed product would no longer contain levels that would cause the product to be adulterated. See also our previous discussion of the importance of this provision during a previous rulemaking to revise the umbrella CGMPs (51 FR 22458 at 22470).

We decline the request to require a statement in commercial documentation when produce is not covered by the produce safety rule. As discussed in section XXVII, we are providing for a narrow use of commercial documentation, when a manufacturer/processor that has identified a hazard requiring a preventive control does not establish a preventive control because it: (1) Relies on its customer to ensure that an identified hazard will be controlled and (2) discloses, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]” (See § 117.136(a)(2), (3), and (4)). That use of commercial documentation reflects the outcome of a hazard analysis—in particular, an outcome in which the manufacturer/processor determines that a hazard requires a preventive control. The vast majority of the produce that we proposed would not be subject to the requirements of the forthcoming produce safety rule would either be produce that is going to commercial processing that adequately reduces the presence of microorganisms of public health significance or produce that is rarely consumed raw. Thus, there would be no benefit to alert potential purchasers to a hazard because such produce has been determined to be low-risk, based on the findings of a qualitative assessment of risk (*e.g.*, for produce rarely consumed raw) or because it will not go directly to the consumer but to commercial processing to adequately reduce pathogens. We see no reason to also establish a broad CGMP requirement that would apply regardless of the outcome of a hazard analysis.

#### *C. Proposed § 117.80(b)(3)—Natural Toxins in Raw Materials and Other Ingredients*

We proposed that raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into

finished food. We also proposed to delete guidance regarding how to comply with this requirement and to delete a requirement for compliance with action levels, which are not binding.

(Comment 325) Some comments ask us to delete “aflatoxin” from the provision because it is redundant with “other natural toxin.”

(Response 325) We decline this request. Aflatoxin is an important natural toxin that is an example illustrating what we mean when we refer to “natural toxins.” An illustrative example does not create a redundancy.

#### *D. Proposed § 117.80(b)(4)—Pests, Undesirable Microorganisms and Extrinsic Materials in Raw Materials and Other Ingredients*

We proposed that raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. We also proposed to delete guidance regarding how to comply with this requirement and to delete the requirement for compliance with action levels, which are not binding.

(Comment 326) Some comments ask us to qualify that the requirement does not apply if the manufacturing process includes steps that serve to decontaminate the food.

(Response 326) We decline this request. We have defined “defect action level” to mean a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action under section 402(a)(3) of the FD&C Act (see § 117.3). It is not uncommon for an establishment to receive raw materials (such as RACs) that contain extraneous material that is removed before production. For example, some methods of harvesting vegetable RACs (*e.g.*, pulling up most of the plant material in the field) result in inclusion of extraneous material that is removed during initial cleaning steps at processing facilities. It is not necessary to revise this long-standing requirement to provide for such common procedures. Moreover, in general we use the term “decontaminate” to refer to an action taken when the substance is a hazardous substance (such as a pathogen) rather than to a non-hazardous substance.

#### *E. Proposed § 117.80(b)(5)—Holding Raw Materials, Other Ingredients, and Rework in Bulk*

We proposed that raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against cross-contact and contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(Comment 327) Some comments express concern that this requirement would make the use of wooden bins in the produce industry problematic and ask us to clarify whether it is our intent to prohibit use of wooden bins. Some comments ask us to clarify whether the provision would preclude using or storing containers (such as trailers and gondolas used in the produce industry) outdoors because such containers cannot be covered.

(Response 327) We do not intend to interpret this provision in such a way that would prohibit the use of wooden bins in the produce industry or preclude using and storing containers such as trailers and gondolas outside. Importantly, these CGMP requirements are long-standing provisions that we have not interpreted as prohibiting wooden containers in the produce industry. See also our “Guide to Produce Farm Investigations” (Ref. 63), which applies during investigations when an outbreak and traceback investigation implicates a farm and related operations, or as a follow-up to a produce sample that tests positive for contamination with a pathogen.

(Comment 328) Some comments ask us to add “in-process” materials to the provision.

(Response 328) We decline this request, which is already covered by § 117.80(c)(7). We note that the requirements directed to raw materials and other ingredients are established in § 117.80(b), whereas the requirements directed to in-process materials are established in § 117.80(c).

#### *F. Proposed § 117.80(b)(7)—Liquid or Dry Raw Materials and Other Ingredients*

We proposed that liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact and contamination.

(Comment 329) Some comments ask us to revise the proposed provision to clarify that liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that

protects against deterioration, as well as in a manner that protects against allergen cross-contact and contamination.

(Response 329) We decline this request. The rule already requires that raw materials and ingredients be stored under conditions that will minimize deterioration (see § 117.80(b)(1)).

*G. Proposed § 117.80(b)(8)—Raw Materials and Other Ingredients That Are Food Allergens*

We proposed to establish a new requirement that raw materials and ingredients that are food allergens, and rework that contains food allergens, be identified and held in a manner that prevents cross-contact.

(Comment 330) Some comments ask us to exempt finished, packaged product that is later reworked from the proposed requirement.

(Response 330) We decline this request. A product that is in finished, packaged form, including label information that identifies any food allergen, would be in compliance with the requirement and need not be exempted. However, when a product is packaged, but not yet labeled, it is necessary to identify the product in a way (other than a product label) that would prevent allergen cross-contact while the packaged product is being held. For example, shelves holding the

product before labeling operations could have a sign such as “Contains peanuts.”

(Comment 331) Some comments ask us to modify the proposed requirement to specify that it applies to raw materials and ingredients that “are or contain” food allergens and that it applies to in-process material, as well as to raw materials and ingredients and to rework. These comments explain that such modifications would provide clarity and completeness.

(Response 331) We decline these requests. The rule defines “food allergen” to mean a major food allergen as defined in section 201(qq) of the FD&C Act, and section 201(qq) of the FD&C Act already specifies that a major food allergen is a food that is one of several specified foods and food groups, or contains protein derived from one of these foods or food groups (78 FR 3646 at 3697). Thus, the request that the provisions be directed to raw materials and other ingredients that “are or contain” food allergens is already addressed in the definition of food allergen. Requirements applicable to in-process material are addressed in § 117.80(c)(5).

**XX. Subpart B: Comments on Proposed § 117.80(c)—Manufacturing Operations**

We proposed that current § 110.80(b) would become proposed § 117.80(c). We also proposed revisions to all provisions

that would be established in § 117.80(c) except for the provisions that would be established in § 117.80(c)(1) and (c)(16).

Some comments support one or more of these proposed provisions without change. For example, some comments support provisions directed to control of, or preventing contamination with, undesirable microorganisms during manufacturing, storage, and handling. Other comments that support the proposed provisions suggest alternative regulatory text (see, e.g., Comment 334) or ask us to clarify how we will interpret the provision (see, e.g., Comment 345 and Comment 346). Other comments that support the proposed provisions ask us to revise or clarify provisions that we proposed to re-establish in part 117 without change (see, e.g., Comment 333).

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we did not propose to revise. After considering these comments, we have revised the proposed provisions as shown in table 25, with editorial and conforming changes as shown in table 52.

TABLE 25—PROVISIONS FOR PROCESSES AND CONTROLS FOR MANUFACTURING OPERATIONS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.80(c)(1)—Condition of equipment, utensils, and finished food containers.	No .....	Yes .....	Yes.
§ 117.80(c)(2)—Conditions and controls for food manufacturing, processing, packing, and holding.	Yes .....	Yes .....	Yes.
§ 117.80(c)(3)—Food that can support the rapid growth of undesirable microorganisms.	Yes .....	Yes .....	No.
§ 117.80(c)(4)—Measures to destroy or prevent the growth of undesirable microorganisms.	Yes .....	Yes .....	No.
§ 117.80(c)(5)—Work-in-Process and Rework .....	Yes .....	Yes .....	No.
§ 117.80(c)(6)—Finished food .....	Yes .....	Yes .....	No.
§ 117.80(c)(7)—Equipment, containers, and utensils .....	Yes .....	Yes .....	No.
§ 117.80(c)(8)—Metal and other extraneous material .....	Yes .....	Yes .....	Yes.
§ 117.80(c)(9)—Disposal of adulterated food, raw materials, and other ingredients.	Yes .....	Yes .....	Yes.
§ 117.80(c)(10)—Manufacturing operations .....	Yes .....	No .....	Yes.
§ 117.80(c)(11)—Heat blanching, and growth and contamination by thermophilic microorganisms, during manufacturing operations.	Yes .....	Yes .....	Yes.
§ 117.80(c)(12)—Batters, breading, sauces, gravies, dressings, and other similar preparations.	Yes .....	Yes .....	Yes.
§ 117.80(c)(13)—Filling, Assembling, Packaging and Other Operations.	Yes .....	Yes .....	No.
§ 117.80(c)(14)—Food that relies on the control of water activity for preventing the growth of undesirable microorganisms.	Yes .....	Yes .....	Yes.
§ 117.80(c)(15)—Food that relies on the control of pH for preventing the growth of undesirable microorganisms.	Yes .....	Yes .....	Yes.
§ 117.80(c)(16)—Requirements for ice used in contact with food.	No .....	Yes .....	Yes.



TABLE 25—PROVISIONS FOR PROCESSES AND CONTROLS FOR MANUFACTURING OPERATIONS—Continued

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
§ 117.80(c)(17)—Food-manufacturing areas and equipment.	Yes (proposed to delete) ...	Yes .....	No (deleted as proposed).

*A. Proposed § 117.80(c)(1)—Condition of Equipment, Utensils, and Finished Food Containers*

We proposed no revisions to the requirements of current § 110.80(b)(1) (proposed § 117.80(c)(1)) that equipment and utensils and finished food containers be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(Comment 332) Some comments assert that this provision precludes the use of wooden bins, because wooden bins cannot be sanitized.

(Response 332) This requirement is a long-standing provision that provides flexibility for an establishment to sanitize when appropriate by specifying that equipment, utensils, and food containers be sanitized “as necessary.” For example, equipment food-contact surfaces are usually sanitized after cleaning to minimize the potential for contaminating food with undesirable microorganisms that accumulate during processing and grow in food residues on the equipment. When containers such as wooden bins cannot be sanitized, the establishment is responsible for taking appropriate steps to adequately clean and maintain the containers to minimize the potential for contaminating food with undesirable microorganisms. To clarify that the standard governing the condition of the equipment, utensils, and finished food containers is the same public health standard that applies to other provisions in § 117.80, we have revised the provision to specify that containers be kept in “adequate” condition rather than “acceptable” condition.

(Comment 333) Some comments ask us to delete the term “finished” from “finished food containers” so that the requirements applicable to the condition of equipment, utensils, and food containers will be more complete.

(Response 333) We agree that the requirements should apply to all food containers used during manufacturing operations, not just to “finished food containers.” We note that we received comments about the most appropriate adjective to describe the food containers subject to this requirement during the

rulemaking to establish this provision in part 110. (See the discussion at 51 FR 22458 at 22471, in which we responded to comments asking us to change “finished product container to “bulk product container” by explaining that finished product containers includes bulk product containers.) Rather than perpetuate questions as to how we are interpreting “finished,” we have deleted this adjective.

*B. Proposed § 117.80(c)(2)—Conditions and Controls for Food Manufacturing, Processing, Packing, and Holding*

We proposed that all food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food. We also proposed to delete guidance regarding how to comply with this requirement.

(Comment 334) Some comments ask us to add “in-process materials and rework,” “cross-contact,” and “or deterioration” for clarity and completeness.

(Response 334) We agree that adding “allergen cross-contact” is necessary for completeness and have revised the proposed provision to include it. We also agree that the provision needs to address deterioration; doing so is consistent with the requirements applicable to raw materials and other ingredients (see § 117.80(b)(1)). We decline the request to add “in-process materials and rework” to this provision because in-process materials and rework are already covered by the phrase “all food.”

*C. Proposed § 117.80(c)(3)—Food That Can Support the Rapid Growth of Undesirable Microorganisms*

We proposed that all food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding. We also proposed to delete recommendations for how to comply with this requirement.

(Comment 335) Some comments ask us to keep requirements for specific temperatures for holding hot food and

cold food because there is a direct correlation between temperature abuse and growth of pathogenic bacteria.

(Response 335) We agree that temperature abuse can lead to growth of pathogenic bacteria. Importantly, the temperatures that have been in current § 110.80(b)(3) were recommendations rather than requirements. As discussed in Response 67, we have deleted non-binding provisions from the rule and intend to issue guidance that will include much of the guidance that we have deleted from the umbrella CGMPs. As noted in the 2013 proposed human preventive controls rule (see table 8, 78 FR 3646 at 3715), the temperatures needed for safe holding may vary and the diversity of food to which the provision applies makes it inappropriate to specify these temperatures in regulation. There is information available currently on appropriate temperatures for a variety of foods (e.g., in the Food Code (Ref. 51) and the PMO (Ref. 64)). Moreover, a continued approach to specific temperatures for holding hot food and cold food through non-binding guidance is particularly appropriate because we can reasonably expect ongoing scientific advances that would alter our thinking on appropriate temperatures to hold hot food and cold food.

(Comment 336) Some comments ask us to require that food that can support the rapid growth of undesirable microorganisms be held at temperatures or “in another manner” that will prevent the food from becoming adulterated. These comments assert that current or future technology may provide other means of preventing microbial growth besides temperature controls—e.g., through use of pressure or in another as-yet-unforeseen manner.

(Response 336) We agree that current or future technology may provide other means of preventing microbial growth besides temperature controls. However, we disagree that it is necessary to modify the requirement to provide for preventing microbial growth by means other than temperature control, because the provision does not identify specific temperatures that must be used to prevent the food from becoming adulterated. If, for example, a food that currently requires refrigeration to

prevent adulteration becomes shelf-stable as a result of new technology, the provision as written would allow the food to be held at room temperature rather than under refrigeration.

*D. Proposed § 117.80(c)(4)—Measures To Destroy or Prevent the Growth of Undesirable Microorganisms*

We proposed that measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(Comment 337) Some comments express concern that the measures listed could be interpreted as an exhaustive list of processing methods and, thus, hinder the development of new technologies. These comments suggest adding “or other measures” at the end of the list.

(Response 337) The phrase “such as” indicates that these are examples of processing methods and that the list is not all inclusive. We believe that the list of examples and wording of the provision adequately express the intent behind this provision and allow the use of other measures without the suggested addition.

*E. Proposed § 117.80(c)(5)—Work-in-Process and Rework*

We proposed that work-in-process and rework must be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms.

(Comment 338) Comments that address this proposed requirement ask us to use the term “in-process materials” rather than “work-in-process.”

(Response 338) As discussed in Response 71, we decline this request.

*F. Proposed § 117.80(c)(6)—Finished Food*

We proposed that effective measures must be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food. Food transported by conveyor must be protected against cross-contact and contamination as necessary.

(Comment 339) Some comments ask us to specify that raw materials,

ingredients, or refuse that are unprotected not be handled simultaneously in “the same area” rather than in “a receiving, loading, or shipping area.” The comments assert that this would be clearer.

(Response 339) We decline this request. We narrowly directed the provision to address the potential for allergen cross-contact and for contamination by unprotected raw materials, ingredients, and refuse when finished food is in a receiving, loading, or shipping area. Broadening the provision to prohibit handling raw materials, ingredients, or refuse in the same area as finished food would imply that raw materials, ingredients, or refuse will never be handled in the production area where they may be needed or generated during production.

(Comment 340) Some comments ask us to revise the provision to add “in-process” food and “cleaning and sanitizing agents, and other chemicals” for clarity and completeness.

(Response 340) We decline this request. Work-in-process foods are covered separately in § 117.80(c)(5), and cleaning and sanitizing agents are addressed in the requirements for sanitary operations (see § 117.35(b)(2)).

*G. Proposed § 117.80(c)(7)—Equipment, Containers, and Utensils*

We proposed that equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against cross-contact and contamination.

(Comment 341) Some comments ask us to specify that the equipment, containers, and utensils also must be cleaned and sanitized during manufacturing, processing, packing, and holding in a manner that protects against cross-contact and against contamination.

(Response 341) We decline this request. Cleaning and sanitizing are addressed in the requirements for sanitary operations (see § 117.35(a)) and do not need to be addressed again in the requirements for manufacturing operations.

(Comment 342) Some comments ask us to add the phrase “where appropriate for food safety” at the beginning of the provision because food gases are manufactured, held, and distributed in a closed pressurized system and are therefore not exposed to personnel or environmental conditions where there is an impact on food safety.

(Response 342) We decline this request. The closed pressurized system described by the comment appears to satisfy the requirements of the provision, as would other systems commonly used in the food industry. The purpose of the provision is to set the standard; it is not necessary to add that no specific actions are necessary for those systems that inherently comply with the requirement.

*H. Proposed § 117.80(c)(8)—Metal or Other Extrinsic Material*

We proposed that effective measures must be taken to protect against the inclusion of metal or other extraneous material in food and to delete guidance regarding how to comply with this requirement.

(Comment 343) Some comments assert that it could be more effective from the perspective of food safety to use a risk-based approach to implementing protective measures against the inclusion of metal or other extraneous material in food. These comments assert that the risk of inclusion of metal is higher in cut fruits or vegetables than in fresh whole fruits or vegetables and, thus, the measures used to protect against the inclusion of metal should be different in cut fruits or vegetables than in fresh whole fruits or vegetables.

(Response 343) We agree that the measures used to protect against the inclusion of metal likely will be different for cut fruits or vegetables than for fresh whole fruits or vegetables and that a risk-based approach can be helpful in determining how to comply with the requirement. To emphasize the utility of a risk-based approach, we have revised the provision to require “adequate” measures rather than “effective” measures; as defined in the rule (see § 117.3), the term “adequate” means that which is needed to accomplish the intended purpose in keeping with good public health practice.

*I. Proposed § 117.80(c)(9)—Disposal of Adulterated Food, Raw Materials, and Other Ingredients*

We proposed that food, raw materials, and ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food or, if the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven to be effective. We also proposed an editorial change to make clear that reconditioning, rather than disposal, is an option and to delete a provision that could be viewed as providing an option to simply

reexamine adulterated food and subsequently find it not to be adulterated.

(Comment 344) Some comments ask us to retain the provision to reexamine adulterated food and subsequently find it not to be adulterated. These comments explain that there are processes that can remove contaminants such as pesticides and heavy metals from foods such as botanical extracts. Although laboratory studies or small-scale pilot batches may give an indication that the reconditioning is likely to be effective, they cannot always guarantee the treatment will be equally effective when scaled up to commercial-scale production batches. Because these methods have not been “proven to be effective,” the appropriate approach to determining whether the reconditioned food is no longer adulterated is reexamination after the reconditioning is complete.

(Response 344) We agree with these comments and have revised the provision to make clearer that reexamination can only be used to subsequently find that the food is not adulterated after the food has been reconditioned. See the regulatory text of § 117.80(c)(9).

(Comment 345) Some comments ask us to clarify that the provision only applies if the food has actually been found to be adulterated. The comments assert that the provision should not apply where product has been placed “on hold” due to an equipment failure (e.g., if product is put on hold due to an inoperative metal detector until the establishment can retest for potential metal contaminants).

(Response 345) The provision only applies if the food is adulterated. In the example described in these comments, if the food is not adulterated, the establishment would not need to dispose of, or recondition, the product.

(Comment 346) Some comments ask us to clarify that the provision does not apply to grains subject to the review inspection provisions provided for by 7 CFR 800.125 and 800.135.

(Response 346) In many cases, grains subject to the review inspection provisions provided for by 7 CFR 800.125 and 800.135 are RACs that are being held or transported by an establishment solely engaged in holding or transporting RACs and subpart B (including § 117.80(c)(8)) would not apply to the grains (see § 117.5(k)). In addition, as noted in Response 345, this provision only applies to food that is adulterated.

*J. Proposed § 117.80(c)(10)—Performing Manufacturing Steps*

We proposed that steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact and contamination. We proposed that food should be protected from contaminants that may drip, drain, or be drawn into food and requested comment on whether to establish the recommendation regarding physical protection of food from contaminants that may drip, drain, or be drawn into the food as a requirement (78 FR 3646 at 3726). We also proposed to delete two recommendations regarding adequate cleaning and sanitizing of food-contact surfaces and regarding the use of time and temperature controls.

(Comment 347) Some comments agree that we should require, rather than recommend, that food be protected from contaminants that may drip, drain, or be drawn into food. Other comments express concern that turning the current recommendation into a requirement could lead to a de facto requirement for closed systems to be used in food production. Some comments ask us to specify that the requirements only apply where food is exposed.

(Response 347) We agree that we should require, rather than recommend, that food be protected from contaminants that may drip, drain, or be drawn into food. We have not revised the regulatory text to specify that the requirements only apply where food is exposed, because such protections would only be needed if foods are exposed to such conditions. Such a requirement would not lead to a de facto requirement for a closed system, because this is not the only way to protect food from such contaminants. For example, covers can be used on kettles and tanks, and shields can be placed over conveyor lines.

*K. Proposed § 117.80(c)(11)—Heat Blanching and Growth and Contamination by Thermophilic Microorganisms During Manufacturing Operations*

We proposed that heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. We proposed that thermophilic growth and contamination in blanchers

should be minimized by the use of adequate operating temperature and by periodic cleaning and requested comment on whether to establish these two recommendations as requirements (78 FR 3646 at 3726).

(Comment 348) Some comments support establishing the recommendations in this provision as requirements. Other comments oppose doing so and assert that these detailed steps may not be important to protect the public health.

(Response 348) We disagree that the use of adequate operating temperature and periodic cleaning are not important to protect public health. Improper cooling can lead to growth of pathogenic sporeforming bacteria if product remains too long at temperatures that support their multiplication. In addition, growth of thermophiles, while not a public health issue, can lead to product spoilage, and, thus, adulteration. We are establishing these two recommendations as requirements in the regulatory text, along with associated editorial changes.

*L. Proposed § 117.80(c)(12)—Batters, Breeding, Sauces, Gravies, Dressings, and Other Similar Preparations*

We proposed that batters, breeding, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against cross-contact and contamination. We also proposed to clarify that these steps require protection against cross-contact and to delete the recommendations for how to comply with this requirement.

(Comment 349) Some comments agree that we should delete the provided examples of mechanisms to achieve compliance.

(Response 349) We have deleted the examples as proposed.

(Comment 350) Some comments ask us to modify the provision to clarify that it applies to preparations that are held and used repeatedly over time and to add “dipping solutions” as another example of such a preparation.

(Response 350) We agree that the provision applies to preparations that are held and used repeatedly over time and that “dipping solutions” is a useful example to add. We have revised the regulatory text as requested by these comments.

(Comment 351) Some comments ask us to add that another purpose of the requirement is to minimize the potential for the growth of undesirable microorganisms.

(Response 351) This request would promote consistency in the requirements throughout § 117.80 and

we have revised the regulatory text accordingly.

*M. Proposed § 117.80(c)(13)—Filling, Assembling, Packaging and Other Operations*

We proposed that filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against cross-contact, contamination, and growth of undesirable microorganisms. We also proposed to delete the recommendations for achieving compliance with this requirement.

(Comment 352) Some comments ask us to specify that the requirement applies only to finished food to differentiate it from other provisions in § 117.80 and assert that without the modification the provision would be redundant.

(Response 352) The specific requirements of § 117.80(c)(13) are not redundant with other provisions in § 117.80. The long-standing provisions of § 117.80 first address general requirements (§ 117.80(a)) and then address more specific requirements applicable to raw materials and other ingredients (§ 117.80(b)) and manufacturing operations (§ 117.80(c)). Although the comment does not define “finished food,” we consider that term to apply to a packaged and labeled food product; filling, assembling, and packaging operations would be conducted on in-process food to create a finished product. Regardless of whether the appropriate term would be “finished” or “in-process food,” the comment provides no reason for why this long-standing provision is not clear without specifying the production stage of a food product that is subject to filling, assembling, and packaging operations.

*N. Proposed § 117.80(c)(14)—Food That Relies on the Control of Water Activity for Preventing the Growth of Undesirable Microorganisms*

We proposed that food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of water activity for preventing the growth of undesirable microorganisms must be processed to, and maintained at, a safe moisture level. We also proposed to delete the recommendations for achieving compliance with this requirement.

(Comment 353) Some comments assert that moisture level is not an adequate food safety control measure. The comments ask us to revise the requirement to reflect that it is the proper maintenance of water activity, rather than moisture level, that will

prevent growth of undesirable microorganisms.

(Response 353) The rule defines safe moisture level as a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product and notes that the safe moisture level is related to water activity (§ 117.3). Although in most cases water activity is the most suitable measurement to predict food safety, moisture content is frequently used to assess the stability of grains and nuts with respect to prevention of growth and mycotoxin production by molds. We are retaining the term “safe moisture level” as a broader term that takes into account the fact that measuring moisture level and measuring water activity are both common industry practice and, depending on the food, can be measures that are appropriate to assess safety. The comments provide no basis for the assertion that this long-standing provision is not an adequate food safety measure.

(Comment 354) Some comments assert that water activity may not be the only factor responsible for preventing the growth of undesirable microorganisms in dry products and ask us to modify the regulatory text to take into account other synergistic barriers for microbial growth and toxin formation.

(Response 354) We agree with these comments and have revised the regulatory text to clarify that such products rely “principally” on the control of water activity.

(Comment 355) Some comments assert that nuts should be “maintained” at an appropriate moisture level rather than “processed to” an appropriate moisture level.

(Response 355) We acknowledge that some products need only be “maintained” at a safe moisture level and may not need to be processed to achieve that level. However, we disagree that it is necessary to modify this long-standing requirement to specify this distinction. The comments do not provide examples of how we have been interpreting this provision in a way that does not accommodate the differences in products.

(Comment 356) Some comments ask us to more closely adhere to the current regulatory text (*i.e.*, food, such as dry mixes . . .) rather than the proposed regulatory text (*i.e.*, food, including dry mixes . . .).

(Response 356) The final rule retains the long-standing language “such as” as requested by the comments. (See also the discussion in Response 68.)

*O. Proposed § 117.80(c)(15)—Food That Relies on the Control of pH for Preventing the Growth of Undesirable Microorganisms*

We proposed that food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below. We also proposed to delete the recommendations for how to comply with this requirement.

(Comment 357) Some comments ask us to use the term “equilibrated pH” or “finished equilibrium pH” for consistency with part 114. Some comments ask us to add a definition for “equilibrated pH” in § 117.3.

(Response 357) We decline these requests. It is not necessary for this long-standing provision in the umbrella food CGMPs to use specialty terms used in the more specific CGMPs that apply to acidified foods in order to make clear that the operative pH for the safety of such foods is 4.6 or below.

(Comment 358) Some comments ask us to more closely adhere to the current language (*i.e.*, food such as acid and acidified food . . .) rather than the proposed language (*i.e.*, food, including acid food and acidified food . . .) to make it clear that the list is not intended to be complete.

(Response 358) The final rule retains the long-standing language “such as” as requested by the comments. (See also the discussion in Response 68.)

*P. Proposed § 117.80(c)(16)—Requirements for Ice Used in Contact With Food*

We proposed no revisions to the requirements of current § 110.80(b)(16) (proposed § 117.80(c)(16)) that when ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice.

(Comment 359) Some comments ask us to replace the requirement that water must be safe and of adequate sanitary quality with a cross-reference to the water quality requirements of § 117.37(a).

(Response 359) We acknowledge that cross-referencing the water quality requirements established in § 117.37(a), without describing those requirements, would accurately convey the requirements for ice used in contact with food. However, we believe there is value added by continuing to emphasize the water quality standard within the requirements for ice used in contact

with food. We have added a cross-reference to § 117.37(a) but have not deleted “safe and of adequate sanitary quality.”

*Q. Proposed Deletion of Current § 110.80(b)(17)—Food-Manufacturing Areas and Equipment*

We proposed to delete the current recommendation that food-manufacturing areas and equipment used for manufacturing human food not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food. We tentatively concluded that this recommendation would be more appropriate in guidance, which could include examples of situations where there is no reasonable possibility for the contamination of the human food.

(Comment 360) Some comments ask us to retain this provision for clarity and as a means to educate small, foreign, and new food processors.

(Response 360) We decline this request. The focus of the provision is to emphasize the importance of manufacturing food in a way that prevents contamination. Other provisions (such as §§ 117.10(b),

117.20(a), 117.35(a), 117.40(a)(1), 117.80(a), and 117.93) already require that an establishment prevent contamination from any source. (See also the discussion in Response 67 about our decision to delete those non-binding provisions of part 110 that we are not establishing as requirements.)

**XXI. Subpart B: Comments on Proposed § 117.93—Warehousing and Distribution**

Current § 110.93 requires that storage and transportation of finished food be under conditions that will protect food against physical, chemical, and microbial contamination, as well as against deterioration of the food and the container. We proposed a series of revisions to these current requirements—*i.e.*, to apply the requirements to “food” rather than to “finished food”; clarify that storage and transportation of food must be under conditions that will protect against allergen cross-contact in addition to protecting against contamination of food; add radiological hazards as an additional category of contaminants; and require protection against “biological,” rather than “microbial” contamination. With all of these

revisions, we proposed that storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container.

Some comments support one or more of these proposed revisions without change. For example, some comments support adding radiological hazards as an additional category of contaminants to the list of contaminants which may be encountered in warehousing and distribution because food may be subject to contamination with radiological hazards. Other comments that support the proposed provisions suggest alternative regulatory text (see, *e.g.*, Comment 361) or ask us to clarify how we will interpret the provision (see, *e.g.*, Comment 363).

In the following sections, we discuss comments that ask us to clarify the proposed provision or that disagree with, or suggest one or more changes to, the proposed provision. After considering these comments, we are finalizing the provision as proposed (see table 26), with editorial and conforming changes as shown in table 52.

TABLE 26—PROVISIONS FOR WAREHOUSING AND DISTRIBUTION

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
117.93—Warehousing and distribution .....	Yes .....	Yes .....	No.

(Comment 361) Some comments express concern that produce will spoil and deteriorate even under the best conditions. These comments ask us to modify the proposed requirements to address these concerns, such as by specifying that the conditions will “reasonably protect” or by revising “will protect” to “will minimize to acceptable levels.”

(Response 361) We decline this request. In some cases, this provision will not apply to produce (*i.e.*, when the produce is a RAC subject to the exemption for an establishment solely engaged in the holding or transportation of one or more RACs; see § 117.5(k)). When the produce is not subject to the RAC exemption (*e.g.*, when the produce is being handled in a fresh-cut processing facility), requiring storage and transportation of produce under the conditions specified in the provision is appropriate. The comments provide no basis that we have been enforcing this long-standing provision in a manner that does not acknowledge practical

issues associated with the short shelf life of produce in such facilities and, thus, that modifications such as those suggested by the comments are necessary.

(Comment 362) Some comments assert that regulations directed to radiological hazards will act as a double regulation to hinder amicable trade activities and will increase economic burden to manufacturers. As discussed in Comment 410, these same comments ask us to provide that a facility subject to the requirements for hazard analysis and risk-based preventive controls may rely on existing systems in place to manage radiological risks, such as steps taken by government officials to inspect ingredients obtained from a geographic region that has been the subject of a nuclear accident.

(Response 362) See Response 410 for a discussion of how a facility may consider existing systems in place to manage radiological risks, but still has responsibilities to establish and implement preventive controls to

address a radiological hazard when circumstances warrant. The comment provides no basis for its assertion that regulations directed to radiological hazards will act as a double regulation to hinder amicable trade activities and will increase economic burden to manufacturers.

(Comment 363) Some comments support our proposal to specify that the requirements apply to “food” rather than to “finished food,” provided that doing so does not affect common and safe practices for the transportation of RACs, such as transporting raw produce from the field, or from packinghouses, in open top containers such as field boxes, totes and gondola trucks.

(Response 363) As discussed in the 2013 proposed human preventive controls rule, we proposed to apply the CGMP requirements for storage and transportation to “food” rather than “finished food” to ensure food safety throughout the food chain, regardless of whether a food product is a raw material or ingredient or in its finished state (78

FR 3646 at 3727). We intend this revision to clarify that the CGMP provisions for warehousing and distribution apply to raw materials and ingredients, including RACs. When a food establishment that stores and transports RACs is subject to the CGMP provisions, common and safe storage and transportation practices such as those described in our 1998 guidance entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (Ref. 13) would be appropriate.

(Comment 364) As noted in Response 324, under the proposed produce safety rule a farm that produces covered produce that is distributed for commercial processing would be required to maintain documentation of the identity of the recipient of the commercial processor. Some comments appear to assume that a farm might distribute such products with information disclosing that such produce was not grown in compliance with part 112, should not be consumed raw, and/or requires commercial processing. These comments ask us to add a provision that no food whose labels, labeling, or commercial

documentation accompanying the sale contain any of the following notices may be sold or otherwise distributed to any user except a commercial processor: Not grown in compliance with part 112; Not for fresh or raw consumption; May require commercial formulation, processing, or both to adequately reduce microorganisms.

(Response 364) We decline to add such a provision to the CGMP requirements for distribution of food. As noted in Response 324, we do not see a benefit to labeling produce as indicated because we believe that the vast majority of such produce is low risk. However, as also noted in Response 324, we are providing for a narrow use of commercial documentation, which would include produce, when a manufacturer/processor that has identified a hazard requiring a preventive control does not establish a preventive control because it: (1) Relies on its customer to ensure that an identified hazard will be controlled and (2) discloses, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control

[identified hazard]” (See § 117.136(a)(2), (3), and (4)).

**XXII. Subpart B: Comments on Proposed § 117.110 (Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazards)**

We proposed to revise the current provisions directed to natural or unavoidable defects in food for human use that present no health hazard. Some comments support one or more of these proposed provisions without change. Other comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 365, Comment 367, and Comment 368).

In the following sections, we discuss comments that ask us to clarify the proposed provisions or that disagree with, or suggest one or more changes to, the proposed provisions, including comments on provisions that we did not propose to revise. After considering these comments, we have revised the proposed provisions as shown in table 27, with editorial and conforming changes as shown in table 52.

TABLE 27—PROVISIONS FOR DEFECT ACTION LEVELS

Provision	Did we propose revisions or request comment on potential revisions?	Did we get comments that disagreed with the proposed provision?	Did we modify the proposed regulatory text?
117.110(a) and (b)—Description of defect action levels	No .....	Yes .....	Yes.
117.110(c)—Quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.	Yes .....	Yes .....	No.
117.110(d)—Mixing adulterated food with food that is not adulterated.	Yes .....	Yes .....	Yes.
117.110(e)—How to obtain the booklet “Defect Action Levels”.	Yes (proposed to delete) ...	Yes .....	Yes (provided Internet address).

We proposed that some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The proposed provisions specify that FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action. The proposed provisions also specify that defect action levels are established for foods when it is necessary and feasible to do so, and that these levels are subject to change upon the development of new technology or the availability of new information (proposed § 117.110(a) and (b)).

We also proposed that compliance with defect action levels does not excuse violation of the requirement in

section 402(a)(4) of the FD&C Act that food not be prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or the requirements in part 117 that food manufacturers, processors, packers, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible (proposed § 117.110(c)).

We also proposed that the mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. (Proposed § 117.110(d)).

We proposed to delete current § 110.110(e), which specifies that a Defect Levels Handbook (a compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard) may be obtained upon request from the Center for Food Safety and Applied Nutrition.

(Comment 365) Some comments assert that the word “defects” may cause confusion in industry, because the term “defects” is commonly used to describe quality or physical type attributes that do not pose a risk to

public health. These comments ask us to consider using another term, such as “contaminant,” in place of the term “defect.”

(Response 365) We decline this request. The specific term requested by the comments (*i.e.*, contaminant) often carries the connotation of hazardous to health. However, we have added a definition of the term “defect action level” to the rule (see Response 165 and § 117.3). The defined term makes clear that the term does not refer to quality or physical type attributes such as those described in the comments. We also have deleted the first two full paragraphs of the proposed provision (proposed § 117.110(a) and (b)), which are no longer necessary to provide context about the regulatory impact of the term “defect action level,” because the new definition of “defect action level” explains that a defect action level is a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action under section 402(a)(3) of the FD&C Act.

(Comment 366) Some comments assert that a facility subject to this provision will implement both CGMPs and a food safety plan as guiding “quality control operations” appropriate for this purpose. These comments also assert that reducing natural or unavoidable defects to “the lowest level currently feasible” does not require a facility to exceed CGMPs or go beyond preventive controls identified through a hazard analysis. In the view of these comments, doing so would run contrary to the risk-based principles that underlie FSMA and leading food safety programs by requiring that all hazards be managed equally without considering the outcomes of the hazard analysis. These comments assert that successful, responsible food safety programs

allocate resources to hazards commensurate with their potential impact to the public health.

(Response 366) We agree that reducing natural or unavoidable defects to “the lowest level currently feasible” does not require a facility to exceed CGMPs or go beyond preventive controls identified through a hazard analysis.

(Comment 367) Some comments assert that the word “reduce” in § 117.110 (c) may not be appropriate for all facilities. As an example, the comments explain that a brownskin almond facility that solely sizes and sorts product before packaging may not have processes to reduce microbial contaminants. Instead, that facility may rely upon custom processors to reduce the level of microbial contamination. In such a case, these comments note that it would be more accurate for the provision to specify using quality control operations that ensure the lowest level currently feasible for natural or unavoidable defects.

(Response 367) We have not revised the provision to account for circumstances such as those described in these comments. We acknowledge that the production of some food products requires that food pass through multiple facilities before the finished food is distributed into commerce, and that a specific pathogen reduction step may occur at only one of the applicable facilities. The comments do not provide any examples of how we have interpreted this long-standing provision in the past in a way that creates practical problems when applying the provision to facilities such as those described in the comments.

(Comment 368) Some comments ask us to retain the provision, in § 110.110(e), specifying that the Defect Levels Handbook may be obtained upon request from the Center for Food Safety and Applied Nutrition. These comments

also ask us to add an FDA Web site where the handbook may be obtained.

(Response 368) We have added a reference to the Defect Levels Handbook (Ref. 36) to the provisions as examples of defect action levels that may render food adulterated, including an address on the FDA Web site where this handbook may be obtained.

**XXIII. Subpart C: Comments on Overall Framework for Hazard Analysis and Risk-Based Preventive Controls**

In the 2014 supplemental human preventive controls notice, we proposed a series of changes to proposed subpart C and reopened the comment period specifically with respect to these changes. The proposed changes included: (1) Eliminating the term “hazard reasonably likely to occur” throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term); (2) adding a new defined term, “significant hazard,” and, in general, using this new term instead of “hazard reasonably likely to occur” throughout the re-proposed regulations; (3) defining “known or reasonably foreseeable hazard” in place of “reasonably foreseeable hazard” and clarifying that the new term means a hazard “that has the potential to be associated with the facility or the food” rather than “a potential . . . hazard that may be associated with the facility or the food”; and (4) providing additional flexibility to address concerns about re-writing existing plans or programs to conform with the requirement of the human preventive controls rule.

We received many comments on the overall framework for hazard analysis and risk-based preventive controls. We discuss each of these comments in the discussion of the specific regulatory text applicable to each comment. We show highlights of the changes we made after considering these comments in table 28.

TABLE 28—REVISIONS TO THE OVERALL FRAMEWORK FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Section	Description	Revision
117.3	Definition of “significant hazard”	Revise the proposed term “significant hazard” to “hazard requiring a preventive control” and revise the definition to emphasize the role of risk in determining whether a hazard requires a preventive control.
117.3	Definition of “corrections”	Define the term “correction” to distinguish “corrections” from “corrective actions.”
117.135(c)(1), 117.140(a), 117.145, 117.155(a), 117.160(a), 117.165(a), 117.165(b).	Flexibility in preventive controls and preventive control management components for monitoring, corrective actions and corrections, and verification.	Clarify that preventive control management components depend on the role of a preventive control in the facility’s food safety system, as well as the nature of the preventive control.
117.130(b)(1), 117.130(b)(2).	Hazard identification	Emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).

TABLE 28—REVISIONS TO THE OVERALL FRAMEWORK FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS—Continued

Section	Description	Revision
117.145(c) .....	Monitoring records .....	Provide for the use of “exception records” for monitoring preventive controls.
117.150(a) .....	Corrective action procedures .....	Clarify that corrective action procedures depend on the nature of the hazard.
117.150(c) .....	Corrections .....	Provide for additional circumstances when corrections, rather than corrective actions, are warranted.
117.160(c) .....	Preventive controls that do not require validation .....	Clarify that a list of preventive controls that do not require validation is not an exhaustive list.
117.165(a)(5) .....	Activities to verify implementation and effectiveness .....	Clarify that there could be alternative verification activities of implementation and effectiveness other than those that we specify in the rule.
117.165(b) .....	Written procedures for verification of implementation and effectiveness.	Clarify that written procedures for verification of implementation and effectiveness are established and implemented as appropriate to the role of the preventive control in the facility’s food safety system, as well as appropriate to the facility, the food, and the nature of the preventive control.
117.170(b) .....	Reanalysis .....	Provide for reanalysis of an applicable portion of the food safety plan (rather than the complete food safety plan) in specified circumstances.

**XXIV. Subpart C: Comments on Proposed § 117.126—Food Safety Plan**

We proposed requirements for a food safety plan. Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 377 and Comment 381) or ask us to clarify how we will interpret the provision (see, e.g., Comment 370).

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the provisions as proposed, with editorial and conforming changes as shown in table 52.

We proposed that the food safety plan be under the oversight of one or more “qualified individuals.” As discussed in section IX.C.25, we have changed the proposed term “qualified individual” to “preventive controls qualified individual” because we are establishing a new definition for “qualified individual,” with a meaning distinct from “preventive controls qualified individual.” To minimize the potential for confusion for when the term “qualified individual” refers to the proposed meaning of the term and when the term “qualified individual” refers to the meaning of that term as finalized in this rule, in the remainder of this document we substitute the new term “preventive controls qualified individual” for the proposed term “qualified individual,” even though the proposed rule used the term “qualified individual.” Likewise, we substitute the new term “preventive controls qualified

individual” for the proposed term “qualified individual” when describing the comments to the proposed rule, even though those comments use the term “qualified individual.”

We proposed that several other provisions of subpart C be under the oversight of a “qualified individual” (now “preventive controls qualified individual”), and also proposed requirements that would apply to the “qualified individual” (now “preventive controls qualified individual”). See, e.g., §§ 117.160, 117.165, 117.170, 117.180, 117.190, and 117.206). As discussed in the preceding paragraph, in the remainder of this document, we substitute the new term “preventive controls qualified individual” for the proposed term “qualified individual,” when describing these proposed provisions and the comments to these proposed provisions.

*A. Proposed § 117.126(a)(1)—Requirement for a Food Safety Plan*

We proposed that you must prepare, or have prepared, and implement a written food safety plan.

(Comment 369) Some comments ask us to emphasize that “written” means “any type of recordable and reproducible format” (e.g., as paper or electronic documents). Some comments ask us to specify that the components of the food safety plan need not be in a single document or stored in one place.

(Response 369) A “written” food safety plan can be either a paper document or an electronic document, as provided by § 117.305(a). The final rule specifies that required information (which would include the food safety plan) does not need to be kept in one

set of records (see § 117.330 (b)), and a food safety plan may be prepared as a set of documents kept in different locations within the facility (e.g., based on where they will be used), provided that each set of documents is onsite. As provided in the recordkeeping provisions, electronic records are considered to be onsite if they are accessible from an onsite location.

(Comment 370) Some comments agree with our previous statements that facilities should be able to group food types or production method types if hazards, control measures, parameters, and required procedures, such as monitoring, are identical (78 FR 3646 at 3730). These comments note that exceptions should be carefully delineated and followed as appropriate. Some comments ask us to clarify that we will allow food safety plans to share common provisions where there are uniform systems in place. Some comments ask us to clarify whether one plan is required for the facility or for each crop/food item individually.

(Response 370) We are requiring that a facility have a written food safety plan that covers all the foods that it manufactures, processes, packs, or holds. We recognize that, to the extent that the controls are the same, there may be common controls that broadly apply to some or all of a facility’s food products. However, any product- or process-specific differences must be carefully delineated and observed in practice.

In some facilities with limited types of products, the written food safety plan may contain a single set of procedures that addresses all of the products produced. For example, a facility



making fruit-flavored beverages may be able to address all of its beverages in the same set of procedures. For other facilities, there may not be a practical way to group the products and the written food safety plan may need to contain more than one set of procedures to address all of its products. For example, a facility that makes both RTE entrees and entrees that are not RTE may choose to group the RTE entrees in one set of procedures, but have a separate set of procedures for the entrees that are not RTE. However, to the extent that some of the written procedures in the food safety plan are the same for both RTE entrees and entrees that are not RTE, the facility need not duplicate those procedures in its written food safety plan. For example, a facility that uses an electronic food safety plan could store written procedures in multiple folders in the electronic system, and the food safety plan for individual products (or groups of products) could simply hyperlink to the written procedures applicable to each product. Likewise, a facility that uses a paper-based food safety plan could store written procedures in a binder or file cabinet, with written cross-references to procedures that apply to more than one product.

(Comment 371) Some comments ask us to provide that the food safety plan be handled at the corporate level rather than the facility level if a corporation owns many facilities.

(Response 371) A corporation may designate an individual at the corporate level as the owner, operator, or agent in charge of a particular facility. In addition, an employee of the corporation, whether at headquarters or at another facility owned by the corporation, may provide input into a particular facility's food safety plan. As previously discussed, the food safety plan needs to be facility specific (see the discussion of the facility-based nature of the food safety plan in the 2013 proposed human preventive controls rule, 78 FR 3646 at 3732). For example, even if a corporation makes similar products at two separate facilities, it is unlikely that the two facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility may affect its approach to preventive controls such as food allergen controls.

(Comment 372) Some comments ask us to provide for facilities that have HACCP plans to build off their existing HACCP programs. As an example, these comments state that we could allow facilities to use terms like "critical

limits" for process controls rather than require these foundational documents to be rewritten simply to change terminology.

(Response 372) A facility that has a HACCP plan (or other food safety plan) in place before this rule becomes effective can build off its existing program and can rely on existing records, supplemented as necessary to include all of the required information and satisfy the requirements of this rule (see § 117.330). The rule does not preclude the use of terms like "critical limits" that are associated with HACCP systems.

(Comment 373) Some comments ask us to provide templates that facilities can use as models to develop their food safety plans. Some comments ask us to accept Good Agricultural Practices (GAPs) food safety plan formats and/or HACCP plans. Some comments provide specific templates for us to consider.

(Response 373) We decline the request to provide templates for facilities to use to develop their food safety plans. The rule does not specify the format of a food safety plan, and a facility has flexibility to format its food safety plan in a way that works best for the facility, provided that the plan includes all required information. In general, internationally recognized food safety plan formats would be acceptable, although modification and supplementation may be necessary to comply with all requirements of the rule (see § 117.330 on the use and adaptation of existing records). Training materials being developed by the FSPCA may be useful in developing food safety plans (see Response 2).

We note that activities of farm mixed-type facilities that are within the "farm" definition (e.g., packing and holding RACs) are not subject to the human preventive controls rule. However, to the extent that some components of GAPs-based food safety plans are relevant to a facility (e.g., for an off-farm packinghouse), the facility has flexibility to format its plan in a way that is consistent with GAPs-based food safety plans.

(Comment 374) Some comments ask us to clarify that a food safety plan is not required when a facility is exempt as a qualified facility (§ 117.5(a)) or as a facility solely engaged in the storage of packaged food that is not exposed to the environment (§ 117.7).

(Response 374) A qualified facility is exempt from the requirements of subparts C and G, including the requirement to prepare and implement a food safety plan, and is instead subject to the modified requirements in § 117.201. Likewise, a facility solely

engaged in the storage of packaged food that is not exposed to the environment is exempt from the requirements of subparts C and G, including the requirement to prepare and implement a food safety plan, and is instead subject to the modified requirements in § 117.206.

(Comment 375) Some comments ask us to clarify that a food safety plan is not required for facilities that store unexposed, refrigerated, packaged TCS foods.

(Response 375) We agree that a facility "solely engaged" in the storage of unexposed, refrigerated, packaged TCS food is exempt from the requirements of subparts C and G, including the requirement to prepare and implement a food safety plan, and is instead subject to the modified requirements in § 117.206 (see § 117.7). However, if a facility engages in other activities in addition to the storage of unexposed, refrigerated, packaged TCS foods, the exemption does not apply. In such a case, the facility must prepare and implement a food safety plan. However, the modified requirements of § 117.206 can be informative with respect to what the food safety plan could include regarding the storage of unexposed, refrigerated, packaged TCS food.

(Comment 376) Some comments ask us to explain why a written food safety plan is necessary, because adoption of a HACCP system is only voluntary under the Codex General Principles of Food Hygiene.

(Response 376) The requirement to prepare and implement a written food safety plan is required by U.S. law (i.e., by section 418(h) of the FD&C Act). In contrast, Codex standards are recommendations for voluntary application by members and, thus, Codex provisions are only mandatory if the standard is adopted by a country in its national legislation.

*B. Proposed § 117.126(a)(2)—  
Preparation of the Food Safety Plan by  
a Preventive Controls Qualified  
Individual*

We proposed that the food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(Comment 377) Some comments ask us to provide for a group of preventive controls qualified individuals to prepare, or oversee the preparation of, a food safety plan.

(Response 377) The proposed regulatory text included in the 2014 supplemental human preventive controls notice provides for the food safety plan to be prepared, or its

preparation overseen, by one or more preventive controls qualified individuals, and we are finalizing that provision as proposed.

(Comment 378) Some comments ask us to specify that oversight of the food safety plan is voluntary rather than required.

(Response 378) We decline this request. The food safety plan is the foundation for a preventive approach to producing safe food. As previously discussed, the food safety plan must be designed to identify, and to significantly minimize or prevent, hazards for the purpose of preventing illness or injury (78 FR 3646 at 3731). The comments fail to explain how a facility could ensure the proper design of an effective food safety plan without oversight by an individual who satisfies the minimum requirements for a preventive controls qualified individual (see the discussion of the requirements for a preventive controls qualified individual in section XXXVI).

(Comment 379) Some comments assert that oversight of the food safety plan by a preventive controls qualified individual should not be required for products subject to the PMO because the production of such products is subject to the NCIMS process.

(Response 379) As discussed in Response 214, we agree we should make use of the existing system of oversight provided for by NCIMS, which has been part of a cooperative program among the U.S. Public Health Service/FDA, the States, and the dairy industry since 1950, and we have provided an extended compliance date in order that the PMO be revised for consistency with this rule. Under a revised PMO, Grade “A” facilities would need a preventive controls qualified individual to make decisions about hazards and verification procedures such as environmental monitoring specific to a facility and to review food safety records.

(Comment 380) Some comments express concern about the cost associated with oversight of the food safety plan by a preventive controls qualified individual, regardless of whether the preventive controls qualified individual is employed by the facility or is a third party. These comments focus on the burden that this oversight would place on farms and small businesses, and note that the food industry is a “low margin” industry. Some comments ask us to provide for an officer or employee of a State agricultural agency to provide oversight of the food safety plan, because such persons have the most specialized knowledge concerning that State, it is more efficient for State officials to travel

to nearby farms, and farmers feel more comfortable working with State employees.

(Response 380) A farm is not subject to this rule for activities within the “farm” definition. A farm mixed-type facility that is a small or very small business and only conducts the low-risk activity/food combinations specified in § 117.5(g) and (h) is exempt from the requirements of subparts C and G, including the requirement for oversight of the food safety plan by a preventive controls qualified individual. Furthermore, a farm mixed-type facility that is a very small business, but does not satisfy the criteria for the exemptions specified in § 117.5(g) and (h), is a qualified facility that is exempt from the requirements of subparts C and G, and is instead subject to modified requirements that do not require oversight of a food safety plan by a preventive controls qualified individual. Moreover, we expect that some training materials and courses will be available online, thereby helping to mitigate costs, both associated with training of a preventive controls qualified individual and loss of production manpower during training.

We disagree that it would be appropriate for an officer or employee of a State agricultural agency to provide oversight of the food safety plan. The food safety plan and its oversight are the responsibility of the facility, not State government officials. The role of an officer or employee of a State agricultural agency would be in determining whether the applicable facility is in compliance with the rule, such as during inspection. State extension agents may be available to assist small businesses, even if those agents are not the designated preventive controls qualified individual for the facility, provided that such agents do not also have any role in determining whether the applicable facility is in compliance with the rule.

We acknowledge that oversight of a food safety plan by a preventive controls qualified individual is a cost associated with the rule, and we have accounted for that cost in the FRIA for this rule (Ref. 38). To minimize the burden on the smallest businesses, the definition of “very small business” establishes a \$1,000,000 threshold, adjusted for inflation, during the 3-year period preceding the applicable calendar year. As already noted, a facility that satisfies the definition of very small business is exempt from the requirements of subparts C and G and instead is subject to modified requirements (see § 117.201), which do not require a food safety plan that is prepared or overseen

by a preventive controls qualified individual.

### C. Proposed § 117.126(b)—Contents of a Food Safety Plan

We proposed that the written food safety plan must include the written hazard analysis, preventive controls (including the supplier program and the recall plan), procedures for monitoring the implementation of the preventive controls, corrective action procedures, and verification procedures. As discussed in more detail in section XLII, we have revised the phrase “supplier program” to “supply-chain program” throughout the regulatory text. In the remainder of this document, we use the phrase “supply-chain program” in section headings and when referring to the provisions of the final rule. We continue to use the term “supplier program” when describing the proposed provisions and the comments regarding the proposed provisions.

(Comment 381) Some comments ask us to specify that sanitation controls must be in the food safety plan. Some comments ask us to require equipment standards in the food safety plan, noting that it is not possible to clean and sanitize equipment that is not designed and constructed to be cleanable by meeting specific standards.

(Response 381) Sanitation controls are one type of preventive control. As appropriate to the facility and the food (e.g., to control hazards such as environmental pathogens), sanitation controls for cleanliness of food-contact surfaces and prevention of allergen cross-contact and cross contamination would be required to be in the food safety plan (§ 117.135(c)(3)).

We are not adding a requirement to include equipment standards in the food safety plan. The CGMPs established in subpart B already require that all plant equipment and utensils be so designed and of such material and workmanship so to be adequately cleanable (§ 117.40(a)(1)). It is not practical to specify equipment standards in the CGMPs due to the wide range of equipment used by the food industry, including equipment subject to ongoing development and improvement.

(Comment 382) Some comments ask us to recognize that existing HACCP plans, such as those developed in accordance with the EU 2004 Food Hygiene law and GFSI-compliant food safety plans, can satisfy the requirements for what must be in a food safety plan.

(Response 382) To the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such

plans to meet the requirements of this rule. We expect that many existing plans will need only minor supplementation to fully comply with these requirements. Relying on existing records, with supplementation as necessary to demonstrate compliance with the requirements of the human preventive controls rule, is acceptable (see § 117.330).

(Comment 383) Some comments ask us to explain the differences between the food safety plan being established to implement FSMA and HACCP plans established under current requirements or guidelines for HACCP systems. These comments ask us to provide exporters

with background information and specific examples of differences, including how firms are directed to set their critical control points and critical limits.

(Response 383) Table 29 compares the provisions of the food safety plan required by this rule to the provisions of HACCP plans in some current requirements or guidelines for HACCP systems. See also the discussion in the 2013 proposed human preventive controls rule (78 FR 3646 at 3730–3732) and our memorandum comparing the provisions of this rule to various existing domestic and international HACCP-based standards (Ref. 65). This

rule does not specify how a facility would identify any applicable CCPs or critical limits. Importantly, this rule explicitly provides that preventive controls include controls other than those at CCPs that are also appropriate for food safety (§ 117.135(a)(2)(ii)). See also Response 2, in which we discuss both future guidance and a preventive controls training curriculum being developed by the FSPCA. We expect that both of these resources will help facilities, including foreign facilities, understand the requirements for a food safety plan.

TABLE 29—A COMPARING THE FOOD SAFETY PLAN TO HACCP PLANS

Requirements	PC Rule	NACMCF HACCP Guidelines	Codex HACCP Annex	Federal HACCP rules for juice, seafood, and meat and poultry
Written plan .. Who is responsible for preparing the plan?	Yes ..... The owner, operator or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan. The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.	Yes ..... A HACCP team may need assistance from outside experts knowledgeable in the hazards associated with the product and process.	Yes ..... Individual businesses, with advice when necessary from other sources.	Yes. The processor.
What does the plan contain?	<ul style="list-style-type: none"> <li>• Written hazard analysis .....</li> <li>• Written preventive controls</li> <li>• Written supply-chain program.</li> <li>• Written recall plan .....</li> <li>• Written procedures for monitoring the implementation of the preventive controls.</li> <li>• Written corrective action procedures.</li> <li>• Written verification procedures.</li> </ul>	<ul style="list-style-type: none"> <li>• Written hazard analysis .....</li> <li>• Must include the hazard, the CCPs, and critical limits.</li> <li>• Must include monitoring procedures.</li> <li>• Must include corrective actions.</li> <li>• Must include verification procedures.</li> <li>• Must include recordkeeping procedures.</li> </ul>	<ul style="list-style-type: none"> <li>• Written hazard analysis .....</li> <li>• Must include CCPs and critical limits.</li> <li>• Must include monitoring procedures.</li> <li>• Must include corrective actions.</li> <li>• Must include verification procedures.</li> <li>• Must include records .....</li> </ul>	<ul style="list-style-type: none"> <li>• Written hazard analysis.</li> <li>• Must list all food safety hazards that are reasonably likely to occur, CCPs, and critical limits.</li> <li>• Must list monitoring procedures.</li> <li>• Must include corrective action procedures.</li> <li>• Must include verification procedures;</li> <li>• Must include recordkeeping procedures.</li> </ul>
Is oversight required by a person qualified by training and experience?	Yes .....	Yes .....	Yes .....	Yes.

*D. Proposed § 117.126(c)—Records*

We proposed that the food safety plan is a record that is subject to the recordkeeping requirements of subpart F. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

*E. Comments on Potential Requirements for Submission of a Facility Profile to FDA*

We requested comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan (78 FR 3646 at 3768). This information, which could be referred to as a “facility profile,” could be submitted through an electronic form using a menu selection approach at the same time as facility registration, and could be updated biennially

simultaneously with the required biennial update of the food facility registration. We described potential benefits to having a facility’s food safety plan in advance of an inspection, such as aiding in the efficient oversight of preventive controls by allowing us to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly contamination with biological hazards). We noted that facilities could benefit from our advance

preparation through interaction with better-informed investigators and potentially reduced inspection time. We requested comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. We also requested comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

We noted that we had previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (**Federal Register** of May 11, 2012, 77 FR 27779). In contrast to the voluntary submission of food facility profile information described in that notice, in the 2013 proposed human preventive controls rule we requested comment on whether the submission of such information should be required.

(Comment 384) Some comments state that submission of a facility profile would be useful and support requiring such a submission. However, most of the comments that addressed our request for comments on such a submission express concern. Some comments assert that requiring submission of a facility profile is outside of FDA’s statutory authority under FSMA. Other comments assert that submitting a facility profile would

not advance food safety goals or have a commensurate benefit to food safety. Some comments express concern about protection of confidential information. Other comments express concern that we would misinterpret the submitted information in the absence of discussion with the facility. Some comments assert that receiving and evaluating the submitted information would be too time-consuming for FDA, whereas other comments assert that submitting the information would be too time-consuming for the facility. Some comments state that a subset of the information that would be submitted could be found in the Establishment Inspection Reports. Some comments assert that we could use information already available through the Reportable Food Registry to identify facilities that have needed to address a serious food safety violation and target our inspectional resources to those facilities. Some comments state that a facility profile is a not a static document and would be very difficult to keep up-to-date.

(Response 384) We have decided that we will not establish a requirement for submission of a facility profile. We will explore other mechanisms to achieve the goals we described in the 2013 proposed human preventive controls rule.

**XXV. Subpart C: Comments on Proposed § 117.130—Hazard Analysis**

We proposed requirements for hazard analysis, including hazard identification

and hazard evaluation. Some comments support the proposed requirements without change. For example, some comments support our proposal for the hazard analysis to address “known or reasonably foreseeable hazards” because this is consistent with Codex. Other comments agree that the hazard analysis should address both the severity of the potential hazard and the probability that the hazard will be present in a food product. Other comments state that testing for environmental pathogens may be impractical in certain situations for facilities in chemical plants that also produce food additives and that the proposed requirements for hazard evaluation make it clear that in such facilities environmental monitoring would not be required. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 385, Comment 395, Comment 406, and Comment 407) or ask us to clarify how we will interpret the provision (see, e.g., Comment 418).

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 30, with editorial and conforming changes as shown in table 52.

TABLE 30—REVISIONS TO THE PROPOSED REQUIREMENTS FOR HAZARD ANALYSIS

Section	Description	Revision
117.130(a)(1) .....	Requirement for a hazard analysis	Specify that a facility must “conduct a hazard analysis” to identify and evaluate known or reasonably foreseeable hazards, rather than merely specify that a facility must “identify and evaluate” known or reasonably foreseeable hazards.
117.130(a)(2) .....	Requirement for the hazard analysis to be written.	Clarify that the hazard analysis must be written, regardless of its outcome.
117.130(b)(1) and (b)(2) .....	Hazard identification .....	Emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).
117.130(b)(1)(iii) .....	Hazard identification .....	Add examples of physical hazards.
117.130(c)(1)(ii) .....	Hazard evaluation .....	Provide that hazard evaluation does not need to include an evaluation of environmental pathogens whenever RTE food is exposed to the environment prior to packaging if the packaged food includes a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.
117.130(c)(2)(x) .....	Hazard evaluation .....	Provide an example of “other relevant factor” that the hazard evaluation must consider (the example is the temporal (e.g., weather-related) nature of some of some hazards (e.g., levels of some natural toxins)).

*A. Proposed § 117.130(a)—Requirement for a Written Hazard Analysis*

We proposed that you must identify and evaluate, based on experience, illness data, scientific reports, and other

information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are significant hazards.

We also proposed that the hazard analysis must be written. As discussed in Response 126, we have revised the term “significant hazard” to “hazard requiring a preventive control.”

(Comment 385) Some comments ask us to specify that the rule requires a written hazard analysis even if the hazard analysis concludes that no hazards exist.

(Response 385) As proposed, the regulatory text would require a written hazard analysis even if the hazard analysis concludes that no hazards exist. To make this clearer, we have made two revisions to the regulatory text. First, we have revised the regulatory text to specify that a facility must “conduct a hazard analysis” to identify and evaluate known or reasonably foreseeable hazards, rather than merely specify that a facility must “identify and evaluate” known or reasonably foreseeable hazards. Second, we have revised the regulatory text to specify that the hazard analysis must be written regardless of its outcome.

(Comment 386) Some comments assert that a facility should not be able to conclude that no hazard exists in its production process and that any such conclusion reached should be a “red flag” to FDA investigators.

(Response 386) The purpose of a hazard analysis is to identify and evaluate known or reasonably foreseeable hazards to determine whether there are any hazards requiring a preventive control. If a facility appropriately determines, under the oversight of a preventive controls qualified individual, that no such hazards exist, then that is the outcome of its hazard analysis, and the facility must document that outcome in its written hazard analysis. (See also Response 222, Response 226, Response 229, Response 232, Response 397, Response 721, and Response 726.)

However, we agree that our investigators should take appropriate steps to evaluate a facility’s hazard analysis when the outcome is that there are no hazards requiring a preventive control. We expect that our investigators would both review the facility’s written hazard analysis and discuss the outcome with the facility. During the initial stages of implementation, we also expect that our investigators will ask subject matter experts in our Center for Food Safety and Applied Nutrition (CFSAN) to review such a hazard analysis. Over time, as our investigators gain experience with appropriate determinations that there are no hazards requiring a preventive control, we expect that there will be fewer circumstances in which our investigators would consult CFSAN about such an outcome.

(Comment 387) Some comments ask us to require facilities to provide supporting documentation in the hazard

analysis and assert that such a requirement would be consistent with the requirements of the FSIS HACCP regulation for meat and poultry.

(Response 387) We made no changes to the regulatory text to specifically require that a facility “provide supporting documentation” in its hazard analysis. A facility has flexibility to determine the appropriate content of its written hazard analysis, provided that the written hazard analysis complies with the requirements for hazard identification and hazard evaluation (see § 117.130(b) and (c)). A facility must be able to justify its hazard analysis decisions, even if the supporting documentation is not specifically included with the hazard analysis. For example, a facility that relies on one or more scientific publications to support its hazard analysis might include a bibliography listing the relevant publications, but not include a copy of the listed publications. Differences in the regulatory text of this rule compared to the FSIS HACCP regulation for meat and poultry reflect the flexible framework provided by FSMA but do not create a conflict.

(Comment 388) Some comments ask us to modify the provision to specify that the hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility, *including hazards in the raw materials and ingredients used in the food* (emphasis added).

(Response 388) We decline this request. Other provisions in the requirements for hazard analysis specify that the hazard evaluation must consider raw materials and ingredients (see § 117.130(c)(2)(iii)). It is not necessary to repeat the specific requirements associated with the hazard evaluation in the provision that directs each facility to conduct a hazard analysis.

(Comment 389) Some comments ask us to modify the provision to use “or” instead of “and” in the clause “based on experience, illness data, scientific reports, and other information” because it is not necessary to evaluate all of the specified criteria in all cases.

(Response 389) We decline this request. We agree that in some cases some of the specified types of information may not be available. For example, if a food product has not been associated with foodborne illness, there would be no illness data. However, modifying the provision as suggested by the comments would establish a regulatory requirement in which a facility could pick and choose which

information to evaluate, irrespective of whether the information is available.

(Comment 390) Some comments point out that the Codex HACCP Annex includes “mileposts” for the identification of hazards, recommending that the HACCP Annex apply to “all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.” These comments ask us to include such “mileposts” in the requirements to conduct a hazard analysis to put the regulations in better alignment with the Codex HACCP Annex and underscore the fact that food producers cannot anticipate or be responsible for customer behavior that is contrary to general principles of food safety.

(Response 390) By “mileposts” for hazard identification, we assume that the comments are referring to the steps included in the Codex HACCP Annex regarding the recommendation to list all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards. These steps include consideration of: (1) The likely occurrence of hazards and severity of their adverse health effects; (2) the qualitative and/or quantitative evaluation of the presence of hazards; (3) survival or multiplication of microorganisms of concern; (4) production or persistence in foods of toxins, chemicals or physical agents; and (5) conditions leading to these factors (Ref. 34).

We agree that a hazard analysis should address known or reasonably foreseeable hazards at each step from primary production, processing, manufacture, and distribution until the point of consumption. For example, a facility that produces cut or shredded RTE carrots might consider pathogens such as *Salmonella* that can occur at primary production; metal from the slicers or shredders, and *L. monocytogenes* as an environmental pathogen, during manufacturing/processing; and refrigeration until the end of the shelf life to prevent the growth of pathogenic sporeforming bacteria.

However, to the extent that these comments are asserting that a facility can ignore consumer behavior that the facility considers contrary to principles of food safety, we disagree. For example, a facility could not conclude that it need not identify and evaluate known or reasonably foreseeable hazards because the facility intends to provide cooking instructions on the label of a packaged food. Consumer research indicates that

consumer cooking practices are not uniform and that many consumers do not follow some cooking instructions, such as those on frozen foods or directions specifying that a product should be cooked until it reaches a certain temperature (Ref. 66) (Ref. 67).

(Comment 391) Some comments ask us to require that the hazard analysis be re-evaluated every three years and updated as needed.

(Response 391) The written hazard analysis is one component of the food safety plan, and the food safety plan is subject to reanalysis at least every three years (see § 117.170).

(Comment 392) Some comments state that the standard for hazard analysis in the human preventive controls rule should both align with the re-proposed requirements for hazard analysis set forth in the supplemental FSVP notice and be consistent with the statutory standard for hazard analysis in section 418(b)(1) of the FD&C Act.

(Response 392) We have aligned the requirements of the human preventive controls rule and the proposed FSVP rule to the extent practicable, consistent with the applicable statutory requirements.

(Comment 393) Some comments ask us to endorse a template, format, or style to be used for a hazard analysis to ensure these analyses are conducted consistently across the food industry and that auditors are consistent in their evaluation.

(Response 393) We decline this request. See Response 373.

#### *B. Proposed § 117.130(b)—Hazard Identification*

We proposed that the hazard identification must consider hazards that include biological, chemical, and physical hazards. We proposed to list examples of biological hazards (*i.e.*, microbiological hazards such as parasites, environmental pathogens, and other pathogens) and chemical hazards (*i.e.*, radiological hazards and substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens). In the preamble (78 FR 3646 at 3734)], we provided examples of physical hazards (*i.e.*, stones, glass, or metal fragments that could inadvertently be introduced into food) but did not propose to include these examples in the regulatory text.

We also proposed that the hazard identification must consider hazards that may be present in the food if they occur naturally, may be unintentionally introduced, or may be intentionally introduced for purposes of economic gain.

(Comment 394) As discussed in Comment 126, some comments express concern that the rule would refer to multiple levels of hazards (*i.e.*, “hazards,” “known or reasonably foreseeable hazards,” and “significant hazards” (which we now refer to as “hazards requiring a preventive control”) and ask us to provide sufficient clarity to be able to distinguish between these types of hazards.

(Response 394) As discussed in Response 126, we have revised the requirements for hazard identification to emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).

(Comment 395) Some comments ask us to include examples of physical hazards in the regulatory text.

(Response 395) We have added stones, glass, and metal fragments as examples of physical hazards in the regulatory text. This is consistent with the regulatory text for biological and chemical hazards, even though the hazards listed in section 418(b)(1) of the FD&C Act include examples of chemical and biological hazards but do not include examples of physical hazards.

(Comment 396) Some comments ask us to separately list some hazards (such as parasites and drug residues) rather than include them as examples of biological hazards and chemical hazards.

(Response 396) We decline this request. Although section 418(b)(1)(A) of the FD&C Act lists such items separately, we believe it is clearer to acknowledge that some of the hazards listed in the statute are in fact a subset of the broader categories of biological and chemical hazards.

(Comment 397) Some comments ask us to rephrase the requirement for hazard identification to specify “The hazard analysis must identify hazards” rather than “The hazard identification must consider hazards.”

(Response 397) We decline this request. The provision is directed to the first step of a hazard analysis—*i.e.*, hazard identification—rather than to the overall hazard analysis (which is addressed in § 117.130(a)). The purpose of the hazard identification is to consider the types of hazards listed in the provision as a step in determining whether there are any hazards requiring a preventive control; the suggestion of the comments implies that such hazards will always be identified. As discussed in Response 386, the outcome of a hazard analysis for a food product could be that there are no hazards requiring a preventive control.

(Comment 398) Some comments ask us to broaden the examples listed for chemical hazards to include “allergens and ingredients associated with food sensitivities.”

(Response 398) We decline this request. Although the presence of an undeclared ingredient associated with a food sensitivity (such as the color additive Yellow #5) can be considered a chemical hazard for the sensitive population, it is neither practical nor necessary for the list of examples of chemical hazards in the regulatory text to be exhaustive.

(Comment 399) Some comments assert that we should not require all food safety plans to specifically address the likelihood of radiological hazards.

(Response 399) The rule only requires that a facility consider whether radiological hazards are known or reasonably foreseeable, and we have described situations where radiological hazards could be considered to be known or reasonably foreseeable (78 FR 3646 at 3667). A facility that appropriately determines that no radiological hazards are known or reasonably foreseeable would document that determination in its written hazard analysis but would not need to establish preventive controls and associated preventive control management components to address radiological hazards.

(Comment 400) Some comments addressing radiological hazards ask us to clarify that radiological hazards are an example of chemical hazards; clarify the requirements by identifying specific radiological hazards and including them in the regulatory text; develop a baseline for acceptable levels and specific monitoring recommendations for each product; defer compliance on the control of radiological hazards until more comprehensive information is available to industry and regulators on how best to control for and assess compliance in controlling the hazard; clarify whether irradiation of produce for phytosanitary purposes must be considered as a potential radiological hazard; confirm that a facility is required to assess only two types of radiological hazards (production water and accidental contamination from accidental release from a nuclear facility); and clarify whether we will require consideration of radiological hazards by processors subject to our HACCP regulations for seafood and juice.

(Response 400) The regulatory text specifies that radiological hazards are an example of chemical hazards. We decline the requests to identify specific radiological hazards, include them in

the regulatory text, and develop a baseline for acceptable levels, with specific monitoring recommendations for each product type. As discussed in the 2013 proposed human preventive controls rule (78 FR 3646 at 3667), radiological contamination of foods is a rare event. The most relevant information that would lead a food facility to consider and evaluate a specific radiological hazard to determine whether it is a hazard requiring a preventive control would be publicly disseminated information following a particular event, such as contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. We already have issued guidance on levels of concern for radionuclides that could be a known or reasonably foreseeable hazard in certain circumstances, such as after an accident at a nuclear facility (Ref. 68). In light of this current guidance, we see no reason to provide additional guidance to address hypothetical circumstances or to defer compliance until more information is available.

A facility does not need to consider sources of radiation used in accordance with a food additive regulation in its hazard analysis. Such sources are safe for their intended use. As with any other equipment and substances used in the manufacture of food, a facility must comply with all applicable safety requirements established either under the terms of a food additive regulation or by an authority such as the Occupational Safety and Health Administration. Although production water and accidental contamination from accidental release from a nuclear facility would be the two most likely sources of radiological hazards that a facility would need to address, we are not limiting the facility's responsibilities to these two sources. We cannot anticipate the future.

We have not taken action to revise either our HACCP regulations for seafood and juice or our current guidance on hazards and controls for seafood and juice (Ref. 42) (Ref. 43) to require or recommend that processors of those products address radiological hazards in their food safety plans. However, in the event of a situation such as an accident at a nearby nuclear facility, it would be prudent for such processors to consider whether the potential for contamination with radiological hazards would warrant modification of their food safety plans.

(Comment 401) Some comments assert that predictable intentional hazards should be in the food safety

plan but unexpected intentional hazards should be part of a food defense plan.

(Response 401) This rule only requires a facility to consider intentionally introduced hazards when such hazards are introduced for purposes of economic gain. Hazards that may be intentionally introduced by acts of terrorism are the subject of the 2013 proposed intentional adulteration rule (78 FR 78014, December 24, 2013).

(Comment 402) Some comments disagree that the human preventive controls rule should address hazards that are intentionally introduced for purposes of economic gain (economically motivated adulteration). Some of these comments assert that economically motivated adulteration is not a good fit for the hazard analysis and preventive controls framework because it is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards. Some comments state that traditional food safety hazards are primarily both identified and addressed at the facility level, but economically motivated adulteration is typically handled by the corporate parent company, where supply chain management programs are typically located. These comments also assert that food safety-related economically motivated adulteration is extremely rare and that predicting economically motivated adulteration to prevent it is extremely difficult. Some comments assert there will be no measurable benefit to food safety by imposing requirements to consider economically motivated adulteration as part of a food safety plan and that doing so will consume limited resources without a corresponding increase in consumer protection. Other comments assert that there is no need to require a facility to identify hazards intentionally introduced for purposes of economic gain because the misbranding and adulteration provisions of the FD&C Act already sufficiently provide safeguards against economic gain.

(Response 402) We agree with the comments stating that the requirement to consider hazards intentionally introduced for purposes of economic gain is narrow. Such hazards will be identified in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. In addition, we define hazards to only include those agents that have the potential to cause illness or injury. Economically motivated adulteration that affects product integrity or quality, for example, but not food safety, is out of the scope of this

rule. We continue to believe that there is benefit in taking this preventive approach to economically motivated adulteration, and not solely on enforcing the preexisting misbranding and adulteration provisions of the FD&C Act after a violation occurs.

As discussed in sections XLII through XLIX, we are finalizing supply-chain program provisions. It is consistent with the framework of this rule for a facility to address hazards requiring a preventive control that may be intentionally introduced for purposes of economic gain through the facility's supply-chain program.

(Comment 403) Some comments express concern about identifying hazards that may be intentionally introduced for purposes of economic gain because there are potentially an unlimited number of unknown or yet-to-be-identified hazards that could be intentionally introduced for purposes of economic gain by an unscrupulous supplier. These comments disagree with our attempt to narrow the field of potential scenarios for economically motivated adulteration to circumstances where there has been a pattern of such adulteration in the past.

Some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration is both too broad and too narrow at the same time. These comments assert that our attempt is too broad, because we expect facilities to consider patterns of adulteration from the past "even though the past occurrences may not be associated with the specific supplier or the specific food product" and a requirement to consider every potential product and potential supplier makes the task open ended. These comments further assert that our attempt is too narrow, because a focus on patterns of adulteration in the past is unlikely to reveal potential future instances of economically motivated adulteration and because those intending to defraud purchasers for economic gain are trying to avoid detection. According to these comments, once a food safety-related instance of economically motivated adulteration is uncovered, perpetrators quickly move to carry out their fraudulent activities in a different way. Some comments assert that there are alternative ways to control hazards that may be intentionally introduced for purposes of economic gain without specific regulatory requirements, such as by having an effective supplier approval program with appropriate qualification and verification activities; through business-to-business relations, expectations, and contracts; and through

a vulnerability assessment and control plan tailored specifically to economically motivated adulteration.

(Response 403) We disagree that the requirement is too broad. A facility must conduct a hazard analysis for each type of food manufactured, processed, packed, or held at the facility. There is no requirement to consider every potential product or potential supplier. We also disagree that the requirement is too narrow. Some individuals intending to defraud purchasers for economic gain will develop entirely novel ways of adulterating food to suit their purposes. We agree that these circumstances may not lend themselves to the preventive approach required here. We encourage, but do not mandate, that facilities adopt other measures they deem appropriate to mitigate the risks of economically motivated adulteration that this rulemaking does not address. Still, the repeated economically motivated adulteration of spices with toxic colorants demonstrates that patterns of economically motivated adulteration can emerge and should be considered as part of a food safety plan (see the examples in the 2014 supplemental human preventive controls notice, 79 FR 58524 at 58550–58551).

(Comment 404) Some comments ask us to limit the requirement to identify hazards that may be introduced for purposes of economic gain to only those hazards that pose a risk to public health for which there has been a pattern in the past. Some comments assert that in those few instances where a hazard was intentionally introduced the underlying intention was to defraud rather than to cause harm, and the food safety hazard was an unintended consequence. Some comments ask us to focus the hazard identification solely on inbound products, because it is obvious that hazards introduced by the facility itself will not be prevented through a hazard analysis. Some comments ask us to narrow the scope of the requirement by specifying that facilities focus on three situations: (1) Situations in which there has been a pattern of similar adulteration in the past; (2) foods or ingredients for which quality assurance methods may not sufficiently characterize the food or ingredient to assure its identity, and; (3) foods or ingredients for which there are substitutes that are likely to be harmful that would be considered obvious to one skilled in food science.

(Response 404) We decline to make the changes suggested in these comments, because they are unnecessary. Because of our definition of hazard, the requirement is already limited to economically motivated

adulteration that has the potential to cause illness or injury. Under the final rule, a facility does not need to identify a hazard related to economically motivated adulteration when there is no risk to public health or when the economically motivated adulteration is not known or reasonably foreseeable.

We agree that the three circumstances suggested by the comments are an appropriate focus for facilities who seek guidance on how to approach the requirements, but decline the request to specify these limitations of the scope in the regulatory text. As already noted, some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration is both too broad and too narrow at the same time (see Comment 403). Although we continue to believe that the instances in which a facility will identify a hazard intentionally introduced for economic gain will be rare, we also consider that limiting the scope of the requirement in the regulatory text would be both prejudging the future and inconsistent with the public health objectives of this rule.

(Comment 405) Some comments ask us to allow implementation of the major provisions in FSMA before establishing requirements to address economically motivated adulteration. These comments assert that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. In addition, because economically motivated adulteration is typically addressed through product specifications, supplier relationships, and good business practices, implementation of these other provisions of the human preventive controls rule are likely to have a positive effect on preventing economically motivated adulteration.

(Response 405) We disagree that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. Hazards intentionally introduced for economic gain are addressed here with the same preventive framework as every other hazard. As such, we do not see a compelling reason to delay implementation of the requirements to address economically motivated adulteration.

### *C. Proposed § 117.130(c)—Evaluation of Whether a Hazard Requires a Preventive Control*

We proposed that the hazard analysis must include an evaluation of the identified hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that

the hazard will occur in the absence of preventive controls; and environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen (proposed § 117.130(c)(1)). We also proposed that the hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer: (1) The formulation of the food; (2) the condition, function, and design of the facility and equipment; (3) raw materials and ingredients; (4) transportation practices; (5) manufacturing/processing procedures; (6) packaging activities and labeling activities; (7) storage and distribution; (8) intended or reasonably foreseeable use; (9) sanitation, including employee hygiene; and (10) any other relevant factors (proposed § 117.130(c)(2)).

(Comment 406) Some comments ask us to revise the requirement to include an evaluation of environmental pathogens to avoid the implication that an intervention is needed when there may be other controls (such as pH or formulation) that would significantly minimize or prevent the pathogen. These comments suggest that we revise the provision to require that a hazard evaluation include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment “or otherwise include a control measure” that would significantly minimize the pathogen.

(Response 406) We have revised the provision on the hazard evaluation for environmental pathogens to specify that the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. We agree that controls such as formulation can function as a “kill step” and that the provision should make clear that such controls can be used in lieu of “treatment.”

(Comment 407) Some comments ask us to clarify what we meant by “other relevant factors” and note that natural disasters (which we previously discussed) (78 FR 3646 at 3738) are “usually exceptional events” that are best managed in a facility crisis management plan. Other comments ask us to specify that the hazard evaluation must consider any relevant geographic, temporal, agricultural, or other factors that may affect the severity or probability of the hazard.



(Response 407) We included “other relevant factors” to emphasize that the list of factors in the provision is not an exhaustive list and that a facility is responsible to consider those factors that play a role in its determination of whether a potential hazard is a hazard requiring a preventive control, regardless of whether those factors are listed in the provision. A facility that already addresses circumstances such as natural disasters in other plans may consider the applicable part of those plans to be part of its food safety plan (see § 117.330).

We agree that geographic, temporal, and agricultural factors are examples of “other relevant factors.” For example, hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some RACs are more of a problem in some years than in others. We have added the temporal nature of some hazards associated with some RACs as an example of “other relevant factors” to consider (see § 117.130(c)(2)(x)).

(Comment 408) Some comments assert that it is unnecessary to establish a specific provision that identifies environmental pathogens as a hazard that is required to be evaluated.

(Response 408) We are retaining the provision, which we proposed to highlight the importance of environmental pathogens in some facilities and to make clear that sanitation controls, with appropriate verification, may be necessary in addition to sanitation measures that the facility establishes as a matter of CGMP.

(Comment 409) Some comments assert that it can be difficult to determine “the severity of the illness or injury if the hazard were to occur” for a food that is not RTE food, especially for raw materials and ingredients.

(Response 409) We acknowledge that determining the severity of the illness or injury if the hazard were to occur can be more difficult for some foods than for other foods. However, recent outbreaks and large-scale recalls demonstrate the potential for some raw materials and other ingredients to cause serious illness or injury (78 FR 3646 at 3656 and 3737). For reasons such as these, the rule requires that a facility identify and evaluate multiple sources of information (*i.e.*, experience, illness data, scientific reports, and other information) and also requires that the food safety plan (which includes the written hazard analysis) be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (see § 117.126(a)(2)).

(Comment 410) Some comments ask us to provide that a facility may rely on

existing systems in place to manage radiological risks, such as steps taken by government officials to inspect ingredients obtained from a geographic region that has been the subject of a nuclear accident.

(Response 410) A facility may consider all available resources in appropriately determining whether a known or reasonably foreseeable radiological hazard is a hazard requiring a preventive control and in appropriately determining what preventive controls, and associated preventive control management components, to establish and implement in light of a radiological hazard that is a hazard requiring a preventive control. However, existing systems in place to manage radiological risks, such as after a nuclear accident, do not absolve a facility of its responsibilities to establish and implement preventive controls to address a radiological hazard when circumstances warrant.

(Comment 411) Some comments assert that there would be no need to evaluate an environmental pathogen if the finished food is inherently incapable of supporting pathogen survival (*e.g.*, in acid or acidified foods). These comments ask us to modify the requirement to narrow the circumstances when it would apply to whenever an RTE food is “capable of supporting pathogen growth to, or survival at, infectious levels.”

(Response 411) The suggestion of the comments pre-judges the outcome of the hazard analysis for a wide variety of food products. A facility can consider factors such as whether the formulation of a food would not support the growth of the pathogen to increased numbers, or would cause pathogens to die off over time, in determining whether an environmental pathogen is a hazard requiring a preventive control. Importantly, for many pathogens the mere presence of the pathogen presents a risk of illness, and the time necessary for pathogens in the food to die off due to the formulation of the food varies. Thus, a facility that appropriately determines that an environmental pathogen is not a hazard requiring a preventive control due to factors such as formulation of a food would need to document the basis for its determination in its written hazard analysis.

(Comment 412) Some comments ask us to include a definition for “exposed to the environment” to avoid confusion. These comments state their understanding that this phrase means that the product is in a form that is exposed and/or subject to direct human contact.

(Response 412) We decline this request. It is not necessary to define every term and phrase included in the rule. See the Appendix to the 2013 proposed preventive controls rule for examples of food products that are, or are not, exposed to the environment (78 FR 3646 at 3819). In the context of doing a hazard analysis, the facility must appropriately determine whether contamination of RTE foods with pathogenic organisms from the production environment can occur; to make such an appropriate determination does not require a definition of “exposed to the environment.”

(Comment 413) Some comments assert that the proposed requirement to consider the effect of “intended or reasonably foreseeable use” on the safety of the finished food for the intended consumer is too open-ended and vague to provide clear direction to industry and regulators pertaining to compliance obligations. These comments ask us to substitute “expected use” for “intended or reasonably foreseeable use.”

(Response 413) We decline this request. We agree that the term “expected use” has potential to communicate both intended use and reasonably foreseeable use but disagree that this interpretation would be universal. We are retaining “intended or reasonably foreseeable use” to be explicit that a facility must consider what is reasonably foreseeable in addition to what is intended. (See also Response 121.)

(Comment 414) Some comments express concern about the potential for a hazard evaluation to overlook food allergens and assert that food allergens must be designated as significant hazards whenever they occur. Other comments assert that a determination of whether a food allergen is a significant hazard should consider protein levels in ingredients. Other comments assert that food allergens are not a problem in produce, except for tree nuts.

(Response 414) The hazard identification must consider chemical hazards, including food allergens (§ 117.130(b)(1)(ii)). Thus, food allergens cannot be overlooked. Whether the protein level of a food allergen in ingredients is a factor that must be considered in the hazard evaluation would be determined by the preventive controls qualified individual who must conduct or oversee the hazard analysis. We agree that most produce does not satisfy the definition of food allergen, but the evaluation of whether a food allergen hazard exists in any particular food still must be considered by the preventive controls qualified individual

who must conduct or oversee the hazard analysis.

(Comment 415) Some comments ask us to specify that the hazard evaluation be more specific about issues relevant to raw materials and ingredients, including how raw materials are selected and shipped, how suppliers are evaluated, and how shipments are inspected on receipt.

(Response 415) We decline this request. When a hazard requiring a preventive control in a raw material or other ingredient is controlled before receipt, the receiving facility would address such specifics in the supply-chain program that would be required as a preventive control (see subpart G). In addition, the rule already specifies that the hazard evaluation must consider the effect of raw materials and other ingredients on the finished food (§ 117.130(c)(2)(iii)).

(Comment 416) Some comments ask us to specify that a hazard evaluation consider the history of the class of product causing outbreaks from a particular pathogen.

(Response 416) We decline this request. The rule already specifies that the hazard analysis must be based on experience, illness data, scientific reports, and other information (see § 117.130(a)).

(Comment 417) Some comments assert that a facility that exports fresh fruit to the United States should not be required to consider storage and distribution of the food because storage and distribution are parts of the supply chain that are not known or controlled by the supplier. These comments also assert that records showing where the facility sent the food should suffice when a facility exports fresh fruit to the United States. Likewise, some comments assert that a facility that exports fresh fruit to the United States should not be required to consider intended or foreseeable use because the facility could not necessarily ascertain the intended or foreseeable use.

(Response 417) Each facility is part of a complex food supply chain and a supplier must consider how its food products are likely to be stored, distributed, and used. For example, entities that transport a food product generally rely on the shipper (in this case, the facility exporting the fruit) to provide information relevant to the safe handling of the food during transport. As another example, a facility exporting fruit could simply assume that its food product will be consumed without any processing to reduce any pathogens that may be on the fruit, unless it knows that its food product is destined for a commercial processing facility that

makes processed fruit products using processes to adequately control pathogens.

(Comment 418) Some comments note our previous discussion about conducting a hazard evaluation for pathogens, including addressing whether a specific product has been documented to be contaminated with such pathogens (78 FR 3646 at 3737). These comments ask us to clarify what we mean by “documented,” particularly in the context of a single incident.

(Response 418) We expect a facility to take appropriate steps to remain aware of current reports of food contamination. For example, such reports are often disseminated through press releases that we post on our Web site when firms send them to us, and a facility can subscribe to our service that alerts interested persons to recalls, market withdrawals, and other safety alerts (Ref. 69). In appropriately determining whether a pathogen is a hazard requiring a preventive control, the facility would consider factors such as the severity of the hazard and the probability that the hazard would occur in the absence of preventive controls. Whether a single incident warrants consideration of a pathogen as a hazard requiring a preventive control may depend on the incident.

(Comment 419) Some comments ask us to specify that the hazard analysis consider the impact of a pathogen on high-risk populations.

(Response 419) We decline this request. The rule requires that a hazard evaluation consider the severity of the illness or injury if the hazard were to occur. This evaluation would consider the expected population of consumers and the severity of consequences when the expected population is exposed to a pathogen that is a known or reasonably foreseeable hazard in the food.

(Comment 420) Some comments assert that the proposed requirements for hazard evaluation could be interpreted in many ways. For example, a facility could conclude that the presence of a hand sink or boot dip prior to entering the processing area will reduce the likelihood of environmental pathogens and that environmental pathogens are not a significant hazard, whereas a regulator could interpret this provision to mean that a facility must always consider an environmental pathogen to be a significant hazard when the criteria in the provision are met, unless the facility can provide evidence to the contrary.

(Response 420) We agree that the requirements for hazard evaluation are subject to alternative interpretations. This is often the case, particularly when

a regulation is new. The provision specifies that a facility must evaluate whether an environmental pathogen is a hazard requiring a preventive control in particular circumstances—*i.e.*, whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. The written hazard analysis must be prepared (or its preparation overseen by) a preventive controls qualified individual (see § 117.126(a)(2) and (b)(1)). The preventive controls qualified individual for a facility that determines that an environmental pathogen is not a hazard requiring a preventive control in such circumstances must document that determination, and a regulator would consider the adequacy of the facility’s documented determination before reaching a conclusion as to whether the facility had failed to satisfy the requirements. However, the use of a hand sink or boot dip prior to entering the processing area to reduce the likelihood of environmental pathogens may also be considered to be part of the sanitation controls for the environmental pathogen.

(Comment 421) Some comments assert that the hazard assessment must document that the benefits of using a particular chemical outweigh the potential risks, such as the risks of the chemical causing antibiotic resistance. Other comments ask us to consider the factors listed in the provision for potential benefits, as well as risks.

(Response 421) A hazard is an agent that is reasonably likely to cause illness or injury in the absence of its control (§ 117.3). As previously discussed, the focus of the requirement on risk (*i.e.*, the severity of the hazard and the likelihood that it will occur) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry (78 FR 3646 at 3735). None of these national or international guidelines or regulations suggest that a risk-benefit analysis is part of a hazard analysis.

Moreover, these comments appear to be directed to a determination by a facility of which raw materials or other ingredients to intentionally add to a food product rather than to biological, chemical, or physical hazards that, for example, occur naturally in the raw materials or other ingredients or may be unintentionally introduced. Any raw material or other ingredient that a facility adds to a food product must be lawful. This rule does not address the

criteria for determining whether a particular raw material or other ingredient is lawful under the applicable statutory provisions (e.g., under section 409 of the FD&C Act regarding food additives).

(Comment 422) Some comments object to the use of sucrose fatty acid esters as an example (in our previous discussion, 78 FR 3646 at 3737) for distinguishing between raw materials and ingredients because sucrose fatty acid esters are an obscure product and the example does not clearly distinguish between the two terms.

(Response 422) As discussed in Response 65, we have decided to return to the phrase “raw materials and other ingredients” (rather than the proposed phrase “raw materials and ingredients”) throughout the rule to make it clear that raw materials are ingredients. As a result, it is not necessary to provide a more broadly applicable example to distinguish between the terms.

(Comment 423) Some comments ask us to clarify how the requirements of this rule apply to transportation practices and assert that a facility receiving product should not be responsible for hazards in foods that are not being transported under its custody. Other comments assert that we should require all entities across the supply chain to identify food transportation as a critical control point under the facility’s hazard analysis.

(Response 423) We address specifics about the responsibilities of shipping facilities and receiving facilities in the 2014 proposed sanitary transportation rule (79 FR 7006). We will address comments regarding the responsibilities of shippers and receivers in the final sanitary transportation rule. For the purpose of the hazard analysis, whether a particular facility would identify food transportation as a critical control point through its hazard analysis would depend on the circumstances, such as whether the food is a TCS food. We expect a facility that identifies temperature control, including during transportation, as a preventive control (whether or not as a CCP), to communicate the need for appropriate temperature control to the person transporting the food.

(Comment 424) Some comments ask us to clarify our previous statements (78 FR 3646 at 3737) regarding whether and how label information, such as cooking instructions, may be a factor to consider in a hazard evaluation.

(Response 424) See Response 390 regarding consumer research about consumer cooking practices.

**XXVI. Subpart C: Comments on Proposed § 117.135—Preventive Controls**

We proposed requirements to identify and implement preventive controls to provide assurances that significant

hazards will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Some comments support the proposed requirements without change. For example, some comments agree that preventive controls must be written and include process controls, food allergen controls, sanitation controls, a recall plan, and other controls as appropriate and necessary. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 428, Comment 431, Comment 432, and Comment 439) or ask us to clarify how we will interpret the provision (see, e.g., Comment 425, Comment 437, and Comment 440).

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 31, with editorial and conforming changes as shown in table 52.

TABLE 31—REVISIONS TO THE PROPOSED REQUIREMENTS FOR PREVENTIVE CONTROLS

Section	Description	Revision
117.135(c)(1) .....	Process controls .....	Clarify that the requirements for process controls depend on the role of the process control in the food safety system.
117.135(c)(2)(i) .....	Food allergen controls .....	Specify that food be protected from allergen cross-contact during handling, as well as during storage.

**A. Proposed § 117.135(a)—Requirement To Identify and Implement Preventive Controls**

We proposed that you must identify and implement preventive controls, including at critical control points, if any, to provide assurances that significant hazards will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. We also proposed that these preventive controls include controls at CCPs, if there are any CCPs, and controls, other than those at CCPs, that are also appropriate for food safety.

Some comments support the flexibility provided to facilities to

implement preventive controls that are appropriate to the facility and the food. Other comments support the clarification, in the 2014 supplemental human preventive controls rule, that not all preventive controls are established at CCPs and that some food safety plans will have not CCPs. We are finalizing the provision as proposed with the editorial and conforming changes in table 52.

**B. Proposed § 117.135(b)—Requirement for Written Preventive Controls**

We proposed that preventive controls must be written.

(Comment 425) Some comments from the almond industry explain that USDA’s regulations for a mandatory program for reduction of *Salmonella* on almonds require almond handlers

(facilities) to subject almonds to a process that delivers a minimum 4-log destruction of *Salmonella*. The process can be applied by the almond handler (facility) or off-site at a “custom processor.” These comments agree that preventive controls should be written, but ask us to clarify whether documentation of treatment by its “custom processor” would be accepted as a “written preventive control” when the “custom processor” controls the hazard.

(Response 425) The question posed by these comments highlights the difference between the records required in the food safety plan and the records documenting the implementation of the food safety plan. The “written preventive controls” are part of the food safety plan, whereas the records

documenting treatment are implementation records. Implementation records documenting treatment, whether by a facility or its “custom processor,” would not satisfy the requirements for written preventive controls. However, specifying that the preventive control for a specific hazard is a particular treatment by a “custom processor,” along with information that describes the treatment, would satisfy the requirement for written preventive controls.

#### *C. Proposed § 117.135(c)(1)—Process Controls*

We proposed that preventive controls include process controls as appropriate to the facility and the food. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the applicable control, parameters associated with the control of the hazard, and the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(Comment 426) Some comments state that assigning a parameter and associated minimum and maximum values for some process controls (such as refrigeration (including freezing), baking, or water activity) may be possible, but not be necessary for food safety. These comments ask us to require minimum and maximum values to be assessed against the applicable food safety need, or otherwise make clear that the implications of not controlling minimum and maximum values must be assessed in light of the circumstances. Other comments express concern that “as appropriate to the applicable control” could be interpreted as suggesting that if it is merely feasible to establish parameters for a process control, they must be established. Other comments express concern that the proposed requirement suggests that if a parameter is not “controlled,” a regulator could conclude that the facility is not in compliance with the rule because it necessarily has not significantly minimized or prevented a significant hazard.

One comment provides two examples of refrigeration controls to explain its view that the management components for refrigeration controls will vary depending on the role of refrigeration within the facility’s overall food safety system. (See Comment 455.) This comment also provides an example to

make a point that water activity may not be necessary for food safety even when maximum or minimum values are assigned. In this example, a parameter for water activity could be set at less than 0.85 based on the control of *Staphylococcus aureus*, but such a parameter would not be necessary for food safety for a product such as a dry seasoning blend that has a water activity of 0.2–0.3. This comment also notes that when there are many different controls working together to minimize or prevent one hazard simultaneously (such as a formulation that uses a combination of moisture, pH, titratable acidity, and salt level), noncompliance with any one parameter will not necessarily result in an unsafe product.

(Response 426) See Response 455. We have revised the regulatory text to specify that process controls must include parameters and minimum or maximum values as appropriate to both the nature of the applicable control and its role in the facility’s food safety system.

(Comment 427) Some comments ask us to delete the phrase “to significantly minimize or prevent a significant hazard.”

(Response 427) We decline this request. “Significantly minimize or prevent a significant hazard” (which we have revised to “significantly minimize or prevent a hazard requiring a preventive control”) is the standard for controlling the hazards. Although the phrase could be viewed as redundant with the standard in the requirement to identify and implement preventive controls (§ 117.135(a)(1)), repeating that standard in the requirements for parameters and the minimum or maximum values associated with control of the hazard emphasizes the standard, which is appropriate for process controls.

#### *D. Proposed § 117.135(c)(2)—Food Allergen Controls*

We proposed that preventive controls include, as appropriate to the facility and the food, food allergen controls that include those procedures, practices, and processes employed for ensuring protection of food from allergen cross-contact, including during storage and use, and for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act.

(Comment 428) Some comments ask us to specify that food be protected from allergen cross-contact during handling, as well as during storage.

(Response 428) We have revised the provision as requested by the comments.

(Comment 429) Some comments assert that food allergen controls should be based on hazard analysis and risk. Other comments provide examples of existing industry guidance that addresses food allergen controls. Some comments note that food allergen controls are addressed in the PMO (e.g., Appendix K, the voluntary HACCP program).

Other comments assert that establishing food allergen controls at this time is premature or that food allergen controls need to be balanced with pathogen controls. Some comments ask us to clarify whether the standard that would be established for food allergen controls is “absolutely allergen free.”

(Response 429) We have acknowledged that it is premature to require validation of food allergen controls (see 78 FR 3646 at 3755 and Response 515). However, we disagree that requiring a facility to establish food allergen controls as a preventive control is premature at this time, as evidenced by the existing industry guidance, and requirements of programs such as Appendix K of the PMO, submitted by comments. We agree that whether a facility appropriately determines that food allergen controls are necessary will be based on the outcome of the hazard analysis (see the requirements for hazard analysis in § 117.130(a) and (c)). A facility that already has established food allergen controls based on recommendations in industry guidelines or requirements of programs such as the voluntary HACCP program of the PMO can incorporate those established food allergen controls into its own, facility-specific food safety plan, and rely on its existing records for those food allergen controls to demonstrate compliance with the requirements of this rule (see § 117.330). Whether a facility needs to establish food allergen controls in addition to pathogen controls depends on the outcome of the facility’s hazard analysis; a facility that determines that both allergens and pathogens are hazards requiring a preventive control in the manufacturing, processing, packing, or holding of a food product must address both hazards.

The requirements for food allergen controls do not establish a particular standard. In general, when we do establish a standard we avoid “absolute” standards such as the “absolutely allergen free” standard mentioned by the comment.

We appreciate receiving examples of food allergen control guides.

(Comment 430) Some comments ask us to revise the proposed requirement from “food allergen controls must

include” to “food allergen controls include.”

(Response 430) In the 2014 supplemental human preventive controls notice, we proposed a series of revisions to the overall framework of the requirements for hazard analysis and risk-based preventive controls, including revisions to the requirements for preventive controls to emphasize that the preventive controls that a facility must establish and implement are those appropriate to the facility and the food (79 FR 58524 at 58541–58543). With respect to food allergen controls, we proposed to first specify what food allergen controls “include” (*i.e.*, procedures, practices, and processes to control food allergens), as requested by these comments. However, we also proposed to continue to specify minimum requirements for what food allergen controls must include when a facility determines that a food allergen is a hazard requiring a preventive control—*i.e.*, those procedures, practices, and processes employed for ensuring protection of food from allergen cross-contact and for labeling the finished food.

To the extent that these comments are asking us to clarify the distinction between a description of what constitutes a food allergen control and the minimum requirements for what food allergen controls must include when a facility determines that a food allergen is a hazard requiring a preventive control, the regulatory text we proposed in the 2014 supplemental human preventive controls notice modified the regulatory text as requested. However, to the extent that these comments are asking us to modify the provision so that it no longer establishes the minimum requirements for what food allergen controls must include when a facility determines that a food allergen is a hazard requiring a preventive control, we disagree. The listed minimum requirements are consistent with long-standing approaches to the control of food allergens and provide flexibility for a facility to identify and implement those procedures, practices, and processes most suited to the control of food allergen hazards in light of the facility and its food products (Ref. 70) (Ref. 71); see also the discussion at 78 FR 3646 at 3741.

(Comment 431) Some comments ask us to revise the requirement that food allergen controls must include labeling controls by adding the phrase “to ensure that major food allergens are properly disclosed.”

(Response 431) We decline this request. The provision requires that the

procedures, practices, and processes employed for labeling the finished food include those for ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act. Requiring that labeling procedures, practices, and processes ensure that major food allergens are properly disclosed would be redundant with the proposed requirement that they ensure that the finished food is not misbranded under section 403(w).

(Comment 432) Some comments ask us to revise the requirement that food allergen controls must include labeling controls by adding the phrase “as appropriate” because section 201(qq)(2)(A) of the FD&C Act excludes highly refined oils from the definition of “major food allergen.”

(Response 432) We decline this request because qualifying that the requirement applies “as appropriate” is not necessary to achieve the outcome requested by the rule comments. If a food ingredient, such as a highly refined oil, is not a major food allergen, it is not subject to the requirements for food allergen controls.

(Comment 433) Some comments assert that quantification or measurement of specific parameters is not appropriate for some food allergen controls.

(Response 433) We agree with these comments. In the 2014 supplemental human preventive controls notice, we clarified that the requirements for parameters and maximum and minimum values apply to process controls.

(Comment 434) Some comments ask us to establish thresholds for food allergens. Other comments assert that we should not have a “zero-tolerance” approach to food allergens. Some comments ask us to require advisory labeling (such as a label statement that a food that does not contain an allergen ingredient was processed in a facility that also processes foods that do have specific allergen ingredients) if we do not establish a “zero-tolerance” policy for food allergen controls. Other comments assert we should allow advisory labeling in light of difficulties in developing food allergen controls.

(Response 434) In 2008, we announced a public hearing on the use of advisory labeling of allergens in foods as part of a long-term strategy to help manufacturers use allergen advisory labeling that is truthful and not misleading, conveys a clear and uniform message, and adequately informs food-allergic consumers and their caregivers (73 FR 46302, October 8, 2008). In that document, we explained our concerns with food allergens, including food

allergens inadvertently incorporated into manufactured foods, due to the number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in a food. We also described our previous actions targeting food manufacturers, including: (1) A notice to manufacturers entitled “Label Declaration of Allergenic Substances in Foods” in 1996 (Ref. 72); (2) an FDA/state partnership to increase industry’s understanding of food allergens and to identify effective manufacturing controls (Ref. 73); and (3) a statement of policy, to our staff, regarding food allergens (Ref. 74).

In 2012, we requested comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in FALCPA (77 FR 74485, December 14, 2012). We noted that regulatory thresholds would help industry to conduct allergen hazard analyses and develop standards for evaluating the effectiveness of allergen preventive controls.

However, establishing regulatory policy or requirements, such as a long-term strategy regarding use of allergen advisory labeling, or a specific threshold for a food allergen or a “zero-tolerance” policy, is outside the scope of this rule. The provisions of this rule, whether the CGMPs in subpart B or the requirements for hazard analysis and risk-based preventive controls in subparts C and G, are directed to procedures, practices, and processes for the safe manufacturing, processing, packing, and holding of food rather than to special labeling policies or specific levels of substances (such as food allergens) that would render food adulterated or misbranded.

(Comment 435) Some comments assert that food allergen controls need not be required in specific situations, such as during the storage and transport of coffee and the storage of packaged foods not exposed to the environment.

(Response 435) Whether food allergen controls are necessary in any particular circumstance depends on the outcome of the facility’s hazard analysis. Although coffee is not a food allergen, whether coffee requires food allergen controls during storage and transport depends on factors such as how the coffee is stored and transported and whether there is potential for allergen cross-contact. Although we agree that the potential for allergen cross-contact during the storage of packaged foods not exposed to the environment is low, it is the responsibility of the preventive controls qualified individual who conducts or oversees the hazard analysis

to make an appropriate determination for an individual facility.

(Comment 436) Some comments assert that implementation of food allergen controls poses particular challenges in the context of milling operations. As an example, these comments explain that most milling operations do not handle soy. However, allergen cross-contact between grains and soy can occur at various points in the chain of production and transport, such that grains arriving at a milling facility might already contain low levels of soy. These comments also assert that the presence in a desired grain of low levels of soy or of other grains is consistent with U.S. Grain Standards. For example, the Grain Inspection, Packers and Stockyards Administration (GIPSA) definition of corn allows for the presence of between 2 percent and 7 percent foreign material, depending on the grade of corn, and the presence of up to 10 percent of other grains for which standards have been set. Although millers use equipment that helps to separate the desired grain from soy or other grains, these comments assert that complete elimination of soy and other grains is not practicable even under CGMP. These comments ask us to acknowledge that complete elimination of allergen cross-contact is not feasible in certain operations even under CGMP and that the intermittent presence of undeclared allergens is possible in certain foods, notwithstanding the observance of CGMP.

(Response 436) We acknowledge that GIPSA standards may allow for the presence of foreign material, and that foreign material could be a food allergen such as soy. However, such standards are not determinative as to whether hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by a facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Thus, as the comments point out, grains that arrive at a facility for milling may contain levels of a food allergen that a milling operation would not be able to eliminate. In circumstances such as these, supply-chain controls directed to the supplier's cleaning procedures, in addition to separation techniques applied at milling, may be necessary to enable the milling operation to satisfy its responsibilities under this rule. For example, a supplier that uses storage bins to hold soybeans at some times and corn at other times could agree to additional "cleaning" of bins previously used to store soybeans by "scouring" the bin with corn before using the bin

to hold corn intended for human consumption. The corn used for scouring would be handled appropriately—*e.g.*, by diverting to use in animal food, because food allergens are not hazards requiring a preventive control in food for animals. Doing so would reduce the potential for residual soybeans to be present in the next lot of corn, sold for human consumption.

(Comment 437) Some comments ask us to clarify when a facility would be expected to establish food allergen controls rather than rely on the CGMP requirements (in subpart B) to prevent allergen cross-contact, particularly for oilseed processors who only need to address soy allergens.

(Response 437) Food allergen controls are applicable to facilities that handle any of the foods that are food allergens. Any facility that handles a single food allergen, such as a processor only handling soybeans to make soybean oil, may simply need to ensure that the products it ships into commerce are labeled with the food allergen. (If the oils are highly refined and do not contain soy proteins, the facility may need to prevent cross-contact with less highly refined oils that may contain soy proteins.) If the facility only produces foods that contain the single food allergen, there would not be any foods for which cross-contact could occur. For facilities that handle more than one allergen-containing food or both foods that contain a specific food allergen along with foods that do not contain that food allergen (such as a facility that roasts almonds, macadamia nuts, and cashews), the facility could establish preventive controls to ensure that common equipment is cleaned between each type of nut. The facility could use CGMPs to ensure that the different nuts are stored separately before and after roasting to prevent cross-contact.

(Comment 438) Some comments ask us to confirm that FSMA does not change prior agency guidance on the reasonable steps that should be taken to prevent allergens from being unintentionally incorporated into the food and the limited use of allergen advisory statements where the risk of allergen cross-contact cannot be eliminated through CGMPs.

(Response 438) Prior agency guidance on the reasonable steps that should be taken to prevent allergens from being unintentionally incorporated into the food and the limited use of allergen advisory statements is still applicable. (See also the discussion in Response 434.)

#### *E. Proposed § 117.135(c)(3)—Sanitation Controls*

We proposed that preventive controls include, as appropriate to the facility and the food, sanitation controls that include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. We also proposed that sanitation controls must include procedures, practices, and processes for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment, and procedures for the prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(Comment 439) Some comments ask us to use the term "primary packaging material" rather than "food packaging material."

(Response 439) We decline this request. See Response 166, in which we discuss what we mean by "food packaging material" (*e.g.*, we do not intend the term "food-packaging materials" to include shipping containers such as cartons and crates that pose no risk of introducing contaminants or food allergens into food).

(Comment 440) Some comments ask us to clarify whether the requirements for sanitation controls apply to all food facilities or only to those that make RTE products.

(Response 440) The requirements for sanitation controls apply to all food facilities, not just those that make RTE products. The facility must determine through its hazard analysis when sanitation controls are necessary to address a hazard requiring a preventive control. It is reasonable to assume that sanitation controls will be more common in facilities that make RTE products than in facilities that make non-RTE products.

(Comment 441) Some comments assert that sanitation controls are not necessary to prevent any hazards in distribution facilities where food-contact surfaces are not present. Other comments assert that sanitation controls should be required in all cases (rather than "as appropriate") given their central importance.

(Response 441) Under the framework established by FSMA—and implemented in this rule—each facility determines through its hazard analysis

when sanitation controls are necessary to control a hazard requiring a preventive control. The rule neither establishes circumstances (such as in distribution centers) where sanitation controls are not necessary nor pre-judges whether sanitation controls are necessary in specific circumstances. Although we do not expect that facilities such as distribution centers would determine through their hazard analysis that sanitation controls are required, we do expect all food establishments that are subject to the CGMP requirements established in subpart B to fully comply with applicable requirements for sanitation.

*F. Proposed § 117.135(c)(4)—Supply-Chain Controls*

We proposed that supplier controls include the supplier program. See the discussion of comments on the supplier program, now in subpart G, in sections XLII through XLIX. As discussed in more detail in section XLII, we have revised the phrase “supplier program” to “supply-chain program” throughout the regulatory text. As a companion change, we have revised § 117.135(c)(4) to refer to “supply-chain controls” rather than “supplier controls.”

*G. Proposed § 117.135(c)(5)—Recall Plan*

We proposed that preventive controls include, as appropriate, a recall plan as

would be required by proposed § 117.137. See the discussion of comments on the recall plan (final § 117.139) in section XXVIII.

*H. Proposed § 117.135(c)(6)—Other Controls*

We proposed that preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of § 117.135(a). Examples of other controls include hygiene training and other current good manufacturing practices.

(Comment 442) Some comments ask us to specify that preventive controls include controls on raw materials and other ingredients.

(Response 442) The final rule specifies that preventive controls include supply-chain controls as appropriate to the facility and the food. The request of these comments is addressed by the requirements for the supply-chain program (see § 117.135(c)(4) and subpart G).

(Comment 443) Some comments refer to our discussion that an example of an “other” preventive control could include temperature control for a TCS refrigerated food, and our discussion that although many refrigerated foods only require refrigeration for food quality, some refrigerated foods do require refrigeration for food safety (78 FR 3646 at 3744). These comments ask us to be clearer about foods that require

refrigeration for food quality rather than for food safety.

(Response 443) Additional information about foods that do not require refrigeration for food safety is available in the Food Code (Ref. 51) (see, e.g., the definition of TCS food and the examples of foods that are not TCS foods in section 1–2 of the Food Code).

**XXVII. Subpart C: Circumstances in Which the Owner, Operator, or Agent in Charge of a Manufacturing/Processing Facility Is Not Required To Implement a Preventive Control (Final §§ 117.136 and 117.137)**

In the 2014 supplemental human preventive controls notice, we provided an opportunity for public comment on potential requirements for a supplier program as a preventive control, including comments on when a supplier program would not be required. As discussed in more detail in section XLII, we have revised the phrase “supplier program” to “supply-chain program” throughout the regulatory text. As summarized in table 32 and discussed more fully in the following paragraphs, after considering comments on when a supplier program would not be required, we are establishing two new provisions. Although both provisions have an effect on the required supply-chain program, they would be implemented outside the framework of a supply-chain program.

TABLE 32—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL

Final section designation	Proposed section designation	Description	Revision
117.136(a)(1) ....	N/A .....	A manufacturer/processor is not required to implement a preventive control if it determines and documents that the type of food (e.g., RACs such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.	N/A.
117.136(a)(2) ....	117.136(a)(1)(ii)(C) .....	A manufacturer/processor is not required to implement a preventive control if it relies on its customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C to ensure that the identified hazard will be significantly minimized or prevented and both (1) discloses in documents accompanying the food that the food is “not processed to control [identified hazard]” and (2) annually obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard.	Includes a requirement for documentation that the food is “not processed to control [identified hazard].”
117.136(a)(3) ....	N/A .....	A manufacturer/processor is not required to implement a preventive control if it relies on its customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and it: (1) Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.	N/A.

TABLE 32—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL—Continued

Final section designation	Proposed section designation	Description	Revision
117.136(a)(4) ....	117.136(a)(1)(ii)(C) .....	A manufacturer/processor is not required to implement a preventive control if it relies on its customer to ensure that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and both: (1) Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]” and (2) annually obtains from its customer written assurance that the customer will both disclose the information that the food is “not processed to control [identified hazard]” and will only sell to another entity that agrees, in writing, it will follow procedures that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C), or obtain a similar written assurance from the entity’s customer.	<ul style="list-style-type: none"> <li>• Addresses the circumstance where an entity (other than the facility’s customer) in the distribution chain controls the hazard.</li> <li>• Includes a requirement for documentation that the food is “not processed to control [identified hazard].”</li> </ul>
117.136(a)(5) ....	N/A .....	A manufacturer/processor is not required to implement a preventive control if it has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product it distributes and documents the implementation of that system.	N/A.
117.136(b) .....	117.136(g)(3) .....	Records documenting the applicable circumstances in § 117.136(a).	Includes a requirement for documentation of the additional circumstances in which a manufacturer/processor is not required to implement a preventive control.
117.137 .....	N/A .....	A facility that provides a written assurance under § 117.136(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.	N/A.

The first provision allows a manufacturer/processor to not implement a preventive control if the manufacturer/processor determines and documents that the type of food (e.g., RACs such as cocoa beans, coffee beans, and grains) could not be consumed without application of the appropriate control (see § 117.136(a)(1)). We describe comments leading to this provision, and our response to those comments, in Comment 444 and Response 444, respectively. Although we are establishing these provisions outside the framework of the supply-chain program, these provisions continue to play a role in the requirements for a supply-chain program, because they also provide an exception to the requirements for a manufacturer/processor to establish and implement a supply-chain program.

The second provision relates to comments we received on a proposed exception to the requirement for a manufacturer/processor to establish and implement a supplier program (proposed § 117.136(a)(1)(ii)(C)). (See Comment 445.) Under proposed § 117.136(a)(1)(ii)(C), a receiving facility

would not have been required to have a supplier program if it relied on its customer to control the hazard and annually obtained from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. As discussed in Response 445, we are replacing this provision with several provisions that apply when a manufacturer/processor identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, but can demonstrate and document that the identified hazard will be controlled by an entity in its distribution chain. A manufacturer/processor that satisfies the criteria in these provisions will not be required to implement a preventive control for the identified hazard. Under these provisions, the combination of three requirements will provide adequate assurance that the food will be processed to control the identified hazard before it reaches consumers. These requirements are: (1) Documentation provided by the manufacturer/processor to its direct

customer that the food is “not processed to control [identified hazard]”; (2) written assurance from customers regarding appropriate procedures to ensure that the food will receive further processing to control the identified hazards; and (3) provisions relating to accountability for written assurances. (In these provisions, “customer” means a commercial customer, not a consumer.)

(Comment 444) Some comments express concern about the ability for distributors/cooperatives to identify the individual farms that harvested the produce when such farms are more than one step back in the food chain from the distributor/cooperative. Some comments assert that receiving facilities should not be required to verify suppliers with which they do not have a direct commercial relationship. These comments note that, in the case of the cocoa bean supply chain, the processing facility likely has no direct relationship with the thousands of farms involved in the growing and harvesting of the beans. Some comments ask for an exemption from supplier verification activities for foods such as cocoa beans because,



although cocoa processors do not currently rely on farms to control hazards, and would therefore not need to verify farms, it is problematic to have a requirement that potentially could necessitate traceback to farms.

(Response 444) We are establishing a provision, applicable to both the supply chain and the distribution chain of a manufacturer/processor, for a circumstance when a manufacturer/processor does not need to implement a preventive control. The specific food product identified by some of the comments (*i.e.*, cocoa beans) is part of a class of food products (principally RACs) that could simply not be eaten without processing that would control the hazards requiring a preventive control. Other RACs in this class of food products are coffee beans, grains, and some RACs that are rarely consumed raw. Therefore, we are providing that a manufacturer/processor does not need to implement a preventive control if it determines and documents that the type of food (*e.g.*, RACs such as cocoa beans, coffee beans, and grains) could not be consumed without application of the appropriate control (see § 117.136(a)(1)). The regulatory text does not specify RACs “rarely consumed raw” because “rarely consumed raw” is not the same as “could not be consumed without application of the appropriate control.” However, depending on the facility, the RAC, and the food produced by the manufacturer/processor, there may be some circumstances where a manufacturer/processor could determine that a particular RAC that passes through its facility satisfies the criterion “could not be consumed without application of the appropriate control.”

In other cases, a facility that conducts a manufacturing/processing activity on produce rarely consumed raw may satisfy the criteria in other new provisions (§ 117.136(a)(2), (3), and (4)) in which it relies on its customer to provide assurance that the food will be processed to control the identified hazard. In still other cases, such a facility may have determined through its hazard analysis that there are no hazards requiring a preventive control, and will not consider whether one of the circumstances in new § 117.136 apply.

As a consequential addition, new § 117.136(b) specifies the records that a manufacturer/processor would need to satisfy the documentation requirements established in new § 117.136(a)(1), and we have added new § 117.136(b) to the list of implementation records (§ 117.190) that are subject to the

recordkeeping requirements of subpart F.

See also Comment 657, in which we discuss comments asking us to add flexibility to the requirements for a supply-chain program such that any entity other than the receiving facility can perform supplier verification activities. As discussed in Response 657, the rule provides additional flexibility in the supply-chain program with regard to who can perform certain activities (see § 117.415).

(Comment 445) Some comments ask us to delete the criterion for control of the hazard by the receiving facility’s customer, with annual written assurance that the customer had established and was following procedures (identified in the written assurance) that would significantly minimize or prevent the hazard. The stated reasons varied. For example, some comments state that a receiving facility may have so many customers that it is not possible to obtain written assurance annually from all customers. Other comments express concern that a customer may be unwilling to describe confidential trade secrets in order to identify in writing the procedures the customer has established and is following to control the hazard. Other comments express concern about “legal issues” when a receiving facility needs to assess the adequacy of the customers’ procedures for controlling a hazard because under current business practices a vendor can provide assurance to a buyer (its customer), but buyers do not typically provide such assurance to vendors. Some comments express concern that written assurance does not guarantee that the customer is actually doing anything to significantly minimize or prevent the hazard.

Some comments ask us to provide an alternative that would allow the receiving facility to provide documentation to its customer about a hazard that needs a preventive control at a processing facility later in the distribution chain rather than obtain written assurance that its customer will control a hazard. If written assurance must be required, these comments ask us to allow the written assurance provided by the customer to state that the customer would evaluate the hazard and if necessary establish and follow procedures to significantly minimize or prevent the hazard.

Some comments state the receiving facility may not know the identity of all its ultimate customers, particularly if the receiving facility sells its products to a distributor who then sells to other entities. Some comments ask us to provide flexibility for facilities to

determine whether annual updates of written assurance are necessary. Other comments ask us to specify that a receiving facility need not establish and implement a supplier program for raw materials and ingredients that are RACs intended for further processing.

Some comments assert that the presence of low levels of pathogens on a raw product that will be subject to a lethal process further downstream does not pose a risk to the consumer, and should not be considered a significant hazard (*i.e.*, a hazard requiring a preventive control). These comments also assert that if we maintain that *Salmonella* contamination is a significant hazard for each member of the supply chain, then we should allow the preventive control to be applied in a subsequent step at another facility. Other comments ask us to clarify that a facility would not need to develop preventive controls where it produces raw materials or ingredients that are subject to subsequent processing that will address known or reasonably foreseeable hazards.

(Response 445) We are establishing several provisions, specifically applicable to the distribution chain of a manufacturer/processor, for circumstances when a manufacturer/processor does not need to implement a preventive control (§§ 117.136(a)(2), (a)(3), (a)(4) and (a)(5), (b)(2), (b)(3), (b)(4), and (b)(5), 117.137, and 117.335). See Response 444 for another new provision that applies to the supply chain in addition to the distribution chain (§ 117.136(a)(1)).

Under the first of these provisions (§ 117.136(a)(2)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer (who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) to ensure that the identified hazard will be significantly minimized or prevented and: (1) Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance, subject to the requirements of § 117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. The manufacturer/processor would include the specific hazard requiring a preventive control (*e.g.*, *Salmonella*) where the statement says “[identified hazard].” A facility that provides the written assurance must act consistently with the assurance and document its

actions taken to satisfy the written assurance (see new § 117.137). The documents could be bills of lading or other papers that accompany the food, or labels on the containers of the food.

Under the second of these provisions, (§ 117.136(a)(3)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer (who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and it: (1) Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. By “customer who is not required to implement preventive controls under part 117” we mean entities such as qualified facilities and retail food establishments.

Under the third of these provisions (§ 117.136(a)(4)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and: (1) Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance, subject to the requirements of § 117.137, that the customer will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”. The manufacturer/processor also must obtain written assurance that its customer will only sell to another entity that agrees, in writing, it will: (1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C), or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C); or (2) obtain a similar written assurance from the entity’s customer.

Under the fourth of these provisions (§ 117.136(a)(5)), a manufacturer/processor is not required to implement a preventive control if it has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product it distributes and documents the implementation of that system. Comments did not provide examples of such a system, but we do not want to preclude the development of such systems.

We have added several other requirements related to these new provisions that we are specifically establishing as circumstances in which a manufacturer/processor need not implement a preventive control. As already noted in this response, new § 117.137 requires that a facility that provides a written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance. In addition, new § 117.136(b)(2), (3), (4), and (5) specify the records that a manufacturer/processor would need to satisfy the documentation requirements established in new § 117.136(a)(2), (3), (4), and (5), and new § 117.335 establishes requirements applicable to the written assurance between a manufacturer/processor and its customer. Taken together, the provisions of §§ 117.137 and 117.335 establish legal responsibilities for a facility that provides a written assurance under § 117.136(a)(2), (3), or (4), even if that facility is not a manufacturer/processor.

The point of these provisions is to ensure that hazards that a manufacturer/processor has determined, through its hazard analysis, require a preventive control, but are not controlled in the supply chain before the manufacturer/processor or by the manufacturer/processor, are in fact controlled by a subsequent entity in the distribution chain. With the assurance from the first manufacturer/processor’s customer that the hazards will be controlled after the food product leaves the manufacturer/processor, it is not necessary for the first manufacturer/processor to implement the applicable preventive control. We continue to believe that annual written assurance from a manufacturer/processor’s direct customer is an appropriate mechanism to ensure that its customer is aware of the identified hazard and is taking steps to ensure that the food is processed to control the identified hazard. We do not believe that a manufacturer/processor will need all of the details of its customer’s process to satisfy the requirement to state in writing the procedures the

customer has established and is following to control the hazard. For example, the customer could merely state that its manufacturing processes include a lethality step for microbial pathogens of concern.

We agree that it is appropriate to require that the manufacturer/processor provide documentation to its customer indicating that the food must be processed to control an identified hazard. Such documentation will be a means of clear communication from the manufacturer/processor to its customer. When the hazard will not be controlled by the customer, the customer will still have documentation that can be passed on to the entity that is expected to process the food to control the identified hazard, so that it will be very clear to that entity that the identified hazard still needs to be controlled.

(Comment 446) Some comments ask us to delete the proposed requirement to maintain the written assurance as a record.

(Response 446) We decline this request. As already discussed in this section, it is the combination of requirements (*i.e.*, for documentation that the food is “not processed to control [identified hazard]”; assurance from customers regarding appropriate procedures to ensure that the food will receive further processing to control the identified hazards; and provisions relating to accountability for written assurances) that will provide adequate assurance that the food will be processed to control the identified hazard before it reaches consumers. Records documenting the written assurances are a key component of the provisions.

#### **XXVIII. Subpart C: Comments on Proposed Requirements for a Recall Plan (Final § 117.139)**

We proposed that you must establish a written recall plan for food with a significant hazard and that the recall plan must include certain procedures. Some comments support the proposed requirements without change. For example, some comments express the view that a written recall plan is critical in the event of a system breakdown where adulterated foods have been distributed. Some comments that support the proposed requirements note that many model plans are available to industry. Other comments state that the proposed requirements for a recall plan mirror guidelines in many fresh produce commodity-specific food safety guidelines and seem appropriate for all types of facilities handling fresh produce. Some comments that support the proposed provisions suggest

alternative or additional regulatory text (see, e.g., Comment 447, Comment 452, Comment 453, and Comment 454).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the requirements as proposed with the conforming revision to use the term “hazard requiring a preventive control” rather than “significant hazard.” See Response 126 and table 52. We also are redesignating the requirements as § 117.139. As discussed in section XXVII, we are establishing a provision applying to certain assurances in § 117.137.

*A. Proposed § 117.137(a)—Requirement for a Written Recall Plan (Final § 117.139(a))*

We proposed that you must establish a written recall plan for food with a significant hazard.

(Comment 447) Some comments ask us to require a written recall plan for all food (rather than just for food with a significant hazard) and to establish the requirements for a written recall plan as CGMP requirements in subpart B rather than as part of the requirements for hazard analysis and risk-based preventive controls in subpart C. These comments assert that all products can be subject to a recall. These comments contrast recall plans with other preventive controls in that recall plans are often specific to a firm or facility, but rarely are specific to particular foods. In addition, these comments note that a recall may be administered and managed at the corporate office rather than at the specific manufacturing facility that produced the food.

Some comments note the requirements for a written recall plan are sufficiently different from other provisions in subpart C that we proposed to specify that the recall plan would not be subject to the preventive control management requirements for monitoring, corrective actions, and verification (see § 117.140(c)). Some comments note that facilities that are exempt from the requirements of subpart C, but remain subject to the CGMP requirements, would not be required to have a recall plan unless we establish the requirements in subpart B.

Some comments note that our authority to require recall plans is not limited to section 418 of the FD&C Act and that we can use other legal authority to impose a requirement for recall plans in subpart B. Some comments note that FSMA specifically amended the FD&C Act to provide us

with the authority to mandate a food recall (section 423 of the FD&C Act). These comments assert that it would be reasonable for us to conclude that in order to efficiently carry out section 423 of the FD&C Act we should issue requirements governing the conduct of recalls, because section 423 of the FD&C Act requires that we provide a firm with an opportunity to voluntarily recall a product before issuing an order to the firm to cease distribution and recall a product.

(Response 447) We decline the request to establish requirements for a written recall plan as a CGMP requirement in subpart B and are establishing the requirements as a preventive control in subpart C as proposed. We acknowledge that a recall plan would be useful to all food establishments, and we encourage all food establishments to have a recall plan. However, the report issued by the CGMP Modernization Working Group did not identify the lack of a written recall plan as something that needed to be changed (Ref. 3). (See 78 FR 3646 at 3651 for a discussion of the CGMP Modernization Working Group and the process leading to its report.) However, going forward we intend to monitor whether the lack of a broader requirement for a recall plan leads to problems when food establishments that are not subject to the requirements of subpart C are faced with recall situations. As we gain experience with the impact of the new requirement for a recall plan on those facilities subject to subpart C, we can reassess at a later date whether to conduct rulemaking to broaden the requirement to apply to all food establishments subject to the CGMP requirements in subpart B. For now, food establishments that are not subject to subpart C can continue to follow our long-standing recall policy in part 7.

Consistent with the overall framework of FSMA, a recall plan (like other preventive controls) is only required when the facility has identified a hazard requiring a preventive control. A facility could establish a recall plan that applies to other foods it manufactures. We recognize that recalls may be managed by the corporate office of a firm rather than at the specific manufacturing facility that produced the food. Nothing in the rule precludes this approach. In such cases the corporate recall policy would be reflected in a facility’s recall plan. (See also (Response 371.) In addition, a facility that identifies one or more hazards requiring a preventive control in multiple food products could use the same recall plan for all applicable food products.

The rule specifies that the requirements for preventive control management components (*i.e.*, monitoring, corrective actions and corrections, and verification) apply as appropriate to ensure the effectiveness of the preventive control, taking into account the nature of the preventive control (§ 117.140(a)). As previously discussed, the preventive control management components are directed at food that remains at the facility, whereas the recall plan addresses food that has left the facility (78 FR 3646 at 3745). Our determination that the nature of the recall plan does not require these preventive control management components demonstrates the flexibility provided by FSMA and this rule, not that the recall plan must be considered a CGMP rather than a preventive control.

We have not yet made a determination of whether we should issue requirements governing the conduct of recalls, rather than rely on the guidelines in part 7, in order to fully implement section 423 of the FD&C Act. However, we have issued draft guidance entitled “Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls” which, when finalized, would address topics such as the criteria for a mandatory recall and the process that FDA must follow for a mandatory recall (Ref. 75).

(Comment 448) Some comments assert that the requirements for a recall plan should only apply to RTE food.

(Response 448) These comments are suggesting that the rule predetermine the outcome of the hazard analysis at all facilities. The framework provided by FSMA and established in this rule makes it the responsibility of each facility to appropriately determine the hazards requiring a preventive control, and establish preventive controls as appropriate to the facility and the food.

(Comment 449) Some comments ask us to cross-reference the provisions of part 7 (21 CFR part 7) rather than establish requirements that these comments assert would be duplicative with the provisions of part 7. These comments ask us to address any more substantive requirements than are already in part 7 as part of a review of part 7. These comments assert that part 117 should require a written recall plan, but not require a “written recall plan for the food,” to be consistent with the approach of part 7.

(Response 449) We decline these requests. Part 7 addresses enforcement policy, and the provisions for recalls in subpart C of part 7 are “Guidance on Policy, Procedures, and Industry Responsibilities.” These recall

provisions do not establish requirements and are not binding on industry. They also are broadly directed to recalls for all FDA-regulated products, not just food. As already discussed (see Response 447), nothing in this rule would prevent a facility that establishes a recall plan for a particular food from using that recall plan for any food product that the facility decides to recall.

*B. Proposed § 117.137(b)—Procedures That Describe the Steps To Be Taken, and Assign Responsibility for Taking Those Steps (117.139(b))*

We proposed that the recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: (1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food; (2) notify the public about any hazard presented by the food when appropriate to protect the public health; (3) conduct effectiveness checks to verify that the recall is carried out; and (4) appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food). We requested comment on whether: (1) The proposed procedures are appropriate for all types of facilities; (2) we should require a recall plan to include procedures and assignment of responsibility for notifying FDA of recalls subject to the plan; and (3) we should include a requirement for a mock recall as a verification activity.

(Comment 450) Some comments ask us to modify the proposed requirements for a recall plan to clearly differentiate between manufacturers and distributors. These comments note that distributors are often not the initial recalling firm and ask us to clarify that the manufacturer, rather than the distributor, is the responsible party for notifying the public. Other comments ask us to modify and simplify the details of the recall plan for smaller businesses based on product, distribution, and other factors.

(Response 450) In the 2014 supplemental human preventive controls notice, we revised the proposed requirements for a recall plan by specifying that the procedures in the recall plan are “as appropriate to the facility.” As a result, the rule explicitly provides flexibility for a recall plan to be different based on characteristics such as size of the facility or the role of the facility in the food supply chain. For example, the rule provides flexibility for

a small business to simply specify that it will telephone its customers. Although we decline the request to specify that the manufacturer, rather than the distributor, is the responsible party for notifying the public, the rule provides flexibility for a distributor to establish, through its business relationships with manufacturers, that this would be the procedure established in the distributor’s recall plan.

(Comment 451) Some comments ask us to delete the proposed requirement that the recall plan include procedures for a facility to notify the public about any hazard presented by the food when appropriate to protect public health. These comments assert that such a requirement would be highly subjective and create a nebulous regulatory burden that could subject facilities to unnecessary regulatory oversight and enforcement actions.

(Response 451) We decline this request. Our guidance for a recall strategy has long recommended issuing a public warning to alert the public that a product being recalled presents a serious hazard to health in urgent situations where other means for preventing use of the recalled product appear inadequate (§ 7.42(b)(2)). Operationally, such notification to the public is so common that our current home page on our Internet site (Ref. 76) gives prominence to recall information, and we have established a free email subscription service for updates on recalls (Ref. 77). Consistent with the long-standing recall policy in part 7, subpart C, the proposed requirement qualifies that the notification to the public is “when appropriate to protect public health.”

(Comment 452) Some comments ask us to specify that food recall plans include a minimum data requirement about the food product in question. These comments assert that information such as lot, batch, product size, and production date are critical in sorting defective products from non-defective ones.

(Response 452) The procedures that must be established in a recall plan are those that describe the steps that will be taken to notify entities that a product must be removed from commerce, to verify that product is removed, and to appropriately dispose of the product. Information (such as lot, batch, product size, and production date) is necessary to be able to carry out the steps that must be included in the procedures and can be a useful component of the procedures that a facility includes in its recall plan, because a facility would need to obtain such information about the specific product being recalled

when conducting a recall. However, we decline the request to specify what a facility must include in its procedures because facilities may use different approaches in how they carry out recalls and the information they need to do so. For example, not all facilities use that same data for identifying the product that may be impacted by a recall.

(Comment 453) Some comments ask us to specify that the procedures require facilities to notify us about a recall to ensure that all suppliers, retailers, and consumers will have adequate notification of the recall action. Other comments agree that it is important for facilities to involve us in a recall situation as soon as possible, but assert that the best way to address such a notification is through the existing RFR system. These comments assert that additional procedures or means to notify us would involve unnecessary additional steps and be duplicative, with no improvement to the public health. Some comments ask us to specify that the appropriate State regulatory agency with inspection jurisdiction be notified in the event of a recall.

(Response 453) We agree with comments that it is important to notify us about a recall and that doing so can help to ensure that suppliers, retailers, and consumers will have adequate notification of the recall action. We also agree that the existing procedures to notify us through the RFR system can accomplish this goal when a food presents a risk of serious adverse health consequences or death and that it therefore is not necessary to duplicate the notification procedures already established in the RFR system in part 117. However, we encourage facilities to include in their recall plan any procedures they have to comply with the RFR or to include a cross-reference to those procedures. Doing so may save time, which is critical during a recall. When the recalled food does not present a risk of serious adverse health consequences or death (and, thus, there is no report to the RFR), our guidance entitled “Guidance for Industry: Product Recalls, Including Removals and Corrections” recommends that recalling firms notify the local FDA District Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press or written notification to customers (Ref. 78). Including this guidance with the facility’s recall procedures may also save time.

Likewise, we agree with comments that it is important to notify appropriate State regulatory agencies about a recall. However, procedures are available for

State regulatory agencies to rapidly receive information from us about food recalls. For example, State regulatory agencies can receive automatic notification about food recalls that we post on our Web site (Ref. 79). We note that whatever methods are used to dispose of adulterated food should comply with State and local requirements.

(Comment 454) Some comments ask us to add a requirement for mock recalls on a regular basis, such as annually. Some of these comments state that mock recalls would familiarize the staff and communications network(s) with the recall process and would improve the facility's capacity to conduct effective and efficient recalls in the event of a contamination event. Other comments assert that mock recalls would be the only way to determine the effectiveness of a recall program. Some comments note that mock recalls would be particularly critical for manufacturers that have limited experience in actual recalls. Other comments note that information from mock recalls could support development of guidance on best practices for recalls. Some comments recommend that any requirement for a mock recall as a verification measure include sufficient flexibility to accommodate diverse procedures and mechanisms.

Some comments acknowledge that a mock recall could be an important element of a recall plan but recommend that mock recalls remain voluntary, such as by including mock recalls as an example of how verification may be accomplished. Other comments note

that the current recall procedures in part 7 do not recommend mock recalls. Some comments assert that a requirement to include a mock recall as a verification activity would be an excessive and inappropriate burden. Some comments note that retail facilities execute multiple recalls each week and that adding the requirement to perform a mock recall would be an unnecessary burden on the retail industry. Likewise, some comments note that foodservice distributors are experts in conducting recall activities, because they are routinely affected by manufacturer recalls.

Some comments ask us to clarify the "metrics" for a mock recall, particularly with respect to the consequences of failing to meet an appropriate metric if a mock recall is conducted as a verification activity.

(Response 454) We agree that a mock recall would familiarize the facility with the recall process, could improve the facility's capacity to conduct effective and efficient recalls during a contamination event, may be particularly helpful for manufacturers that have limited experience in actual recalls, and could support the development of guidance on best practices for recalls, and we encourage facilities to conduct one or more mock recalls to accomplish these goals. However, as previously discussed, a recall plan would address food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at food while it remains at the facility. Comments are mixed regarding

whether the rule should require a mock recall as a verification activity for the recall plan, and we have decided to not require a facility to conduct a mock recall as a verification activity for its recall plan so that the focus of the monitoring, corrective actions, and verification in the rule remains focused on food being produced rather than on food that is distributed in commerce. A facility that voluntarily conducts a mock recall would establish metrics appropriate to its plan and take action (such as modifications to its procedures, or additional training for its employees) if it is not satisfied with the results of the mock recall.

We note that retail companies are not subject to this rule and, thus, are not subject to the requirement to have a written recall plan.

**XXIX. Comments on Proposed § 117.140—Preventive Control Management Components**

We proposed preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control. Most of the comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 455).

In the following sections, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 33, with editorial and conforming changes as shown in table 52.

TABLE 33—REVISIONS TO THE PROPOSED REQUIREMENTS FOR PREVENTIVE CONTROL MANAGEMENT COMPONENTS

Section	Description	Revision
117.140 .....	Flexible requirements for preventive control management components.	Provide that preventive control management components take into account both the nature of the preventive control and its role in the facility's food safety system.

*A. Proposed § 117.140(a)—Flexible Requirements for Monitoring, Corrective Actions and Corrections, and Verification*

We proposed that, with some exceptions, the preventive controls would be subject to three preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control: monitoring, corrective actions and corrections, and verification.

(Comment 455) Some comments support our proposal to provide flexibility in the oversight and

management of preventive controls, including the explicit provision that preventive control management components take into account the nature of the preventive control. Some of these comments state that the provisions for the preventive control management components will allow facilities to tailor their food safety plans to their specific facility, product, and process and ensure that the regulatory requirements are risk-based. Other comments state that the proposed approach acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs,

and provides for a framework whereby appropriate decisions may be reached regarding hazards that require management controls that may include monitoring, corrections or corrective actions, verification, and records. Other comments state that the provisions will allow businesses to allocate resources to spend the most time and resources controlling and monitoring those hazards that pose the greatest risk to public health.

However, many of these comments also ask us to convey not only that the application of a particular management component be appropriate (*i.e.*, capable

of being applied), but also that it be necessary for food safety (*i.e.*, to meet the overall FSMA food safety goals or to ensure a particular control is effective) by specifying that the preventive control management components take into account both the nature of the preventive control and its role within the facility's overall food safety system. Some of these comments ask us to make companion changes reflecting that the preventive control management components take into account both the nature of the preventive control and its role within the facility's overall food safety system throughout applicable provisions of the rule, such as the definition of "significant hazard" (which we now refer to as "hazard requiring a preventive control") and in the requirements for preventive controls, monitoring, corrective actions and corrections, and verification. Some comments ask us to consistently refer to "the nature of the preventive control" (rather than simply to "the preventive control") when communicating the flexibility that a facility has in identifying preventive controls and associated preventive control management components.

One comment provides two examples of refrigeration controls to explain its view that the management components for refrigeration controls will vary depending on the role of refrigeration within the facility's overall food safety system. In the first example, a facility that manages the process of cooling a cream cheese as a CCP would validate its refrigeration control, establish time and temperature parameters that must be met, monitor those parameters and confirm their use through verification, and, if the parameters were not met, then follow a specific corrective action procedure to address the situation. In contrast, after the initial cooling process for the hot-filled product, the facility would manage refrigerated storage differently. The facility would not keep validation data to support the specific temperature chosen because the temperatures needed to keep food safe are widely known and accepted. Although the facility may choose to establish temperature parameters, the facility typically would not apply such values as hard and fast limits in the same way as it would for a CCP (*e.g.*, because a 5 degree increase over the upper end of the temperature range for a short time would not be meaningful to food safety). The facility may choose not to monitor temperature continuously and, even if the facility does monitor temperature continuously it would only generate "exception records" when the

temperature exceeds a specific value. The facility also would find it unnecessary to verify its ongoing monitoring.

(Response 455) We agree that preventive control management components should take into account both the nature of the preventive control and its role in the facility's food safety system and have modified the regulatory text of § 117.140 to incorporate this suggestion. We reviewed the full regulatory text of proposed subpart C and made similar modifications to the regulatory text for the definition of "hazard requiring a preventive control" (§ 117.3); process controls (§ 117.135(c)(1)); monitoring (§ 117.145); verification (§ 117.155); validation (§ 117.160); and verification of implementation and effectiveness (§ 117.165).

(Comment 456) Some comments assert that the flexibility explicitly provided in the regulatory text could result in some facilities taking a broad approach to significant hazards and other facilities taking a more detailed approach. These comments express concern that inspectors will view the detailed approach (*e.g.*, with more preventive controls) as the standard to judge compliance with the rule. Other comments express concern that identifying a large number of preventive controls could also undermine the value of HACCP programs because treating too many controls as CCPs will pull resources from those controls that are truly critical.

(Response 456) We agree that facilities are likely to take different approaches to complying with the rule. A facility-specific approach is consistent with FSMA, which places responsibility for hazard analysis and risk-based preventive controls on the owner, operator, or agent in charge of the facility (section 418(a) of the FD&C Act). We agree that having too many CCPs could dilute their significance, but not every hazard will require a CCP to be controlled. See table 6 in the 2014 supplemental preventive controls rule for two examples of preventive controls that would not be CCPs (79 FR 58524 at 58542).

During the initial stages of implementation, we expect that our investigators will ask subject matter experts in CFSAN to review the outcome of the facility's hazard analysis, the preventive controls established by the facility, and the associated preventive control management components that the facility has established and implemented. Over time, as our investigators gain experience, we expect

that there will be fewer circumstances in which our investigators would consult CFSAN about such an outcome. See also Response 5.

(Comment 457) Some comments express concern with the number of provisions that will impact certain types of operations. As an example, these comments assert that a fresh-cut produce facility potentially could be required to implement supplier verification, environmental monitoring, and product testing, whereas a peanut butter producer may not be required to implement any of those three provisions. According to these comments, supplier verification most likely would not be required if the manufacturing operation of the peanut butter manufacturer includes a kill step to significantly minimize *Salmonella*, because the "significant hazard" would be addressed at the receiving facility. These comments interpret our previous discussions about product testing, in the 2013 proposed preventive controls rule, as evidence that such a peanut butter manufacturer also would likely not conduct product testing. If the peanut butter product is hot-filled into jars, there would be no RTE food exposed to the environment and, thus, the facility's hazard analysis would not be required to consider the potential for contamination with environmental pathogens.

(Response 457) We acknowledge that some facilities will need to do more than others, because the rule is flexible and risk-based. Importantly, the rule does not require every fresh-cut produce operation to conduct environmental monitoring, even though it does require each fresh-cut produce operation to consider whether it is necessary.

We disagree that the flexibility provided in the regulatory text would lead a peanut butter manufacturer to conclude that there would be no RTE food exposed to the environment when peanut butter is hot-filled into jars. In the production of peanut butter, the kill step (*i.e.*, roasting) happens before the rest of the manufacturing process, and the roasted peanuts are exposed to the environment before the filling step. At the filling step, the temperature is hot enough to fill the jars but is not hot enough to act as a kill step to significantly minimize any pathogens that contaminated the peanuts after they were roasted. As a result, in contrast to the interpretation of the comments, the peanut butter production described by the comments does involve RTE food exposed to the environment, and the facility's hazard analysis must consider the potential for contamination with environmental pathogens. However,

when a peanut butter manufacturer concludes that it requires sanitation controls for environmental pathogens, it is more likely that the peanut butter manufacturer would conduct environmental monitoring (rather than product testing) as a verification of its sanitation controls. (The peanut butter manufacturer may also conclude that product testing is a useful tool to verify its overall food safety system.) Likewise, a facility that buys peanut butter for use in an RTE food would need to consider whether it needs supply-chain controls for the manufacturer that performed the kill step for *Salmonella* and whether it needs sanitation controls for environmental pathogens and environmental monitoring as verification of its sanitation controls.

(Comment 458) Some comments state that USDA's regulations (in 7 CFR 205.201(a)(3)) for the NOP include regulatory text to "ensure the effectiveness" of measures in that program and that this regulatory text is similar to regulatory text in the requirements for preventive control management components. These comments assert that this type of regulatory text has created compliance challenges and ask us to consult with USDA about its experience with implementing effectiveness language associated with monitoring practices and procedures and ensure that the final rule uses regulatory text that will be clearly understood and readily implementable by those subject to its provisions.

(Response 458) Under the USDA regulation cited by these comments, an organic production or handling system plan must include a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to "verify that the plan is effectively implemented." We have not consulted with USDA regarding its experience in evaluating compliance with this requirement because we addressed the issue likely to cause these compliance challenges for monitoring practices and procedures in an organic production or handling system plan when we established our requirements for monitoring preventive controls. Specifically, we require that a facility monitor the preventive controls with adequate frequency to "provide assurance that they are consistently performed," not to "verify that the plan is effectively implemented." Our requirements more clearly distinguish the purpose of monitoring and verification activities. See our previous discussion of the relationship between monitoring and verification, and our

tentative conclusion to require monitoring of the performance of the preventive controls (78 FR 3646 at 3747). We are affirming that conclusion in this rule (see Response 461).

(Comment 459) Some comments assert that regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) would prevent a facility from monitoring employee health if it establishes a Good Worker Hygiene Program as a preventive control.

(Response 459) The basis of these comments is unclear. We do not expect that activities associated with monitoring of employee health would include activities that would be contrary to provisions of the Health Insurance Portability and Accountability Act of 1996. Employee health could be addressed through long-standing CGMP provisions (see § 117.10(a) and (b)). Specifically, with respect to disease control there could be supervisory observation of illness or conditions such as an open lesion, with appropriate action to exclude the worker from operations in which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated (§ 117.10(a)). Generally, the regulations described in this comment (commonly referred to as "the Privacy Rule") apply to disclosures made by a health care provider, not to the questions of an employer (Ref. 80). See 45 CFR 160.103, which defines a "covered entity" as a health plan; a health care clearinghouse; and a health care provider who transmits any health information in electronic form in connection with a transaction covered by the Privacy Rule. The Privacy Rule does not prevent a supervisor, human resources worker or others from asking an employee for a doctor's note or other information about health if the employer needs the information to administer sick leave, workers' compensation, wellness programs, or health insurance (45 CFR 164.512(b)(1)(v)).

*B. Proposed § 117.140(b)—Applicability of Preventive Control Management Components to the Supply-Chain Program*

We proposed that the supplier program (which we now refer to as "supply-chain program") is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program, taking into account the nature of the hazard controlled before receipt of the raw material or ingredient: (1) Corrective actions and corrections, taking into account the

nature of any supplier non-conformance; (2) review of records; and (3) reanalysis. We address comments on the supply-chain program in sections XLII through XLIX. We are finalizing the applicability of preventive control management components to the supply-chain program as proposed.

*C. Proposed § 117.140(c)—Recall Plan Is Not Subject to Preventive Control Management Components*

We proposed that the recall plan would not be subject to the preventive control management components.

(Comment 460) As discussed in Comment 447, some comments ask us to establish requirements for a written recall plan as a CGMP requirement in subpart B rather than as a preventive control in subpart C. As a companion change, some of these comments ask us to delete our proposed provision that the recall plan would not be subject to the preventive control management components.

(Response 460) As discussed in Response 447, we are establishing the requirements as a preventive control in subpart C as proposed. Therefore, we are finalizing the provision that the recall plan not be subject to the preventive control management components.

**XXX. Subpart C: Comments on Proposed § 117.145—Monitoring**

We proposed to establish requirements for monitoring the preventive controls. We also discussed our tentative conclusion that the language of section 418 of the FD&C Act regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the "performance" of preventive controls.

Some comments agree with our tentative conclusion regarding the ambiguous nature of section 418. For example, some comments state that our interpretation seems appropriate because requiring monitoring of the "effectiveness" of the preventive controls would be redundant with required verification activities. In addition, requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Some comments support the proposed provisions without change. For example, some comments note that the proposed requirement for written procedures for monitoring is similar to globally recognized food safety standards and current industry practices and is a proactive measure to help facilities prevent problems. Some comments that support the proposed

provisions suggest alternative or additional regulatory text (see, e.g., Comment 466 and Comment 467) or ask us to clarify how we will interpret the provision (see, e.g., Comment 465 and Comment 468).

In the following paragraphs, we discuss comments that disagree with

our tentative conclusion or with the proposed requirements, or ask us to clarify the proposed requirements or suggest one or more changes to the proposed requirements. After considering these comments, we are affirming our tentative conclusion that the language of section 418 of the FD&C

Act regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the “performance” of preventive controls. We also have revised the proposed requirements as shown in table 34, with editorial and conforming changes as shown in table 52.

TABLE 34—REVISIONS TO THE PROPOSED REQUIREMENTS FOR MONITORING

Section	Description	Revision
117.145	Flexibility in requirements for monitoring.	Provide that monitoring take into account both the nature of the preventive control and its role in the facility’s food safety system.
117.145(c)(1)	Records of monitoring	Provide that records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.
117.145(c)(2)	Records of monitoring	Provide for exception records for monitoring of preventive controls other than refrigeration.

*A. Our Tentative Conclusion To Require Monitoring of the Performance of Preventive Controls*

(Comment 461) Some comments disagree with our tentative conclusion that it would be appropriate to require monitoring of the “performance” of preventive controls and assert that the concept of “performance evaluation” is too complex to be included in the rule.

(Response 461) These comments may have misinterpreted what we meant by “monitoring performance of preventive controls.” We used the term “performance” to mean “the execution or accomplishment of an action, operation, or process undertaken or ordered” (78 FR 3646 at 3747). We acknowledge that the definition of “monitoring” that we are establishing in this rule includes that the purpose of observations or measurements conducted as part of monitoring is to “assess” whether control measures are operating as intended. However, we provided examples showing that this assessment is a straightforward determination of whether a process is operating as intended and is not a complex evaluation as asserted by the comments. (See, e.g., the discussion of monitoring the temperature of a process for roasting nuts, 78 FR 3646 at 3746–3747.)

(Comment 462) Some comments that support monitoring the performance of preventive controls assert that our proposed definition of “monitoring” (proposed § 117.3), and our preamble discussions of “monitoring,” have the potential to confuse “monitoring the performance of preventive controls” with verification activities that address ongoing implementation of control measures.

(Response 462) See Response 106, in which we discuss comments on the definition of monitoring and describe the changes we have made to that definition to address concerns about the potential to confuse “monitoring the performance of preventive controls” with verification activities that address ongoing implementation of control measures.

(Comment 463) Some comments assert that authority should be explicitly granted to the States to conduct food safety monitoring and that we should maintain our responsibilities for product tracing.

(Response 463) These comments misinterpret the provisions of section 418 of the FD&C Act and this rule. Section 418 places the responsibility for establishing and implementing a food safety system (including hazard analysis, risk-based preventive controls, preventive control management components (including monitoring, corrective action procedures, and verification), and recordkeeping) on the owner, operator, or agent in charge of a facility, not on FDA or any other regulatory authority. This requirement for monitoring within the framework of hazard analysis and risk-based preventive controls is distinct from regulatory oversight of food safety, such as during inspections and investigations of outbreaks of foodborne illness, which generally involve product tracing. We agree that it is important to coordinate regulatory oversight of food safety with the States and other food safety partners. As discussed in Response 5, we are working through the PFP to develop and implement a national Integrated Food Safety System consistent with FSMA’s emphasis on

establishing partnerships for achieving compliance (see section 209(b) of FSMA).

(Comment 464) Some comments express concern about monitoring for radiological hazards. Some comments claim hardships for fruit packinghouses required to analyze and monitor radiological hazards. Some comments object to comprehensive monitoring for radiological hazards and note that the Codex Principles of Food Hygiene (Ref. 81) do not address radiological hazards. Some comments from foreign entities request an exemption from the requirements to monitor radiological hazards because their government already monitors the food supply for radiological safety at a national level.

(Response 464) These comments misinterpret the proposed requirements for monitoring. In this rule, “monitoring” means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended, such as measuring temperature during a process in which temperature is critical to controlling a hazard. The comments seem to be referring to a situation in which a receiving facility would find it appropriate to test incoming raw materials or other ingredients to ensure that they are not contaminated with a radiological hazard. In such a circumstance, testing the incoming materials would not be monitoring, but rather would be a preventive control (different from its usual role in verification). Regardless, whether a facility would need to conduct such testing (e.g., after an accident at a nuclear facility near one of the facility’s suppliers) would be determined based on the outcome of its hazard analysis.



As part of its hazard analysis, a facility that identifies a radiological hazard as a hazard requiring a preventive control, and determines that testing raw materials and other ingredients is an appropriate preventive control, could consider the extent to which any testing conducted by its government on raw materials and other ingredients reduces the need for, or extent of, its own testing.

*B. Proposed § 117.145(a)—Flexibility in Requirements for Monitoring*

We proposed that, as appropriate to the preventive control, you must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls, and monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(Comment 465) Some comments assert that some food allergen controls are not “monitored” in the sense that HACCP controls are monitored. Some comments support a “visibly clean” standard for monitoring for food allergens.

(Response 465) To the extent that these comments are asserting that the types of monitoring activities that a facility would establish likely would be different for food allergen controls than for a control at a CCP for a product subject to a HACCP plan, we agree. Under the rule, a facility has flexibility to establish preventive control management components, including monitoring, as appropriate to the preventive control, and the nature of any monitoring activity will depend on the nature of the preventive control and its role in the facility’s food safety system. In addition, a facility could determine, for example, that it will visually observe food allergen controls as a verification activity and not establish a separate “monitoring” activity within the meaning of § 117.145. For example, a facility that uses several food allergens as ingredients could store each of the food allergens in a separate area of the facility, and then “visually observe” that the various food allergens are in their assigned storage areas. We agree that “visibly clean” can be a minimum standard that a facility could apply during verification of food allergen controls by visual observation.

(Comment 466) Some comments ask us to require continuous monitoring of preventive controls because the NACMCF HACCP guidelines recommend continuous monitoring of controls where possible.

(Response 466) We decline this request. The NACMCF HACCP guidelines characterize continuous monitoring as the ideal situation and specifically note that continuous monitoring is always preferred “when feasible.” The NACMCF HACCP guidelines also note that continuous monitoring is possible with many types of physical and chemical methods. However, as we previously discussed, both the NACMCF HACCP guidelines and the Codex HACCP Annex acknowledge that continuous monitoring may not be possible, or even necessary, in all cases (78 FR 3646 at 3748).

(Comment 467) Some comments agree that frequency and areas to be tested and monitored need to be determined based on each product and facility and ask us to allow each individual facility to determine the frequency and areas to be monitored based on a completed risk assessment. Some comments ask us to specify that the frequency of monitoring preventive controls must have a scientific basis.

(Response 467) It is unclear whether the comment agreeing that monitoring frequency and areas to be tested need to be determined based on each product and facility was directed to the monitoring provision or to environmental monitoring. Regardless, by requiring written procedures for monitoring, and specifying that the procedures include the frequency with which the procedures are to be performed, the rule provides that each facility must determine the frequency of monitoring, as well as details such as the areas to be monitored. However, we decline the request to specify that these procedures be based on a completed “risk assessment.” The rule requires the facility to conduct a hazard analysis, which determines whether there are any hazards requiring a preventive control, and the facility would establish preventive controls for such hazards as appropriate to the facility and the food. The facility must consider factors associated with risk (*i.e.*, the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls) in evaluating whether any potential hazard is a hazard requiring a preventive control (§ 117.130(c)). Risk could be relevant to a facility’s identification of appropriate preventive controls for a particular hazard requiring a preventive control. However, it is the nature of the preventive control, rather than the risk associated with the hazard, that is more relevant to the frequency of monitoring and the areas to be monitored.

Accordingly, the rule specifies that the facility establish written procedures and conducts monitoring as appropriate to the preventive control, rather than based on risk associated with the hazard. (See, *e.g.*, the discussion of monitoring the temperature of a process for roasting nuts, 78 FR 3646 at 3746–3747.)

We decline the request to specify that the frequency of monitoring preventive controls must have a scientific basis. Monitoring should take place with sufficient frequency to detect a problem in the performance of a preventive control. The importance of the preventive control to the safety of the food can be one factor in setting a frequency. We acknowledge that scientific information may be appropriate in determining the frequency of monitoring in some cases. For example, the frequency may be statistically based, such as with statistical process control. However, in some cases factors other than scientific information may be appropriate in determining the frequency of monitoring. For example, historical information on the consistency of the control measure can be a factor in determining frequency. When variability of the process is low, the frequency may be less than with a process that has more variability. As another example, a process that is operated at a point close to a food safety parameter limit may be monitored more frequently than one where there is a large safety margin built into the process.

*C. Proposed § 117.145(b)—Records*

We proposed that all monitoring of preventive controls must be documented in records that are subject to verification and records review.

(Comment 468) Some comments point out that table 6 in the 2014 supplemental human preventive controls notice includes an example of a monitoring activity that generally would not require monitoring records (*i.e.*, monitoring for foreign material with x-rays) (see 79 FR 58524 at 58542). These comments assert that this example is in conflict with the proposed regulatory text and ask us to modify the regulatory text to provide the flexibility we acknowledged in the 2014 supplemental human preventive controls notice. Other comments ask us to specify that monitoring must be documented as appropriate to the nature of the preventive control.

Some comments ask us to recognize the acceptability of monitoring systems that exclusively provide exception reports. These comments describe exception reporting as a structure where

automated systems are designed to alert operators and management on an exception basis—*i.e.*, only when a deviation from food safety parameter limits are observed by the system. These comments assert that, in many cases, monitoring of preventive controls can be done by automated systems that provide exception reporting in a much more efficient manner than if performed by operators and that automated monitoring allows for increased sampling frequency (often continuous) and reduction of human error. The comments provide an example of a refrigeration temperature control that notifies on exception (*e.g.*, high temperature alarm) and may only record temperatures that exceed the specified temperature (without recording temperatures that meet control requirements). These comments acknowledge that such systems must be validated and periodically verified to ensure they are working properly. These comments ask us to clarify in the preamble to the final rule that monitoring systems can work affirmatively or by exception and that both types of systems and their related documentation are acceptable.

(Response 468) We have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary. We agree that the exception reporting described in these comments, including validation and periodic verification to ensure that the system is working properly, would be an acceptable monitoring system in the

circumstances provided in the comments—*i.e.*, for monitoring refrigeration temperature. Therefore, we have revised the regulatory text to provide that records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control. Although the comments specifically requested that we clarify our view on exception records in the preamble, we believe that clarifying the regulatory text will be more useful, both to facilities and to regulatory agencies that conduct inspections for compliance with the rule. If a facility uses “exception records,” the facility must have evidence that the system is working as intended, such as a record that the system has been challenged by increasing the temperature to a point at which an “exception record” is generated. (See also Response 602 and Response 610.)

We also have revised the regulatory text to provide that exception records may be adequate in circumstances other than monitoring of refrigeration temperature. For example, in table 6 of the 2014 supplemental human preventive controls notice the example we provided of a monitoring activity that generally would not require monitoring records is monitoring for foreign material with x-rays. We believe that an x-ray system that monitors for foreign material with x-rays would

result in a record only when the system detects foreign material.

**XXXI. Subpart C: Comments on Proposed § 117.150—Corrective Actions and Corrections**

We proposed to establish requirements for corrective actions and corrections. Some comments support the proposed requirements without change. For example, some comments assert that there is virtually no reason to have a food safety plan unless there are proper corrective actions in place so the product can be properly disposed of. Some comments agree that there should be written procedures for corrective actions and note the importance of identifying and evaluating the problem, correcting it, and documenting the corrective action. Some comments express the view that the proposed requirement for clear corrective action in the event of an unanticipated problem, and documenting all corrective actions, contributes to a comprehensive safety plan. Some comments that support the proposed provisions suggest alternative or additional regulatory text (*see, e.g.*, Comment 469, Comment 470, Comment 479, Comment 480, and Comment 485).

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 35, with editorial and conforming changes as shown in table 52.

**TABLE 35—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CORRECTIVE ACTIONS AND CORRECTIONS**

Section	Description	Revision
117.150(a) .....	Corrective action procedures .....	Clarify that corrective action procedures depend on the nature of the hazard, as well as the nature of the preventive control.
117.150(a)(1) .....	Corrective action procedures .....	Clarify that the specified list of corrective action procedures is not intended to be exhaustive.
117.150(b) .....	Corrective action in the event of an unanticipated food safety problem.	Specify that the requirement applies when “a corrective action procedure” (rather than “a specific corrective action procedure”) has not been established.
117.150(b)(1)(ii) .....	Corrective action in the event of an unanticipated food safety problem.	Specify that the requirement applies when a preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective (rather than just when a single preventive control has been found to be ineffective).
117.150(c)(2) .....	Corrections .....	Provide for additional circumstances when corrections, rather than corrective actions, are warranted.

**A. Proposed § 117.150(a)(1)—Requirement To Establish and Implement Corrective Action Procedures**

We proposed that, with some exceptions, as appropriate to the preventive control you must establish and implement written corrective action procedures that must be taken if

preventive controls are not properly implemented. The corrective action procedures must include procedures to address, as appropriate, the presence of a pathogen or appropriate indicator organism in an RTE product detected as a result of product testing, as well as the presence of an environmental pathogen

or appropriate indicator organism detected through environmental monitoring.

(Comment 469) Some comments note that we proposed to list two circumstances that require written corrective active procedures (*i.e.*, product testing and environmental

monitoring) and that it is not clear whether this list is intended to be exhaustive or not (*i.e.*, whether written corrective action procedures are required in only these two circumstances, or whether there may be other circumstances that require written corrective action procedures). These comments ask us to insert “but are not limited to” after “must include” if we intend that the list is not exhaustive. Likewise, other comments state our proposal to specifically require corrective action procedures may result in a misunderstanding by some facilities about the need to take corrective actions in circumstances other than in response to testing results, other non-conformances, or other types of verification activities. These comments assert that it would be better for food safety if the regulatory requirements took a more principled approach and generally required corrective action procedures, with the importance of corrective action procedures for testing programs addressed through guidance. If, however, we conclude that specific requirements for corrective action procedures for testing programs are necessary, these comments ask us to clarify that the nature and extent of any corrective actions should be proportional to the nature of the test findings.

(Response 469) We have revised the regulatory text, with associated editorial revisions and redesignations, to clarify that the specified list of corrective action procedures is not intended to be exhaustive (*i.e.*, not limited to the two corrective action procedures that we specified in the proposed human preventive controls rule). The approach we used in the modified regulatory text (*i.e.*, “You must establish and implement written corrective action procedures . . ., including procedures to address, as appropriate . . .” is similar to the approach used in several other provisions of the rule. (See, *e.g.*, requirements for allergen controls (§ 117.135(c)(2)); sanitation controls (§ 117.135(c)(3)(i)); and monitoring (§ 117.145(a).) We decline the suggestion to modify the regulatory text by adding “but is not limited to” after “includes.” The word “includes” does not need to be followed by “but is not limited to” to clearly communicate that a following list is not complete. (See Response 68.) We agree that the nature and extent of any corrective actions in response to the findings of testing programs should be proportional to nature of the test findings. (See Response 470.)

(Comment 470) Some comments state that the nature and extent of the

corrective actions should be proportional to the nature of the testing results. These comments ask us to require that a facility establish and implement corrective action procedures that must be taken if preventive controls are not properly implemented as appropriate to the nature of the hazard, the nature of the control measure, and the extent of the deviation.

(Response 470) We have revised the regulatory text to specify that the corrective action procedures are established and implemented based on the nature of the hazard in addition to the nature of the preventive control. We agree that the nature of the hazard plays a key role in the corrective actions that a facility would take. Although a facility’s corrective action procedures likely would specify actions to take based on the extent of the deviation, we consider this a detail that does not need to be specified in the rule.

(Comment 471) Some comments ask us to revise the provisions to clarify that corrective action procedures are not always necessary when testing detects the presence of a pathogen or indicator organism. These comments assert that the extent of the corrective actions should be proportional to the nature of the testing results themselves because the level of contamination matters for those microorganisms with thresholds that need to be taken into account and because the location of contamination in the food processing environment matters (*e.g.*, the zone in the facility where the contamination is detected). (For information about zones associated with environmental monitoring, see 78 FR 3646 at 3816.)

(Response 471) We decline this request. These comments appear to be confusing the requirement to establish and implement corrective action procedures with the content of the corrective action procedures. These comments also appear to assume that a requirement to have corrective action procedures (which describe the steps to be taken to ensure that appropriate action is taken to identify and correct a problem and, when necessary, to reduce the likelihood that the problem will recur; that all affected food is evaluated for safety; and that all affected food is prevented from entering into commerce when appropriate) pre-determines the outcome of following the corrective action procedures. This is not the case. If, as the comments assert, a facility concludes, for example, that the nature of some test results do not warrant steps to reduce the likelihood that the problem will recur and that affected food is safe and lawful (or, in the case of finding a pathogen in some zones in

the facility, that no food is affected), then that is what its corrective action procedures would say. The reason to have corrective action procedures is to consider the likely scenarios in advance, with appropriate input from the facility’s food safety team and preventive controls qualified individual, rather than react to these scenarios on an ad hoc basis.

(Comment 472) Some comments ask us to require that corrective actions include an analysis to determine the root cause of a problem, not only identify it. These comments also ask us to require follow-up actions to ensure the corrective action was effective and assert that although the requirements address the need to reanalyze the food safety plan they do not appear to specifically address a review of the corrective action.

(Response 472) The requests of these comments do not require any revisions to the regulatory text. The rule does not use the term “root cause” but it does require the facility to take appropriate action, when necessary, to reduce the likelihood that the problem will recur (see § 117.150(a)(2)(ii)). Root cause analysis is simply part of a common approach to complying with this requirement. (Knowing the root cause is key to reducing the likelihood that a problem will happen again.) The rule also requires a review of records of corrective actions, but does so as a verification activity rather than as part of the corrective action procedures (see § 117.165(a)(4)).

(Comment 473) Some comments ask us to revise the proposed rule to address corrective actions in a more general way and then outline areas where specific corrective action procedures would be helpful, such as for testing programs, in guidance.

(Response 473) The proposed provisions do not prescribe the outcome of the corrective action procedures, but merely direct the facility to the types of actions that the procedures must address. In essence, the proposed provisions already do, as the comments request, address corrective actions in a general way.

(Comment 474) Some comments ask us to specify that the requirements also apply when a preventive control is found to be ineffective.

(Response 474) We have not revised the regulatory text as requested by these comments. The appropriate action when a preventive control is found to be ineffective is to reanalyze the food safety plan and to establish and implement a preventive control that is effective, not follow a corrective action procedure. A corrective action

procedure is intended to address a problem that happens when following the procedures in a food safety plan that previously was verified to be valid, not to fix problems on an ongoing basis when a preventive control is ineffective (and, thus, the food safety plan is not valid). We agree that some of the steps that apply to corrective actions may need to be taken, such as evaluating affected food for safety and ensuring that adulterated food does not enter commerce. This is addressed by the provisions for corrective actions in the event of an unanticipated problem (§ 117.150(b)(1)(ii)), which require specific corrective actions to be taken (§ 117.150(b)(2)).

*B. Proposed § 117.150(a)(2)—Content of Corrective Action Procedures*

We proposed that corrective action procedures must describe the steps to be taken to ensure that: (1) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (2) appropriate action is taken to reduce the likelihood that the problem will recur; (3) all affected food is evaluated for safety; and (4) all affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

(Comment 475) Some comments assert that the corrective action procedures should not consider food to be “affected” if it is immediately subjected to an additional (or repeat) preventive control after determining that the initial preventive control was not properly implemented. These comments discuss an example in which there is a temperature deviation below accepted parameter limits for a given process, and the incorrectly processed product is re-processed correctly, and assert that it would be illogical to consider the food to be “affected” in this circumstance. Other comments ask us to modify the requirements to specify that they apply to all affected food “if any.”

(Response 475) We decline the request to modify the regulatory text to specify that the requirements apply to all affected food “if any.” Food is “affected” if a preventive control is not properly implemented during its production. However, the rule does not pre-determine the consequences when food is “affected.” Instead, the rule requires the facility to evaluate the affected food for safety. If, as in the example described by the comments, the facility re-applies the preventive control such that the food is safe and is

not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, there would be no need to take steps to prevent that food from entering commerce.

(Comment 476) Some comments assert that the proposed regulatory text could be misunderstood as a requirement to establish a new preventive control after implementing a corrective action procedure. These comments also assert that it would be inappropriate to assume that corrective action procedures always correct a problem with the implementation of a new or additional preventive control.

(Response 476) We received these comments before we issued the 2014 supplemental human preventive controls notice. The proposed regulatory text in the 2014 supplemental human preventive controls notice addresses the issues identified in these comments by clearly separating the requirement to take appropriate action to identify and correct a problem that has occurred from the requirement to take appropriate action, when necessary, to reduce the likelihood that the problem will recur.

(Comment 477) Some comments ask us to provide that requirements for corrective actions be principle-based (e.g., containment of affected product, control restored to operation before commencing production) rather than prescriptive.

(Response 477) The requirements for corrective actions established by this rule are principle-based in that they require the facility to describe the steps that it will take rather than prescribe the steps that it will take.

(Comment 478) Some comments ask us to revise the provision to make re-sampling and/or re-testing one of the first steps in a corrective action procedure to take into account human error. These comments assert that mishandling during sampling, transport, and testing can contribute to a false positive result and that if the results of a follow-up test are negative, then the previous test could be considered an anomaly that could be ignored.

(Response 478) We decline this request. We disagree that an appropriate approach to positive findings of a test for contamination is to re-sample and re-test and to consider positive findings to be an anomaly if subsequent test results are negative. Many food products are not homogeneous and contamination is localized. Even for homogeneous food products (such as fluids), the problem could be the sensitivity of the method if the level of contamination is low. See our guidance entitled “Guidance for Industry: Testing

for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods” (Ref. 82).

*C. Proposed § 117.150(b)—Corrective Action in the Event of an Unanticipated Problem*

With some exceptions, we proposed that you must take corrective action to identify and correct a problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure if any of the following circumstances apply: (1) A preventive control is not properly implemented and a specific corrective action has not been established; (2) a preventive control is found to be ineffective; or (3) a review of records finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions. We also proposed that if any of these circumstances apply, when appropriate you must reanalyze the food safety plan to determine whether modification of the food safety plan is required.

(Comment 479) Some comments ask us to delete the proposed requirement that a facility must reanalyze the food safety plan in the event of an unanticipated problem. These comments argue that FSMA does not specify reanalysis in the event of an unanticipated problem. In addition, these comments assert that the proposed requirement for reanalysis in the event of an unanticipated problem would be redundant with the proposed requirements for reanalysis as a verification activity (proposed § 117.170) and would not add value for food safety. These comments also assert that the term “problem” is ambiguous and ask us to replace “problem” with “food safety issue” if we retain the provision in the final rule.

(Response 479) We acknowledge that section 418 of the FD&C Act does not explicitly specify that a facility must reanalyze its food safety plan in the event of an unanticipated problem. However, as previously discussed, requiring reanalysis of the food safety plan after an unanticipated problem is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry (78 FR 3646 at 3752). In the 2014 supplemental human preventive controls notice, we clarified that reanalysis would be conducted “when appropriate.” For example, if a problem

occurs because personnel did not understand the procedures or carry out the procedures correctly, additional training for applicable personnel may be warranted, but there likely would be no need to reanalyze the food safety plan.

We disagree that the term “problem” is ambiguous. The term “problem” signifies that something is wrong, whereas the term suggested by the comments (*i.e.*, “issue”) may or may not signify that something is wrong. The analogous provisions in the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood, juice, and meat and poultry is “deviation.” We avoided the term “deviation” because “deviation” has the potential to signify that the requirements of this rule for corrective actions only apply when a preventive control is at a CCP, which is not the case. We agree that the requirements are directed to problems related to food safety, and in the 2014 supplemental human preventive controls notice we modified the title of the requirement to be “Corrective action in the event of an unanticipated food safety problem.” However, we continue to use the simpler term “problem” in the remainder of the regulatory text. Specifying that the nature of the problem is “food safety” in the title is sufficient to focus the requirement on food safety.

We agree that there is a relationship between the requirements for corrective actions in the event of an unanticipated food safety problem and the requirements for reanalysis. To reduce redundant regulatory text, in the 2014 supplemental human preventive controls notice we proposed to modify the regulatory text of the requirements for reanalysis to specify that reanalysis is required when appropriate after an unanticipated food safety problem, and we are establishing that modified provision in this final rule. Importantly, the provisions for reanalysis continue to require reanalysis when a preventive control is found to be ineffective. We are not aware of any circumstances in which it would not be appropriate to reanalyze the food safety plan if a preventive control is found to be ineffective.

(Comment 480) Some comments assert that the word “specific” is not appropriate as a modifier for “corrective action procedure” because many preventive controls will have corrective action procedures that allow flexibility based on the nature of the hazard and control. These comments also state that the term “specific” in this context is more appropriate for a CCP control in a HACCP system.

(Response 480) We have revised the regulatory text to delete the word “specific.”

(Comment 481) Some comments ask us to emphasize that reanalysis is required only when a combination of two events occurs (*i.e.*, a preventive control is not properly implemented, and the facility has not established a corrective action procedure).

(Response 481) In the 2014 supplemental human preventive controls notice, we proposed revisions to the regulatory text to clearly specify the circumstances requiring reanalysis. One such circumstance is when a preventive control is not properly implemented and a corrective action procedure has not been established (§ 117.150(b)(1)(i)). The final provision includes the revisions included in the 2014 supplemental human preventive controls notice and is consistent with the request of these comments.

(Comment 482) Some comments ask us to add that corrective actions in the event of an unanticipated problem also apply when a preventive control is “missing.”

(Response 482) We have revised the regulatory text to require corrective actions whenever a preventive control, combination of preventive controls, or the food safety plan as a whole, is ineffective. (See § 117.150(b)(1)(ii).) In assessing what the comment might mean by a preventive control that is “missing,” we concluded that an unanticipated problem could, in some cases, mean that a combination of preventive controls, or the facility’s food safety plan as a whole (rather than a single preventive control), simply was not effective. If this is the case, reanalysis would be appropriate, and we also have modified the requirements for reanalysis to specify that a facility must reanalyze its food safety plan whenever it finds that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective. (See also Response 556.)

(Comment 483) Some comments assert that fresh and fresh-cut produce operations are unlikely to prevent recurrence of occasional detections of human pathogens (particularly *L. monocytogenes*, which is a soil microorganism whose normal habitat is in the field) because there is no “kill step” for pathogens and because the source of contamination may not be identified. These comments point out that we recognize that preventive controls may only be able to “significantly minimize” significant hazards and assert that our acknowledgement that preventive controls may not always be able to

prevent significant hazards is inconsistent with an expectation to prevent recurrence.

(Response 483) We disagree that our acknowledgement that preventive controls may not always be able to prevent significant hazards is inconsistent with an expectation to prevent recurrence. Even when a preventive control is not always able to prevent a hazard requiring a preventive control, it can reduce the likelihood that the hazard will adulterate the food within the meaning of section 402 of the FD&C Act or misbrand the food within the meaning of section 403(w) of the FD&C Act. For example, a facility processing fresh-cut produce can reduce the likelihood of contamination of incoming fresh produce with *L. monocytogenes* through enhanced supply-chain controls for incoming fresh produce, along with appropriate sanitation controls. As discussed in Response 470, we have revised the regulatory text to specify that the corrective action procedures are established and implemented based on the nature of the hazard in addition to the nature of the preventive control, because the nature of the hazard plays a key role in the corrective actions that a facility would take. When a preventive control is not able to prevent a hazard, the facility must focus on minimizing the hazard.

(Comment 484) Some comments ask us to replace the term “reanalyze” with the term “reassess.”

(Response 484) We decline this request. See Response 551.

#### *D. Proposed § 117.150(c)—Corrections*

We proposed that you do not need to comply with the requirements for corrective actions and corrections for conditions and practices that are not consistent with specified food allergen controls or sanitation controls if you take action, in a timely manner, to correct such conditions and practices.

(Comment 485) Some comments support our proposal to provide for corrections, rather than corrective actions, for sanitation controls and some food allergen controls in some circumstances. Other comments assert that situations in which “corrections” can be applied are not limited to sanitation and food allergen controls and could include actions to address other preventive controls such as preventive maintenance controls or CGMPs. As discussed in Comment 164, some comments emphasize the importance of distinguishing between the terms “correction” and “corrective action.”

(Response 485) We have revised the regulatory text, with associated editorial revisions and redesignations, to provide for corrections, rather than corrective actions and corrective action procedures, for minor and isolated problems that do not directly impact product safety. As discussed in Response 164, we also have defined the term “correction” to mean an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

*E. Proposed § 117.150(d)—Records*

We proposed that all corrective actions (and, when appropriate, corrections) must be documented in records and that these records are subject to the verification requirements in §§ 117.155(a)(3) and 117.165(a)(4)(i). We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

**XXXII. Subpart C: Comments on Proposed § 117.155—Verification**

In the 2013 proposed human preventive controls rule, we proposed verification activities that would

include validation, verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, written procedures, reanalysis, and documentation of all verification activities. We also requested comment on whether we should specify the verification activities that must be conducted for verification of monitoring (78 FR 3646 at 3756) and for verification of corrective actions (78 FR 3646 at 3756), and if so, what verification activities should be required.

To improve clarity and readability, in the 2014 supplemental human preventive controls notice we proposed to move the more extensive verification requirements for validation, implementation and effectiveness, and reanalysis from the single proposed section (proposed § 117.150) to separate sections (proposed §§ 117.160, 117.165, and 117.170, respectively). In addition, to address comments that asked us to provide more flexibility to facilities, including flexibility in determining whether and how to conduct verification activities, in the 2014 supplemental human preventive controls notice we proposed that the verification activities be performed “as appropriate to the preventive control.”

In this section, we discuss the proposed requirements for verification of monitoring, verification of corrective

actions, and documentation of verification activities. See sections XXXIII through XXXV for comments on the proposed requirements for validation, verification of implementation and effectiveness, written procedures, and reanalysis. See table 37, table 38, and table 39 for a summary of the revisions to those proposed requirements.

Some comments support the proposed requirements for verification of monitoring, verification of corrective actions, and documentation of verification activities without change. For example, comments support the documentation of verification activities (see section XXXII.C). In the following paragraphs, we discuss comments on the flexibility provided for a facility to conduct verification activities as appropriate to the nature of the preventive control. We also discuss comments that address our request for comment on whether we should revise the regulatory text to specify the verification activities that must be conducted for verification of monitoring and for verification of corrective actions, or express concern that the requirements as proposed are too prescriptive. After considering these comments, we have revised the verification requirements described in § 117.155 as shown in table 36.

TABLE 36—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VERIFICATION

Section	Description	Revision
117.155 .....	Flexibility to conduct verification activities.	Provide that verification activities take into account both the nature of the preventive control and its role in the facility’s food safety system.

*A. Flexibility in Requirements for Verification*

(Comment 486) Some comments support the flexibility provided by use of the phrase “as appropriate to the preventive control” in the requirement that verification activities must include, as appropriate to the preventive control, specified verification activities (*i.e.*, validation, verification that monitoring is being conducted, verification that appropriate decisions about corrective actions are being made, verification of implementation and effectiveness, and reanalysis). These comments emphasize that verification activities must be tailored to the preventive control and assert that the use of the word “must” is potentially confusing in light of this flexibility—*e.g.*, because not all preventive controls must be validated for food safety, and those preventive controls that do not need monitoring

would not need verification of monitoring. Other comments ask us to allow facilities flexibility to verify that preventive controls are effective in the manner prescribed by FSMA—*i.e.*, such controls should be deemed to be effective by an appropriate means as determined and supported by the facility within its food safety plan.

(Response 486) The provisions for preventive control management components make clear that all preventive control management components, including verification, are required as appropriate to ensure the effectiveness of the preventive control, taking into account the nature of the preventive control and its role in the facility’s food safety system (see § 117.140). Likewise, the provisions for each of the preventive control management components (*i.e.*, monitoring, corrective actions and

corrections, and verification) individually provide flexibility, either by specifying that the provisions apply as appropriate to the nature of the preventive control and its role in the facility’s food safety system (*i.e.*, for monitoring and verification) or both the nature of the preventive control and the nature of the hazard (*i.e.*, for corrective actions and corrections). The word “must” specifies the type of activities that a facility can use to satisfy the requirements for a particular preventive control management component.

We are retaining the term “must.” However, we agree that the rule should provide flexibility for additional verification of implementation and effectiveness. To provide that additional flexibility, we have revised the specific requirements for verification of implementation and effectiveness to provide for other activities appropriate

for verification of implementation and effectiveness (see § 117.165(a)(5)). As a conforming revision, we have revised the requirement for review of records to include a review of records of “other verification activities” within a reasonable time after the records are created (see § 117.165(a)(4)(ii)).

*B. Proposed § 117.155(a)—Verification Activities*

1. Proposed § 117.155(a)(1)—Validation

We proposed that verification activities must include, as appropriate to the preventive control, validation in accordance with § 117.160. See section XXXIII for comments on validation as a verification activity.

2. Proposed § 117.155(a)(2)—Verification of Monitoring

We proposed that verification activities must include, as appropriate to the preventive control, verification that monitoring is being conducted in accordance with § 117.145. We requested comment on whether we should specify the verification activities that must be conducted for monitoring, and, if so, what verification activities should be required.

(Comment 487) Comments that address our request for comment on whether we should specify the verification activities that must be conducted for monitoring ask us to not do so because this prescriptive approach would be too limiting. These comments ask us to instead provide flexibility for the facility to determine the appropriate verification activities.

(Response 487) We agree that we should provide flexibility for the facility to determine these verification activities, and are not specifying the verification activities that must be conducted for monitoring.

(Comment 488) Some comments express concern that the proposed requirements for verification of monitoring would bring food CGMPs to the same level as pharmaceutical CGMPs. These comments assert that our example of how verification of monitoring could be conducted when a metal detector is a preventive control is impractical (FR 3646 at 3756). These comments explain that a quality control officer is not likely to go out onto the plant floor every shift to verify the operator’s metal detector readings but would instead document the metal detector readings, which would be captured as part of the batch record review. These comments suggest that a more appropriate description of what a facility would do when a metal detector is a preventive control would be to

“check” whether the metal detector is rejecting test pieces of metal.

(Response 488) We are establishing the requirements for verification of monitoring as part of a system for hazard analysis and risk-based preventive controls, not as a matter of CGMP. As previously discussed (78 FR 3646 at 3756), verification of monitoring is consistent with the FSIS HACCP regulation for meat and poultry, which requires direct observations of monitoring activities as an ongoing verification activity (9 CFR 417.4(a)(2)(ii)). We disagree that our example of how verification of monitoring could be conducted when a metal detector is a preventive control is impractical; observation of the operator conducting the check with test pieces by a supervisor, or having a quality assurance person run a test, is not uncommon. However, in the 2014 supplemental human preventive controls notice, we clarified that verification that monitoring is being conducted is required as appropriate to the preventive control. With this added flexibility, a facility could, for example, determine that it would satisfy the requirement for verification of monitoring by reviewing records under § 117.165(a)(4). Doing so would be consistent with the NACMCF HACCP guidelines (Ref. 35), the Codex HACCP guidelines (Ref. 34), and FDA’s HACCP regulations for seafood and juice, which all address verification of monitoring through the review of records (78 FR 3646 at 3756).

3. Proposed § 117.155(a)(3)—Verification of Corrective Actions

We proposed that verification activities must include, as appropriate to the preventive control, verification that appropriate decisions about corrective actions are being made in accordance with § 117.150. We requested comment on whether this section should specify the verification activities that must be conducted for corrective actions, and if so, what verification activities should be required.

(Comment 489) Some comments ask us not to specify the verification activities that must be conducted for corrective actions because this approach would be too limiting. These comments ask us to instead provide flexibility for the facility to determine the appropriate verification activities.

(Response 489) We agree that we should provide flexibility for the facility to determine the appropriate verification activities for corrective actions, and are not specifying the

verification activities that must be conducted for corrective actions.

4. Proposed § 117.155(a)(4)—Verification of Implementation and Effectiveness

We proposed that verification activities must include, as appropriate to the preventive control, verification of implementation and effectiveness in accordance with § 117.165. See section XXXIV for comments on verification of implementation and effectiveness.

5. Proposed § 117.155(a)(5)—Reanalysis

We proposed that verification activities must include, as appropriate to the preventive control, reanalysis in accordance with § 117.170. See section XXXV for comments on reanalysis as a verification activity.

*C. Proposed § 117.155(b)—Documentation of Verification Activities*

We proposed that all verification activities must be documented in records. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

*D. Comments on Potential Requirements Regarding Complaints*

We requested comment on whether and how a facility’s review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards (78 FR 3646 at 3768).

(Comment 490) Some comments ask us to require review of consumer complaints as a verification activity and note that our HACCP regulations for seafood and juice require that verification activities include a review of consumer complaints to determine whether they relate to the performance of the HACCP plan or reveal the existence of unidentified CCPs. Some comments note circumstances in which consumer complaints have identified food safety problems that resulted in a company report to the RFR.

Some comments state that the frequency and type of complaints a facility receives is a very good indicator of the underlying issues associated with food production, reviewing these records would provide valuable insight into the type of issues that should be investigated, and this type of verification activity could be therefore be extremely effective with little to no cost because the facility would already be performing this type of activity. Some comments state that many

foodborne outbreaks have been identified through complaints and a review of complaints is a critical component of a food safety system.

Other comments state that a food safety review of complaints is a prudent part of a food safety program but that the value of such a review is in providing information and feedback for continuous improvement of the food safety management system rather than as a verification of preventive controls. These comments caution against use of consumer complaints as a regulatory requirement for verification of the food safety plan because most complaints relate to product quality. If such a requirement is nonetheless established in the final rule, these comments recommend that the rule only require follow-up and documentation for the rare occurrences where consumer complaints relate to food safety issues.

Other comments ask us not to require review of complaints as a verification activity. Some of these comments assert that complaints rarely relate to food safety or yield information that leads to discovery of a food safety issue. Some comments assert that requiring review of consumer complaints could result in unnecessary time and effort being spent on an activity with a limited correlation

to food safety. Other comments assert that complaints would be acted upon immediately for business reasons, and that waiting to react to complaints until conducting a review of records as a verification activity would be too late. Other comments assert that complaints are sensitive business information. Other comments assert that some consumer complaints are false or emotional (rather than factual) and have no place in development of preventive controls. Some comments assert that FSMA does not expressly direct us to require review of complaints. Some comments assert that review of complaints is not a precise scientific process, and that consumer comments are often open to different interpretations.

(Response 490) We are not establishing a requirement for a review of complaints as a verification activity. We agree that review of complaints is more likely to be useful in providing information and feedback for continuous improvement of the food safety system rather than as a verification of preventive controls. However, we encourage facilities to do such a review, as they occasionally do uncover food safety issues such as an undeclared allergen.

**XXXIII. Subpart C: Comments on Proposed § 117.160—Validation**

We proposed to establish requirements for validation of preventive controls. Some comments support the proposed requirements without change. For example, some comments agree that validation must be performed by (or overseen by) a preventive controls qualified individual and that some preventive controls (*e.g.*, food allergen controls, sanitation controls, and recall plans) do not require validation. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, *e.g.*, Comment 491, Comment 500, Comment 501, Comment 503, and Comment 513) or ask us to clarify how we will interpret the provision (see, *e.g.*, Comment 499, Comment 502, and Comment 508).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 37, with editorial and conforming changes as shown in table 52.

**TABLE 37—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VALIDATION**

Section	Description	Revision
117.160(a) .....	Flexibility for validating preventive controls.	Provide that validation be conducted as appropriate to both the nature of the preventive control and its role in the facility's food safety system.
117.160(b)(1) .....	Circumstances requiring validation	Provide that, when necessary to demonstrate the control measures can be implemented as designed, validation may be performed: (1) Within 90 days after production of the applicable food first begins; or (2) within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification.
117.160(b)(1) .....	Circumstances requiring validation	Add an additional circumstance requiring validation— <i>i.e.</i> , whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards requiring a preventive control.
117.160(c) .....	Preventive controls that do not require validation.	Clarify that a list of preventive controls that do not require validation is not an exhaustive list.

**A. Flexibility in the Requirements To Validate Preventive Controls**

With some exceptions (see discussion of proposed § 117.160(b)(3) in section XXXIII.D), we proposed that you must validate that the preventive controls identified and implemented in accordance with proposed § 117.135 to control the significant hazards are adequate to do so (proposed § 117.160(a)).

(Comment 491) Some comments assert that the regulatory text is in conflict with the preamble discussion in

the 2014 supplemental human preventive controls notice because the regulatory text (*i.e.*, “[e]xcept as provided by . . .”) narrowly provides exceptions only for validation of food allergen controls, sanitation controls, supplier controls, and the recall plan, whereas the preamble discussion provides other examples of preventive controls that would not require validation (*i.e.*, zoning, training, preventive maintenance, and refrigerated storage). These comments also assert that although the regulatory

text specifies that validation requirements apply “as appropriate to the nature of the preventive control,” that phrase could be interpreted to mean that only the validation act itself can be tailored and that the facility does not have the flexibility to conclude that validation isn’t necessary.

Some comments assert that the proposed regulatory text would prevent us from requiring validation of specific allergen or sanitation controls where it may be prudent to do so, either now or in the future as a result of a newly



identified hazard, establishment of regulatory allergen threshold(s), or the development of a tool, such as a test method, that would enable validation of the control for the specific hazard.

(Response 491) We have deleted “except as provided by paragraph (b)(3) of this section” from proposed § 117.160(a) to remove the limitation seen by the comments on the exceptions to the requirement for validation of preventive controls. We also have revised the regulatory text of § 117.160(c) to provide that a facility does not need to validate other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility’s food safety system. We specified that the determination that validation is not required must be made by the preventive controls qualified individual to emphasize that specialized experience is necessary to evaluate whether validation is required. We made a conforming revision to the list of responsibilities of the preventive controls qualified individual (see § 117.180(a)).

(Comment 492) Some comments ask us to separate requirements for validation from requirements for verification because verification and validation are two different concepts and combining them is confusing. Some comments point out that while section 418(f)(1) of the FD&C Act explicitly requires verification, it does not require validation. Some of these comments assert that our proposed requirements for validation exceed the mandate of FSMA while others argue that the lack of explicit language in section 418 of the FD&C Act gives us legal flexibility in determining whether and how to require validation.

(Response 492) Our approach is consistent with section 418 of the FD&C Act. Section 418(f)(1) of the FD&C Act requires verification of the preventive controls, and validation is an element of verification (see both the NACMCF HACCP guidelines (Ref. 35) and our HACCP regulation for juice (§ 120.3(p))). We agree that the purpose of validation is different from the purpose of other verification activities, and we have revised the definitions of both terms to make this clearer. Although we are establishing a separate regulatory section for the validation requirements, we did so to improve clarity and readability rather than as a substantive change relevant to the issues discussed in these comments (See Response 150).

(Comment 493) Some comments assert that validation is more appropriate for a HACCP regulation and that requiring the validation of all preventive controls does not reflect the flexibility mandated by section 418(n)(3)(A) of FSMA. Other comments assert that effective preventive measures may be identified in the future that are not amenable to validation and it would be counterproductive for them not to be employed in food safety plans because they cannot meet the validation requirements. These comments explain that certain control measures are not suitable for validation activities due to the nature of the activity or previous validation by another entity (*e.g.*, a supplier).

(Response 493) The 2013 proposed human preventive controls rule would not have required the validation of all preventive controls. For example, we specifically proposed that the validation of preventive controls need not address food allergen controls, sanitation controls, and the recall plan. To emphasize that a facility has flexibility in appropriately determining which other preventive controls require validation, in the 2014 supplemental human preventive controls notice we revised the proposed regulatory text to require validation “as appropriate to the nature of the preventive control.” See (Response 491 for additional revisions we have made to the regulatory text to provide flexibility for a facility to determine that validation is not necessary.

(Comment 494) Some comments ask us to allow validation of the whole system instead of individual controls.

(Response 494) See the discussion of the definition of validation in Response 150. Under the definition, validation can be directed to a control measure, combination of control measures, or the food safety plan as a whole.

(Comment 495) Some comments ask us to align validation requirements with the relative risk of operations.

(Response 495) Validation requirements apply only to preventive controls that are established and implemented based on the outcome of a hazard analysis, which requires consideration of risk. We also require validation as appropriate to the nature of the preventive control and its role in the facility’s food safety system. This provides flexibility with respect to validation and allows consideration of risk.

(Comment 496) Some comments ask whether we will endorse certification under GFSI as satisfying the requirements for validation.

(Response 496) GFSI was established to support improvements in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide (Ref. 83). GFSI has developed a guidance document that specifies a process by which food safety schemes may gain recognition by GFSI, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (*e.g.*, contract sanitation services or food transportation), in relation to food safety (Ref. 83). We have no plans to endorse certification under GFSI (or any other standard setting organization) as satisfying the requirements for validation. However, to the extent that scientific and technical information available from GFSI or another standard setting organization provides evidence that a control measure, combination of control measures, or the food safety plan as a whole is capable of effectively controlling the identified hazards, a facility may use such information to satisfy the validation requirements of the rule.

(Comment 497) Some comments ask us to provide guidance and clarification on topics relevant to validation, such as commodity-specific guidance to help facilities understand what preventive controls are capable of being validated and to design testing to ensure validation conditions always exceed conditions during production. Some comments ask us to clarify our expectations for a validated process and on conducting studies for validation purposes, particularly for preventive controls applied to fresh and fresh-cut produce (such as reduction of pathogens in wash water for fresh-cut leafy greens with the use of sanitizers, which the comments characterize as scientifically difficult and time consuming). Some comments ask us to provide resources for validation, noting that some preventive controls will be difficult to validate and that no scientific research or data are available for certain controls. Some comments ask us to delay enforcement for the validation requirements until a readily accessible repository of validated processes, and scientific and technical information, can be created to assist stakeholders in complying with the validation requirements.

(Response 497) We intend that the guidance we are developing will address topics such as those recommended in the comments. (See Response 2.) In addition, there is a “wash water validation group” with members from government (including

FDA, USDA and CDC) and industry (including producers, chemical suppliers, and equipment suppliers) developing information on how to validate the efficacy of antimicrobial chemicals in wash water for fresh-cut produce processes to demonstrate that the antimicrobials in the washing process are effective for minimizing the risk of cross-contamination. The FSPCA and the Produce Safety Alliance (PSA) are developing information for training, which may be useful to facilities, including facilities that process produce. We are not requiring facilities to comply with the rule, including the validation requirements, for 1, 2, or 3 years depending on the size of the facility. We expect that segments of the food industry will work together and with the FSPCA and the PSA to develop scientific and technical information that can be used as evidence to validate a variety of preventive controls, and that this information will be helpful to facilities.

(Comment 498) Some comments ask us to develop a mechanism for industry to make sure their approach and studies meet the requirements of the rule, such as certification of process authorities or the establishment of a liaison between FDA and industry to ensure validation protocols are in compliance.

(Response 498) As discussed in Response 2, we are developing several guidance documents within FDA, including guidance on validation. In addition, as part of a collaborative effort with the FSPCA we are obtaining technical information useful for developing commodity/industry sector-specific guidelines for preventive controls and outreach to industry, and we intend that effort to include guidance on approaches to satisfy the validation requirements of the rule. We do not intend to develop a mechanism for certification of process authorities or establish a liaison between FDA and industry to ensure validation protocols are in compliance. The guidance we are developing on validation should help industry determine whether their validation approaches are likely to be acceptable to us.

*B. Proposed § 117.160(b)(1)—When Validation Must Be Performed and Role of the Preventive Controls Qualified Individual in Validation*

We proposed that validation of the preventive controls must be performed by (or overseen by) a preventive controls qualified individual prior to implementation of the food safety plan (or, when necessary, during the first 6 weeks of production) and whenever a

reanalysis of the food safety plan reveals the need to do so.

(Comment 499) Some comments ask us to clarify whether an individual attending food safety training by an entity such as a cooperative extension or a State department of agriculture could be a “preventive controls qualified individual” for the purpose of performing or overseeing the validation of preventive controls.

(Response 499) See the discussion in section XXXVI.B.1 for additional information about training applicable to a preventive controls qualified individual. We have not specified additional requirements for a preventive controls qualified individual with respect to validation. A person may be a preventive controls qualified individual through job experience, as well as training. Food safety training provided by an entity such as a cooperative extension specialist or a State department of agriculture could be appropriate training for many of the functions of the preventive controls qualified individual if the training is consistent with the standardized curriculum being developed by the FSPCA.

(Comment 500) Some comments that discuss the distinction between validation and verification ask us to align with the distinction made in FSIS’ Compliance Guidelines on HACCP Systems Validation (FSIS Validation Guidelines) (Ref. 84). As discussed in those guidelines, there are two distinct elements to validation: design and execution. The design element addresses the scientific or technical support for the system design, and the execution element addresses the initial, practical, in-plant demonstration that the system can perform as expected.

(Response 500) As discussed in Response 150, the definition of validation focuses on whether a control measure, combination of control measures, or the food safety plan as a whole is capable of controlling the identified hazards and, thus, captures the design element of validation. We have revised the validation requirements to clarify that it may be necessary to perform validation during production to demonstrate the control measures can be implemented as designed.

(Comment 501) Some comments question whether 6 weeks is enough time to perform all applicable validation studies that would address the execution element of validation. Some comments ask us to explain the basis for the proposed 6-week timeframe. Some comments ask us to align with the 90-day timeframe in the FSIS Validation

Guidelines (Ref. 84). Some comments note that food additives may only be produced a few times per year at plants that also produce industrial, cosmetic, and excipient grade products, and that this production schedule may make it impractical to meet the proposed 6-week timeframe. Some comments note that the seasonal nature of production of some food products may make it impractical to perform all required validations within 6 weeks. Some comments suggest that validation be performed within a specified number of production batches, such as 10 production batches. Some comments emphasize the need for flexibility and ask us to both adopt a 90-day timeframe and provide for a longer timeframe with a written justification, or provide for ongoing evidence of process validation. Some comments ask us to specify that validation be performed within a reasonable time as justified by the preventive controls qualified individual. Some comments ask for more time for small businesses to perform validation studies.

(Response 501) We note that the 90-day timeframe for validation is established in FSIS’ regulations at 9 CFR 304.3(b) and (c) and 9 CFR 381.22(b) and (c) (Conditions for receiving inspection for meat and meat products and poultry and poultry products, respectively). The FSIS Validation Guidelines are a companion to those regulations. We have revised the regulatory text, with associated editorial changes, to make two changes to the proposed 6-week timeframe for validation of preventive controls. First, we have adopted the 90-day timeframe already established in FSIS’ regulations by specifying that when necessary to demonstrate the control measures can be implemented as designed, validation may be performed within 90 days after production of the applicable food first begins. Although we had proposed a 6-week timeframe based on the 3 to 6-week timeframe suggested in the Codex Guidelines for the Validation of Food Safety Control Measures (Ref. 39) (Codex Validation Guidelines), we agree that practical limitations associated with the production of some food products may make it difficult to perform validation within 6 weeks. The 90-day timeframe in FSIS’ regulations, and incorporated into the FSIS Validation Guidelines, reflects more than 15 years of experience with validating HACCP systems for meat and poultry. Although we have provided for validation to be performed within 90 days after production of the applicable food first begins, we do not believe it

would take a full 90 days of production to determine whether the facility can provide assurances that a control measure is working as intended to control the hazard.

Second, we have provided for validation within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable food first begins. We acknowledge that practical limitations such as those described in the comments could prevent a facility from performing the validation within 90 days after production of the applicable food first begins. A timeframe that exceeds 90 days after production of the applicable food first begins will be the exception rather than the norm and we are requiring that the preventive controls qualified individual provide (or oversee the preparation of) a written justification for such a timeframe. We made a conforming revision to the list of responsibilities of the preventive controls qualified individual (see § 117.180(a)).

(Comment 502) Some comments ask us to clarify that the time period when validation is performed would be considered as production time rather than “down time.” These comments explain that many farms with on-farm processing activities conduct those activities sporadically for a brief period. For a processing activity that may be conducted for only 2 or 3 days within a six week period, the facility may not have enough production run time to validate controls.

(Response 502) As discussed in Response 501, we have provided for validation within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable food first begins. A facility would design a preventive control that is valid based on scientific and technical information and then determine that the control can be applied in the facility. It is unlikely that this will require a full 90 days of production, and we see no reason for a facility to significantly extend the validation time—*e.g.*, to a year or more—because it only produces for 2–3 days every 6 weeks.

(Comment 503) Some comments ask us to add another circumstance when validation would be required—*i.e.*, whenever a change is made to the control being applied.

(Response 503) We have revised the regulatory text to require validation whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards requiring a preventive control. Under this provision, a facility would re-validate a preventive control if, for example, a different type of equipment is used to deliver a heat process, because it would be necessary to determine that the new equipment can consistently achieve the required temperature and time of the process. However, a facility would not need to re-validate a preventive control if, for example, a thermal process is changed by increasing the time or temperature, because a less stringent thermal process would already have been validated.

(Comment 504) Some comments ask us to require validation both before production and 6 weeks after production begins.

(Response 504) We decline this request. A facility has flexibility to perform validation as appropriate to the nature of the preventive controls, whether before production (*e.g.*, by obtaining and evaluating generally available scientific and technical information or by conducting studies), after production begins (to demonstrate the control measures can be implemented as designed during full-scale production), or both.

(Comment 505) Some comments assert that qualified third parties should conduct all process validations.

(Response 505) The critical factor is that the validation be performed (or overseen) by an individual who has the appropriate training and experience to validate the control measures. This preventive controls qualified individual could be a third party or an employee of the facility. Employees of the facility have a vested interest in ensuring that the controls are effective, including by appropriately validating the controls, just as a “disinterested” third party would have.

#### *C. Proposed § 117.160(b)(2)—What Validation Must Include*

We proposed that the validation of preventive controls must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards.

(Comment 506) As discussed in Comment 150, some comments ask us to revise the definition of “validation” to be consistent with the Codex definitions.

(Response 506) The Codex definition of validation is “Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.” The definition of “validation” we are establishing in this rule specifies that validation means obtaining and evaluating scientific evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards, which more closely aligns with the Codex definition. As a conforming change for consistency with the revisions we made to the definition, we have revised the proposed requirements for validation of preventive controls to specify that validation of preventive controls must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards. (See also Response 150.)

(Comment 507) Some comments assert that our discussion of validation refers to “scientific proof” for the validation of a processing step and ask us to define what is and is not considered scientific proof for validation.

(Response 507) We used terms such as “scientific and technical information” and “scientific and technical basis” rather than “scientific proof” when discussing validation. For information about what we mean by “scientific and technical information,” see 78 FR 3646 at 3753–3754.

(Comment 508) Some comments ask us to clarify expectations of validations for basic sanitary processes.

(Response 508) The requirements for validation only apply to preventive controls. To the extent that the comment is referring to sanitary practices governed by CGMPs (such as in §§ 117.35 and 117.37), the validation requirements would not apply. To the extent that the comment is referring to sanitation controls established as a preventive control, those sanitation controls are excluded from the validation requirements (see § 117.160(a)(3)(ii)).

(Comment 509) Some comments ask that we not require further validation of well-accepted preventive controls, such

as refrigeration temperature and roasting coffee.

(Response 509) A facility may rely on generally available scientific and technical information to demonstrate the adequacy of controls such as refrigeration and roasting processes for coffee, but must obtain that information and establish it as a record (see § 117.155(b)).

(Comment 510) Some comments express concern that specific methods are not available to enable validation. Some comments express concern that the requirement to “conduct studies” might be intended, or could be interpreted, to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices). These comments assert that any such requirement would incur extreme costs and burdens without delivering commensurate public health benefits.

(Response 510) We do not intend the requirement to “conduct studies” to mean that firms are required to develop or validate analytical methods.

(Comment 511) Some comments ask us to clarify that dry pasta facilities would not be required to validate that their extrusion or drying process provides a 5-log reduction for *Salmonella*. These comments assert that a “kill step” is not necessary for foods such as dry pasta because consumers cook the product before consumption and that validation would be costly, time-consuming, and impractical.

(Response 511) The rule does not require any specific performance standards, such as the 5-log reduction standard in our HACCP regulation for juice (see § 120.24). A dry pasta facility that evaluates *Salmonella* as a known or reasonably foreseeable hazard may determine that the nature of the dry pasta product (and, thus, its reasonably foreseeable use) makes it unlikely that it would be consumed without a “kill step” (i.e., cooking sufficient to adequately reduce *Salmonella*) by the consumer and the facility could conclude that its extrusion or drying process is not a preventive control. In contrast, when the nature of the product (such as refrigerated cookie dough) is such that its reasonably foreseeable use includes consumption without cooking (or without cooking sufficient to adequately reduce *Salmonella*) by the consumer, it would not be appropriate to rely on cooking by the consumer to forestall a known or reasonably foreseeable biological hazard.

(Comment 512) Some comments recommend validation via indirect methods such as scientific publications, government documents, predictive

modeling, and other technical information from equipment manufacturers and other sources. These comments assert that the development of validation data is not appropriate for a number of preventive controls in fresh-cut operations (e.g., temperature control, employee hygiene practices, and product separation protocols). Other comments assert that there are a variety of circumstances in which the collection and evaluation of scientific and technical information is not necessary (e.g., the use of sieving or metal detectors to control physical hazards).

(Response 512) See Response 491 and Response 493. We agree that not all preventive controls require validation, and the facility has flexibility to take into account the nature of the preventive control when determining whether to perform validation. The regulatory text, which provides for scientific and technical evidence that a control measure is capable of effectively controlling the identified hazards, provides for the use of “indirect methods” as recommended by the comments. However, even when sources such as scientific publications are the basis for validation, studies may be needed to demonstrate that the process used can be implemented in the facility to control the hazard. For example, scientific publications may support use of a specific concentration of sanitizer in produce wash water to prevent cross-contamination. The facility would still need to demonstrate it can consistently maintain that concentration under operating conditions.

#### *D. Proposed § 117.160(b)(3)—Preventive Controls for Which Validation Is Not Required*

We proposed that validation need not address food allergen controls, sanitation controls, the recall plan and the supplier program (which we now refer to as the “supply-chain program”).

(Comment 513) Some comments ask us to eliminate the specific list of controls that are excluded from the validation requirement and instead revise the regulatory text to provide the facility with flexibility to determine when validation is appropriate. (See also Comment 491.)

(Response 513) As discussed in Response 491, we have deleted “except as provided by paragraph (b)(3) of this section” from proposed § 117.160(a) to remove the limitation seen by the comments on the exceptions to the requirement for validation of preventive controls. We also have revised the regulatory text of § 117.160(c) to provide that a facility does not need to validate

other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility’s food safety system. We see no reason to also eliminate the list of those controls for which we have already determined that validation is not necessary, and require each facility to develop its own rationale for concluding that validation is not necessary based on the nature of these preventive controls. The rule would not prevent a facility from validating one of these preventive controls, such as a food allergen control, if it chooses to do so. (See also Response 514.)

(Comment 514) Some comments assert that the proposed regulatory text would prevent us from requiring validation of specific allergen or sanitation controls where it may be prudent to do so, either now or in the future as a result of a newly identified hazard, establishment of regulatory allergen threshold(s), or the development of a tool, such as a test method, that would enable validation of the control for the specific hazard. Other comments assert that validation of food allergen controls for some food allergens is possible now and that we should not preclude future requirements as it becomes possible to validate food allergen controls for other allergens in the future. Other comments state that a preventive controls qualified individual should determine appropriate validation for food allergen controls. Other comments state that scientific studies are not needed to validate food allergen controls because monitoring is sufficient.

(Response 514) This rule establishes requirements that will apply when the rule becomes effective. It does not address the potential for additional requirements that we could establish, through additional rulemaking, in the future. The rule does not preclude a facility from validating any of its food allergen controls, and we encourage facilities to validate food allergen controls as appropriate to the facility, the food, and the specific food allergen control. However, if a facility decides to validate any of its food allergen controls, the rule does not require that such validation be conducted or overseen by a preventive controls qualified individual.

As previously discussed, we agree that food allergen controls generally are not evaluated through scientific studies and that monitoring (e.g., by visual observation) that these activities do not

result in allergen cross-contact provides sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared food allergens in the food due to allergen cross-contact (78 FR 3646 at 3755).

(Comment 515) Some comments assert that validation of food allergen controls and sanitation controls is already possible through sample swabs and, thus, that reliance strictly on visual observation for potential allergen cross-contact and sanitation controls does not appear to be appropriate.

(Response 515) As discussed in Response 150, validation is directed to determining whether a control measure, when properly implemented, is capable of effectively controlling a hazard. Procedures such as sample swabs (e.g., of equipment used for food containing an allergen to determine if the allergen protein is present after cleaning, and of equipment following a dry cleaning procedure to determine microbial load)

are generally directed to verifying that a control measure is functioning as intended rather than whether the control measure is capable of effectively controlling the hazard. However, they can also be part of a validation study to determine whether a sanitation procedure effectively removes a food allergen from equipment surfaces if a facility decides to validate such procedures.

**XXXIV. Subpart C: Comments on Proposed § 117.165—Verification of Implementation and Effectiveness**

We proposed that you must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. We proposed that to do so you must conduct specified activities (i.e., calibration, product testing, environmental monitoring, and review of records) as appropriate to the facility, the food, and the nature of the

preventive control. We also proposed that you must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments, product testing, and environmental monitoring.

Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 516, Comment 519, Comment 539, Comment 540, Comment 544, and Comment 545) or ask us to clarify how we will interpret the provision (see, e.g., Comment 522, Comment 523, Comment 528, and Comment 536). In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 38.

TABLE 38—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VERIFICATION OF IMPLEMENTATION AND EFFECTIVENESS

Section	Description	Revision
117.165(a) .....	Flexibility in the requirement to conduct activities to verify implementation and effectiveness.	Provide that activities for verification of implementation and effectiveness take into account both the nature of the preventive control and its role in the facility's food safety system.
117.165(a)(1) .....	Verification of implementation and effectiveness for process monitoring instruments and verification instruments.	Provide for accuracy checks in addition to calibration.
117.165(a)(4)(i) .....	Timeframe for review of records of monitoring and corrective action records.	Provide for records review within 7 working days after the records are created, or within or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification.
117.165(a)(5) .....	Other activities appropriate for verification of implementation and effectiveness.	Clarify that there could be alternative verification activities of implementation and effectiveness other than those that we specify in the rule.
117.165(b) .....	Written procedures for verification of implementation and effectiveness.	Clarify that written procedures for verification of implementation and effectiveness are established and implemented as appropriate to the role of the preventive control in the facility's food safety system, as well as appropriate to the facility, the food, and the nature of the preventive control.
117.165(b)(1) .....	Written procedures for verification of implementation and effectiveness for process monitoring instruments and verification instruments.	Require written procedures for accuracy checks in addition to calibration.

*A. Flexibility in the Requirement To Conduct Activities To Verify Implementation and Effectiveness*

We proposed that you must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards by conducting specified activities as appropriate to the facility, the food, and the nature of the preventive control. We proposed to specify the following verification activities: (1) Calibration; (2) product

testing; (3) environmental monitoring; and (4) review of records.

In the following paragraphs, we discuss comments generally directed to the need for a facility to have flexibility to apply these requirements (particularly the requirements for product testing and environmental monitoring) in a manner that works best for the facility in light of its food products and the nature of the preventive controls that would be verified. In sections XXXIV.B through XXXIV.F, we discuss the requirements for calibration, product testing,

environmental monitoring, and review of records more specifically.

(Comment 516) Some comments express support for the flexibility provided by specifying that verification activities must be conducted "as appropriate to the facility, the food, and the nature of the preventive control." Some comments state that the proposed provision means that, based on risk, a fresh fruit packing operation could decide whether or not to do product testing and, when applicable, the type of test and the testing frequency. Some comments agree with the proposed

provisions because they address product testing through flexible written procedures that consider both testing and corrective action plans rather than through mandatory or prescribed requirements. Other comments agree with the proposed provisions because they require facilities to develop and use testing programs that are tailored to their facility, equipment, processes, products, and other specific circumstances and do not prescribe specific requirements for testing, such as finished product testing. Some comments state that product testing may not be effective in identifying the acceptability of a specific ingredient or finished product lot on any given day, but it can help assess and verify the effectiveness of a food safety plan as a whole and the facility's capability to consistently deliver against it.

Some comments assert that the preamble discussion in the 2014 supplemental human preventive controls notice is in conflict with the proposed regulatory text and ask us to modify the regulatory text to provide the flexibility we signaled in that supplemental notice. These comments express concern that the term "must" (*i.e.*, "you must conduct activities that include the following") could be interpreted to mean that activities listed in the regulatory text (in particular, product testing and environmental monitoring) are always required in some form. Some comments ask us to clarify whether product testing and environmental monitoring are required or optional. Other comments assert that facilities should have the flexibility to determine whether to conduct product testing and environmental monitoring based on a risk assessment. Some comments assert that there are circumstances (such as in warehouses and distribution centers; in the production of gases used in food; in operations that hull and shell nuts; and in the production of refined vegetable oils) where these tests would not be necessary. Some comments assert that a determination to conduct environmental monitoring should be on a case-by-case basis and that other verification activities may be used (such as process verifications or testing of intermediates) to verify implementation and effectiveness. Some comments assert that there would be no reason to conduct environmental monitoring in the shell egg processing plant, given the testing in henhouses required by part 118. Other comments ask us to exempt operations when their hazard analysis appropriately concludes that there is no foreseeable risk.

See also Comment 486.

(Response 516) The provisions for verification provide flexibility by specifying that they apply as appropriate to the nature of the preventive control and its role in the facility's food safety system. As noted by some comments, the provisions address testing through flexible written procedures that allow facilities to develop and use testing programs that are tailored to their facility, equipment, processes, products, and other specific circumstances. We agree that an appropriate outcome of the hazard analysis for some facilities will be that product testing and environmental monitoring are not required; it is not necessary to grant an "exemption" to allow a facility to achieve this outcome. For example, environmental monitoring would be required to verify effectiveness of sanitation controls when an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen because such environmental monitoring is appropriate to the facility (one manufacturing RTE foods), the food (an RTE food exposed to the environment), and the nature of the preventive control (sanitation controls). Foods such as peanut butter, soft cheeses, dried dairy products for use in RTE foods, and roasted nuts are among the products for which manufacturing operations would need to have an environmental monitoring program when such foods are exposed to the environment. In an FDA memorandum on environmental monitoring, we discuss several outbreaks of foodborne illness attributed to contamination from the environment (Ref. 55). These examples illustrate the severe consequences that can occur when environmental pathogens contaminate a product as a result of inadequate preventive controls and how environmental monitoring can be used to verify the adequacy of the preventive controls.

We discuss product testing for microbial pathogens in another FDA memorandum, including the use of pathogens and indicator organisms and microbial testing of foods for process control and for problem solving (Ref. 85). The circumstances in which product testing would be required are dependent on a variety of factors, as described in that memorandum and in the Appendix to the 2013 proposed human preventive controls rule (78 FR 3646 at 3818–3820, with reference numbers corrected in 78 FR 17142 at

17149–17151). As with environmental monitoring, product testing must be conducted as appropriate to the facility, the food, and the nature of the preventive control. For example, a raw material or other ingredient added to an RTE food after a pathogen "kill step" must be tested before use when the raw material or other ingredient has been associated with a pathogen and has not been treated to significantly minimize or prevent that pathogen (*e.g.*, spices added to snack chips, a food that has been previously involved in an outbreak of foodborne illness). Product testing would be required because it is appropriate to the facility (one making an RTE food), the food (spiced snack chips), and the nature of the preventive control (there is no control applied to the spices added to the snack chips).

When process control testing for an indicator organism, or environmental monitoring for an indicator organism, indicates an RTE food is reasonably likely to be contaminated with a pathogen, that food must be tested for the pathogen. For example, if environmental monitoring reveals food-contact surfaces that are used in the production of soft cheese are contaminated with *Listeria* spp. and additional environmental monitoring following corrective actions indicates food-contact surfaces are still contaminated with *Listeria* spp., product testing would be required because it is appropriate to the facility (one making an RTE food), the food (soft cheese, which supports the growth of *L. monocytogenes*), test results from environmental monitoring (which show the presence of an indicator organism for *L. monocytogenes* on food-contact surfaces in the food processing environment), and the nature of the preventive control (sanitation controls to prevent contamination by environmental pathogens, which appear to be inadequate).

The word "must" specifies the type of activities that a facility can use to satisfy the requirements for a particular preventive control management component, and we are retaining the term "must." However, we agree that the rule should provide flexibility for additional verification of implementation and effectiveness. To provide that additional flexibility, we have revised the specific requirements for verification of implementation and effectiveness to provide for other activities appropriate for verification of implementation and effectiveness (see § 117.165(a)(5)). (See also Response 486.)

(Comment 517) Many comments ask us to issue guidance, rather than

requirements, for product testing and environmental monitoring based on concerns such as the following: The value of environmental monitoring will be reduced if it becomes a minimum regulatory requirement; in many cases environmental pathogens can be eliminated by proper preparation by the consumer; there are well-known limitations to product testing and negative results from product testing can create a false sense of security; product testing is not preventive, would put industry into a reactive mode, and would pull valuable resources from activities focused on preventing contamination; there is limited technology available to test fresh produce, and limited time available due to the perishable nature of the commodity; any regulatory requirement will soon be outdated as products change and science improves; neither product testing nor environmental monitoring are required by HACCP systems; product testing would vastly increase the cost of the rule and will drive many businesses out of business without necessarily improving food safety; and requirements for product testing would require the States to direct resources to respond to non-compliant product testing results, and such resources would be better directed to environmental monitoring.

Some of these comments emphasize the need for flexibility so that product testing and environmental monitoring are options that are available to the facility rather than requirements for all facilities. Other comments assert that guidance provides greater opportunity for industry innovation and stakeholder participation to determine the appropriate use of verification measures, and avoids a “one-size-fits-all” approach to regulations. Some of these comments state that we should encourage environmental monitoring to be conducted “through facility specific food safety plans,” which would provide the flexibility necessary to monitor risks associated with exposures of RTE foods. Other comments state that operators should be given the necessary flexibility to implement any requirements in the most effective and efficient manner using a risk-based approach and taking into account the specific conditions of their facilities and operations. Some comments express concern that including a requirement makes it difficult for businesses to justify a conclusion that testing is not necessary.

Some comments ask us to solicit drafts of proposed guidance documents from the sustainable agriculture and local/regional food system community;

publish a list of possible topics for future guidance each year; seek input in advance from the sustainable agriculture and local/regional food system community before preparing draft guidance (including public meetings, workshops, and formation of an advisory committee); hold public meetings on draft guidance after publication; and present draft guidance to an advisory committee including representatives from the sustainable agriculture and local/regional food system community.

(Response 517) We are retaining the requirements for product testing and environmental monitoring in the rule, with the revisions, already discussed, to provide that verification activities depend on the role of the preventive control in the facility’s food safety system (see Response 455); corrective action procedures depend on the nature of the hazard (see Response 470); and written procedures for product testing and environmental monitoring are established and implemented as appropriate to the role of the preventive control in the facility’s food safety system (see Response 455). These revisions clarify in the regulatory text the flexibility that we discussed in the 2014 supplemental human preventive controls notice (79 FR 58524 at 58543–58545). Some of the comments that ask us to issue guidance rather than requirements appear to believe that only guidance can provide sufficient flexibility for product testing and environmental monitoring. This is not the case. See Response 516.

We disagree that environmental monitoring will become a minimum regulatory requirement in all cases; the decision to conduct environmental monitoring is made by the facility and some comments discuss specific examples of when environmental monitoring or product testing would not be warranted (see Comment 516). We acknowledge that in some cases environmental pathogens can be eliminated by proper preparation by the consumer, but this rule will not change consumer behavior (see, e.g., our discussion of a prepackaged, refrigerated cookie dough that was implicated in an *E. coli* O157:H7 outbreak that caused 76 confirmed cases of illness, including 35 hospitalizations (78 FR 3646 at 3665)). Also, as noted in Response 390, we note that many consumers do not follow some cooking instructions. Moreover, the fact that consumer preparation would be capable of eliminating an environmental pathogen is not a reason to not take reasonable measures to prevent contamination from the environment

and to verify that such measures are effective through environmental monitoring.

We have acknowledged limitations of product testing (78 FR 3646 at 3819–3820) and agree that a facility should consider such limitations when determining whether to conduct product testing and keep such limitations in mind when obtaining negative results from product testing. We also agree that product testing is not preventive. However, the mere facts that there are limitations, and that product testing is itself not a preventive measure, do not eliminate all benefits of product testing; we agree with comments (described in Comment 516) that although product testing may not be effective in identifying the acceptability of a specific ingredient or finished product lot on any given day, it can help assess and verify the effectiveness of a food safety plan as a whole and the facility’s capability to consistently deliver against it. We agree that there is limited technology available to test fresh produce and expect testing of fresh produce by a facility as a verification of its food safety plan as a whole would be the exception rather than the norm.

We disagree that regulatory requirements for product testing and environmental monitoring will soon be outdated as products change and science improves; the rule requires reanalysis of the food safety plan as a whole at least every 3 years, and requires reanalysis of the food safety plan as a whole, or the applicable preventive control, in light of new information (see § 117.170(a) and (b)(2)). We disagree that the lack of specific provisions for product testing and environmental monitoring in HACCP systems should preclude us from establishing requirements for product testing and environmental monitoring in this rule; as previously discussed, not every provision in section 418 of the FD&C Act is identical to HACCP as described in current literature (78 FR 3646 at 3660). Moreover, the HACCP systems have provisions for verification activities, as we consider these to be. We agree that there are some costs to product testing, but the rule provides flexibility for the facility to determine when product testing is appropriate. We acknowledge that the States will be required, in many cases, to follow up on positive findings obtained during product testing but disagree that this is a reason to eliminate the proposed requirements. The States would only be directing resources when the findings indicate contamination of food, and doing so will protect public health.

We will follow the procedures in § 10.115 for issuing guidance documents. Under § 10.115(f), members of the public can suggest areas for guidance document development and submit drafts of proposed guidance documents for FDA to consider. Under § 10.115(g), after we prepare a draft guidance we may hold public meetings or workshops, or present the draft guidance document to an advisory committee for review; doing so is not common and is determined on a case-by-case basis.

(Comment 518) Some comments ask us to consider the volume of product produced in establishing the verification testing requirements because volume-based testing is a way to address the burden that testing requirements may create for small facilities.

(Response 518) We decline this request. Although a facility would establish the frequency of testing if it determines, through its hazard analysis, that product testing or environmental monitoring is warranted, volume does not play a role in most statistical sampling plans. See the discussion of statistical sampling plans in the Appendix to the 2013 proposed human preventive controls rule (78 FR 3646 at 3819–3820).

#### *B. Proposed § 117.165(a)(1)—Calibration*

We proposed to require calibration of process monitoring instruments and verification instruments.

(Comment 519) Some comments distinguish “calibration” from an accuracy check, which the comments describe as a test to confirm that a particular equipment or measurement device is accurate. These comments assert that calibration may not be possible for certain equipment or measurement devices, and the appropriate corrective action may be replacement or application of corrective values. These comments ask us to specify that an accuracy check may be used as a verification activity in lieu of calibration.

(Response 519) We have revised the proposed requirements to require calibration of process monitoring instruments and verification instruments, or checking them for accuracy. However, if the outcome of an accuracy check is that a process monitoring instrument or verification instrument is not accurate, the facility must follow up by calibrating the device, rather than by applying corrective values, when it is practical to do so and replace the device when it is not practical to calibrate it.

#### *C. Comments Directed to Proposed Requirements for Both Product Testing (Proposed § 117.165(a)(2) and (b)(2)) and Environmental Monitoring (Proposed § 117.165(a)(3) and (b)(3))*

We proposed that to verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards you must conduct activities that include product testing and environmental monitoring, as appropriate to the facility, the food, and the nature of the preventive control (§ 117.165(a)(2) and (a)(3)). We also proposed that you must establish and implement written procedures for product testing and for environmental monitoring.

(Comment 520) Some comments ask us to revise the regulatory text to be explicit that there are circumstances when product testing and environmental monitoring would not be necessary.

(Response 520) We decline this request. We discussed examples relevant to this request in memoranda that we placed in the docket for this rule as references to the 2014 supplemental human preventive controls notice (Ref. 55) (Ref. 85). However, the actual decision as to whether product testing and environmental monitoring are warranted depend on the actual facility and its food product, as well as the nature of the preventive control and its role in the facility’s food safety system, and a slight variation on circumstances that would lead one facility to conclude that such testing programs were not required could lead a different facility to the opposite conclusion.

(Comment 521) Some comments discuss topics for us to include in guidance on procedures for product testing and environmental monitoring, such as which pathogens to test for; the range of products that should be tested; circumstances that warrant testing; what a facility would document and what factors the facility would consider before determining that product testing is not appropriate for its food product; frequency of sampling and number of samples to be collected; actions to take after a positive result; available test methods; reporting requirements for results; compliance strategies; and criteria for laboratories conducting the testing.

(Response 521) The memoranda that we placed in the docket for this rule as references to the 2014 supplemental human preventive controls notice (Ref. 55) (Ref. 85) address many of these topics.

(Comment 522) Some comments ask us to clarify that tests can be performed by third-party facilities or laboratories, as well as by the facility itself. Some comments ask us to clarify that we will accept test results in the same format as the format used for other purposes, such as third-party certification services.

(Response 522) The rule places no restrictions on who conducts testing. However, facilities have a responsibility to choose testing laboratories that will produce reliable and accurate test results. (See Response 524.) The rule does not specify the format of test results, provided that the record documenting testing satisfies the recordkeeping requirements of subpart F.

(Comment 523) Some comments express concern about requirements for product testing and environmental monitoring in light of section 202 of FSMA (section 422 of the FD&C Act). (Section 422 of the FD&C Act addresses laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances and including requirements for accredited laboratories to report the results of laboratory testing to FDA in certain circumstances.) These comments express concern that requirements for facilities to submit results of environmental monitoring to us will create an additional disincentive to looking for pathogens established in the facility. These comments assert that the results of environmental monitoring tests should be available to us for inspection but not submitted to us if product has not been distributed and that submitting the results of routine tests would be burdensome without benefit. These comments ask us to clarify whether facilities or laboratories would be required to submit the results of environmental monitoring tests to us. Likewise, some comments ask us to clarify whether product testing (including testing of raw materials or other ingredients as part of supplier controls) is subject to the requirements of section 422 of the FD&C Act for using accredited laboratories and for reporting test results to us. Other comments ask us to establish standards and procedures for certifying laboratories that would perform the tests. These comments assert that these standards and procedures are needed to ensure the credibility of the testing and to provide direction for facilities that establish in-house testing facilities. Other comments urge us to establish regulations implementing section 422 of the FD&C Act because they would complement the requirements of the human preventive controls rule and because



model laboratory standards that address quality controls, proficiency testing, training, and education of laboratory personnel offer the protections necessary for ensuring reliable, accurate test results. Other comments assert that if laboratories are not accredited or samples are not collected in a sanitary manner, there is no guarantee the results will be scientifically valid.

(Response 523) Section 422 of the FD&C Act would require, in relevant part, that food testing be conducted by an accredited laboratory (and the results of such testing be sent directly to FDA) whenever such testing is conducted in response to a specific testing requirement established under the FD&C Act or its implementing regulations, when applied to address an identified or suspected food safety problem, or to support admission of a food under an Import Alert that requires food testing. Although another rulemaking will address the requirements of section 422 of the FD&C Act, our current thinking is that routine product testing and environmental monitoring conducted as a verification activity is not being applied to address an identified or suspected food safety problem that requires food testing and would not be subject to requirements to use an accredited laboratory that would submit the results to FDA. We will review the results of environmental monitoring and product testing, if any, during inspections.

The primary concern expressed in these comments was with respect to laboratories reporting results to FDA and not with use of accredited laboratories. The rule requires a facility to establish and implement written procedures for product testing and environmental monitoring and that the procedures for such testing be scientifically valid. One way to comply with the requirement that testing procedures be scientifically valid is to use an accredited laboratory.

(Comment 524) Some comments ask us to expand the proposed requirement to identify the laboratory conducting the testing to also specify whether that laboratory is accredited and uses the appropriate standards (such as quality control, proficiency testing, and trained laboratory staff). These comments assert that such information would be useful to facilities.

(Response 524) We decline this request. These comments appear to be asking us to establish in the human preventive controls rule requirements related to section 422 of the FD&C Act. Doing so in advance of regulations implementing section 422 of the FD&C Act is premature. However, facilities

have a responsibility to choose testing labs that will produce reliable and accurate test results even if the rule does not require the facility to specify whether the laboratory is accredited.

(Comment 525) Some comments express concern about how the requirements for product testing will apply to the produce industry. For example, some comments assert that product testing on intact RACs is not an effective way to ensure food safety and assume that product testing would apply only to foods we consider to pose a greater risk, like fresh fruits and vegetables consumed raw. Some comments assert that product testing would be an excessive and unnecessary cost on farms and in low-risk facilities that pack and hold RACs. Other comments strongly object to mandatory product testing for fresh and fresh-cut produce. These comments assert that the results of product testing are unlikely to provide useful information for RACs and support application of GAPs and CGMPs rather than product testing. Some comments express concern that the fresh-cut produce industry will be dramatically changed if every lot of product needs to be tested and that such testing would certainly add expense without making the food any safer. Other comments assert that produce contamination occurs at so low a frequency that product testing for produce (including tree nuts) is not economically feasible through any scientifically valid sampling protocol. These comments also assert that “test and hold” would require building additional cooling operations in all facilities and that, because of short shelf life, testing of produce would negatively impact quality and marketing. Other comments assert that industry data have shown a sporadic and limited finding of pathogens in product and statistical sampling profiles do not provide sufficient evidence that product testing is an effective use of time and money. Other comments assert that facilities handling produce RACs are a unique type of facility and repeat previous requests that we allow all produce operations handling RACs to be covered by the produce safety rule, rather than the human preventive controls rule, to ensure that such facilities will not be expending resources on testing that could be better directed to implementation of preventive controls.

Likewise, some comments express concern about how the requirements for environmental monitoring will apply to the produce industry. For example, some comments express concern that off-farm packinghouses would be subject to environmental monitoring

because certain produce RACs are classified as RTE foods. Other comments reiterate requests that we not interpret produce held in vented crates to be “exposed to the environment,” so that facilities that only hold food could qualify for the exemption for facilities solely engaged in the storage of unexposed packaged food. These comments assert that holding produce in vented crates presents a low risk of contamination from environmental pathogens and that environmental pathogens do not qualify as a hazard requiring preventive controls. Some comments assert that neither product testing nor environmental monitoring would be warranted for facilities that hull and dry walnuts because at this stage walnuts are not a finished commercial commodity or an RTE food.

Some comments that express concern about the requirements for environmental monitoring focus on the environmental pathogen *L. monocytogenes*. Some of these comments assert that fresh produce poses a unique challenge in that *L. monocytogenes* is routinely found in the outdoor environment and its occasional transient detection on raw produce in low numbers does not necessarily indicate poor practices, that a contamination event has occurred due to insanitary conditions, or that such occasional transient detection presents an elevated public health risk. These comments assert that the occasional detection of transient *L. monocytogenes* in low numbers on food-contact surfaces where produce is handled is to be expected and must be considered and addressed in the drafting of environmental monitoring procedures for produce facilities. Other comments state that not all produce operations will be susceptible to harborage of *L. monocytogenes*. Other comments state that they will not support mandatory environmental monitoring for facilities that handle RACs until we amend our policies regarding the regulatory consequences of a single detection of potentially transient and low levels of *L. monocytogenes* on a food-contact surface.

(Response 525) We acknowledge the limitations of product testing for produce RACs and fresh-cut produce. As discussed in Response 517, the product testing that this rule requires as a verification activity is to help assess and verify the effectiveness of a food safety plan and the facility’s capability to consistently deliver against it, not as a “hold and test” procedure to establish the acceptability of every lot or batch. We do not expect either product testing or environmental monitoring to be

common in facilities that process, pack, or hold produce RACs. We agree that there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold produce RACs that are rarely consumed raw, such as potatoes. We expect that many facilities that process, pack, or hold produce RACs that are RTE foods may conclude, as a result of their hazard analysis, that neither product testing nor environmental monitoring is warranted. We also expect that many facilities that process, pack, or hold produce RACs that are RTE foods will conclude that the limitations of product testing when applied to produce reduce the value of product testing for their products and would direct their resources to food safety practices and verification measures other than product testing. In addition, we expect that some facilities will see benefits in conducting environmental monitoring as a verification measure and would direct resources to such activities.

We disagree that produce held in vented crates is not exposed to the environment (see Response 170), but agree that holding produce in vented crates presents a low risk of contamination from environmental pathogens. We do not expect that facilities that store produce in vented crates would conclude, as a result of their hazard analysis, that environmental pathogens are a hazard requiring preventive controls during storage activities. See Response 25 for a discussion of how this final rule broadens the number of packinghouses that will be governed by the provisions of the produce safety rule. See the discussions, in the 2014 supplemental human preventive controls notice (79 FR at 58535–536) and in Response 25, of the similarities and differences for off-farm packing and holding compared to on-farm packing and holding. We note that some of the comments express concern related to operations that, as a result of changes in the farm definition, may fall within that definition (e.g., some walnut hullers and dryers) and would not be subject to the requirements of this rule.

We agree that not all produce facilities are susceptible to harborage with *L. monocytogenes*. For example, harborage with *L. monocytogenes* is more likely to be a potential hazard in certain wet packing operations (e.g., wet packing operations for cantaloupes) (Ref. 86). Comments that we previously received about our draft guidance entitled “Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance” (Ref. 87) have

raised issues, similar to the issues described in these comments, regarding the detection of *L. monocytogenes* on food-contact surfaces, and we intend to re-issue that draft guidance for public comment in the near future.

The memoranda that we prepared on product testing and environmental monitoring for the 2014 supplemental human preventive controls notice (Ref. 55) (Ref. 85) include some examples relevant to facilities that process, pack, or hold produce. In light of the questions we have received regarding similarities and differences for off-farm packing and holding compared to on-farm packing and holding, we are considering developing a separate guidance on this topic.

(Comment 526) Some comments express concern about the cost of testing and suggest creation of a one-time grant program for very small businesses that would assist them in developing their initial food safety plans and testing programs.

(Response 526) Very small businesses are qualified facilities that are subject to modified requirements, which do not require testing or development of a food safety plan. We intend that the guidance we are developing will be helpful to all sizes of businesses that are subject to the requirements for product testing and environmental monitoring. (See Response 2.)

#### *D. Proposed § 117.165(a)(2)—Product Testing*

(Comment 527) Some comments ask us to require finished product testing for food products designated as high-risk, particularly when the product supports pathogen growth during its shelf life. Other comments suggest that finished product or ingredient testing should be implemented as appropriate in situations where a risk has been identified and an effective preventive control cannot be implemented. Other comments ask us to require product testing if an environmental pathogen is identified as a significant hazard.

(Response 527) We decline these requests. A facility’s decision to conduct product testing, and to establish the frequency of such testing, will reflect a risk-based approach consistent with its hazard analysis. Consequently, we expect that facilities that produce foods that have frequently been associated with outbreaks of foodborne illness, or produce food for which an effective preventive control cannot be implemented, would establish product testing programs more often than facilities that do not produce such foods.

A facility that identifies an environmental pathogen as a hazard requiring a preventive control such as sanitation controls would conduct environmental monitoring. Such a facility would decide what, if any, role product testing would play as a verification activity, or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility’s food safety system.

(Comment 528) Some comments ask us to clarify (or specify) when product testing would be directed at raw materials and other ingredients and when product testing would be directed at finished product. Some comments favor testing raw materials and other ingredients as part of “product testing,” whereas other comments state that testing raw materials and other ingredients should be considered part of a supplier program rather than verification of implementation and effectiveness. Other comments state that it is unclear what preventive control step would be verified by product testing and what types of facilities would be required to perform product testing. One comment from a supplier of produce states that testing its product (i.e., produce testing) is not an adequate measure of its cleaning and sanitation program and asks us to clarify that product testing is not on final product and that final product testing is not required.

(Response 528) We use the term “product testing” to mean testing any food product, whether raw materials or other ingredients, in-process foods, or finished products (Ref. 85) and, thus, product testing can be directed to any of these food products. For example, testing raw materials and other ingredients could be verification of a supplier; testing in-process material after a kill step could be verification of process control; testing finished product could be verification of the food safety plan as a whole, and capture a problem introduced during manufacture, including from contaminated raw materials and other ingredients. Product testing generally is not the most effective means of measuring the adequacy of cleaning and sanitation programs, but such testing is common to track a facility’s overall hygienic production measures.

(Comment 529) Some comments assert that a facility that implements supplier verification and environmental monitoring (or other measures) should not be required to perform product

testing in addition to the other controls and verification measures.

(Response 529) The facility determines whether product testing is necessary as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system. The factors mentioned by the comment are examples of factors that a facility would consider in making its determination.

(Comment 530) Some comments ask us to revise the requirement for product testing to clarify that product testing applies to significant hazards.

(Response 530) We decline this request. Product testing is a verification activity for a preventive control, and a preventive control is established for a "significant hazard" (which we now refer to as "hazard requiring a preventive control"). It is not necessary to repeat, for each type of verification activity, that the activity applies to hazards requiring a preventive control.

(Comment 531) Some comments assert that the real point of product testing is to test all lots or batches. These comments explain that they would be required to retest every lot of product in order to pass an analysis of the product on to its customers, even if testing had already been performed by their vendors (*i.e.*, suppliers), because each of their customers receives a proprietary blend. These comments further explain that it is not economically or physically possible to retest small lots of product already tested by their vendors, and that the risk has already been mitigated by its vendors.

(Response 531) The situation described by these comments appears to be a supplier-customer relationship in that the customer—not this rule—has established a requirement for a certificate of analysis for every lot of received product. As discussed in Response 517, the product testing that this rule requires as a verification activity is to help assess and verify the effectiveness of a food safety plan and the facility's capability to consistently deliver against it, not to establish the acceptability of every lot or batch.

(Comment 532) Some comments assert that we should set out a consultation process by which identification of hazards, situations, or product types that may require finished product testing is undertaken (noting that there may be significant international differences) before establishing requirements for product testing in the rule. These comments also assert that before product testing is mandated as a potential control step, as opposed to as part of a general

verification program, Competent Authorities are obligated to demonstrate that it will directly deliver demonstrable food safety benefits. According to these comments, other than for specific pathogens, random, intermittent finished product testing should primarily be used as a measure of process control, not for acceptance testing; product testing should normally be viewed as a monitoring and review tool, not as a product conformance verification tool. Testing programs for product conformance verification should be the exception rather than the rule. Other comments suggest seeking advice from either the National Advisory Committee on Microbiological Criteria for Foods or the FDA Food Advisory Committee on establishing statistically based product testing programs for process control.

(Response 532) These comments appear to have misunderstood the proposed requirements for product testing. Consistent with the views expressed by these comments, we proposed requirements for product testing as a verification measure of the food safety plan as a whole, not for product conformance or lot acceptance. We do not intend to initiate the consultation process described by these comments; however, we may consider requesting the assistance of advisory committees on process control testing in the future.

*E. Proposed § 117.165(a)(3)—  
Environmental Monitoring*

We proposed to require environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples.

(Comment 533) Some comments assert that requirements for environmental monitoring as a verification activity would be unnecessary in light of proposed revisions to some CGMP requirements, such as: (1) A requirement to use chemical, microbial, or extraneous-material testing procedures where necessary to identify sanitation failures or possible allergen cross-contact and food contamination (§ 117.80(a)(5)); (2) a requirement for raw materials and ingredients to either not contain levels of microorganisms that may render the food injurious to the health of humans, or to be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated (§ 117.80(b)(2)); and (3) a requirement

for all food manufacturing, processing, packing, and holding to be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food (§ 117.80(c)(2)).

(Response 533) Environmental monitoring would be a verification activity to ensure that sanitation controls are being implemented and are effective. The CGMP testing requirement cited by the comments neither explicitly requires environmental monitoring, nor describes the circumstances in which environmental monitoring would be needed. The cited CGMP requirement for raw materials and ingredients would not negate the need for environmental monitoring to verify that sanitation controls are preventing environmental pathogens from becoming established in a "niche" or harborage site (78 FR 3646 at 3814). The cited CGMP requirement to minimize the potential for the growth of microorganisms or for the contamination of food does not specify that a food establishment verify that it is meeting this requirement through environmental monitoring.

(Comment 534) Some comments ask us to specify that environmental monitoring of pathogens be executed according to a risk analysis.

(Response 534) We decline this request. See the discussion in Response 467, which explains how risk applies to the facility's hazard analysis and the determination by the facility to establish preventive controls for hazards requiring a preventive control as appropriate to the facility and the food. In contrast, the requirements for environmental monitoring are a verification activity that a facility would conduct to verify that one or more preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards requiring a preventive control and would be established as appropriate to the facility, the food, and the nature of the preventive control rather than according to a risk analysis.

(Comment 535) Some comments ask us to expand the requirements for environmental monitoring. For example, comments ask us to broadly require environmental monitoring in the following circumstances: as a component of every food safety program; in any facility in which there is a risk of contamination by an environmental pathogen, not just facilities that make RTE food; whenever there is a risk of environmental contamination if a likelihood exists that a person may consume the food raw; for spores of pathogenic sporeforming

bacteria if there is a possibility the spores could germinate and multiply in a packaged food or under storage or preparation conditions in the home; and for unintended food allergens.

(Response 535) We decline these requests. We are requiring a facility to evaluate environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen (§ 117.130(c)(1)(ii)). This risk-based requirement is a minimum requirement; a facility can do more if its preventive controls qualified individual determines that doing so would be appropriate.

The definition of RTE food does include food for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards (§ 117.3). The definition of environmental pathogen (§ 117.3) excludes the spores of pathogenic sporeforming bacteria, and we decline the request to require environmental monitoring (by revising the definition of environmental pathogen) for such spores if there is a possibility the spores could germinate and multiply in a packaged food or under storage or preparation conditions in the home. As previously discussed, pathogenic sporeforming bacteria are normally present in foods and unless the foods are subjected to conditions that allow multiplication, they present minimal risk of causing illness. Because pathogenic sporeforming bacteria are so commonly present in food, a more appropriate approach to the risks presented by pathogenic sporeforming bacteria would be to focus on their potential presence in raw materials and other ingredients and implement appropriate measures to prevent their growth (e.g., formulation, refrigeration) rather than to monitor for them in the food processing environment.

We decline the request to expand the requirement to all foods, not just RTE foods. Although facilities are required to apply CGMPs to prevent contamination of foods that are not RTE, these foods will receive a treatment that will significantly minimize or prevent environmental pathogens at a later stage.

Environmental monitoring is directed at microbiological hazards, not chemical hazards such as food allergens. The rule requires a facility to evaluate known or reasonably foreseeable food allergen hazards and to establish food allergen controls when the outcome of the

hazard analysis is that a food allergen hazard is a hazard requiring a preventive control (§ 117.130(b)(1)(ii) and (c)). A facility that determines that a food allergen hazard requires preventive controls could, for example, establish sanitation controls for food allergens and a swabbing program to verify those sanitation controls. Even though the facility would take swabs from the food processing environment, such swabs would not be considered “environmental monitoring” as that term is used in this rule.

(Comment 536) Some comments ask us to clarify whether the requirement for environmental monitoring “if contamination of an RTE food with an environmental pathogen is a significant hazard” refers to all RTE foods.

(Response 536) The requirements for environmental monitoring are addressed to RTE foods (including RACs, as well as processed foods) that are exposed to the environment unless the packaged RTE food receives a treatment or otherwise includes a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. See § 117.130(c)(1)(ii) and the discussion in Response 406. See also Comment 525 and Response 525 for a discussion of environmental monitoring as it could apply to the produce industry.

(Comment 537) Some comments suggest that a mechanism to reduce costs could be to clarify that environmental testing should only be done on food-contact surfaces.

(Response 537) We disagree that it would be appropriate to focus environmental monitoring only on food-contact surfaces. It is well-established that successful environmental monitoring programs look to eliminate environmental pathogens from non-food-contact surfaces as a means to keep the pathogens from contaminating food-contact surfaces and thereby contaminating food.

#### *F. Proposed § 117.165(a)(4)—Review of Records*

We proposed to require review of specified records by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. We proposed to require review of records of monitoring and corrective action records within a week after the records are made, and review of records of calibration, product testing,

environmental monitoring, and supplier verification activities within a reasonable time after the records are made.

(Comment 538) Some comments assert that it is not necessary for a preventive controls qualified individual to conduct or oversee review of records as a verification activity, noting that review of records in another food safety regulation (i.e., the LACF requirements in part 113) can be done by persons adequately trained in recordkeeping and review of records.

(Response 538) The rule does not preclude review of records by persons other than the preventive controls qualified individual, provided that the preventive controls qualified individual provides oversight for that review. Oversight by a preventive controls qualified individual is necessary because the review of records is critical to assessing the facility’s application of the preventive controls system and, thus, is fundamental to ensuring its successful operation (78 FR 3646 at 3757–58). Oversight by a preventive controls qualified individual is consistent with requirements of Federal HACCP regulations for seafood, juice, and meat and poultry, and with NACMCF HACCP guidelines (Ref. 35) (78 FR 3646 at 3757–58).

(Comment 539) Some comments ask us to provide for a timeframe longer than one week (such as 7 working days) for review of records of monitoring and corrective actions. Some comments ask us to provide the same flexibility for review of records of monitoring and corrective actions as we proposed for review of records of calibration, product testing, environmental monitoring, and supplier verification activities (“within a reasonable time” after the records are made)—e.g., because some preventive controls may be monitored less frequently than is typical in a traditional HACCP plan dominated with CCPs. Some comments note that corrective actions may not be fully implemented within 7 days and ask us to provide for review of these records within a week or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce. Some comments ask us to retain the one week timeframe for review of records associated with perishable foods, but to extend the timeframe to one month for nonperishable foods.

Some comments state that some food processors that operate on a batch production basis (rather than a continuous production basis) review all records related to a particular batch all at once just before release of the batch

for distribution. These comments assert that it would be inefficient, unnecessary, and needlessly complicated to require management to review a few production records in advance of the normal complete records review, particularly when laboratory testing conducted on the batch by an outside laboratory takes several weeks to complete.

(Response 539) We have revised the proposed requirement to require review of records of monitoring and corrective actions within 7 working days after the records are made or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days. A timeframe that exceeds 7 working days will be the exception rather than the norm. For example, reviewing records before release of product may be considered adequate by a facility, although this may be later than one week after the records were created. A facility may determine that all records for a lot of product will be reviewed after product testing or environmental monitoring records relevant to that lot of product are available, which may be more than a week after monitoring records were created. We made a conforming change to the list of responsibilities of the preventive controls qualified individual to address the requirement for the preventive controls qualified individual to provide (or oversee the preparation of) a written justification for such a timeframe (see § 117.180(a)).

We are not requiring that a facility review records of monitoring and corrective actions before release of product or that the timeframe for the review depend on the shelf life of the food. The purpose of reviewing records is not to determine whether to release product. Instead, the purpose of reviewing records is to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. However, a facility will have flexibility to review records of monitoring and corrective actions within a timeframe that exceeds 7 working days, such as before product release, provided that the facility provides a written justification for doing so. As discussed in Response 542, depending on the nature of the record, a facility that reviews these types of records in a timeframe that exceeds 7 working days, and finds a problem, may be faced with recall decisions for a

relatively large number of affected lots of product.

(Comment 540) Some comments ask us to revise the provisions for review of records by more generally referring to records of “verification testing (e.g., product testing and/or environmental monitoring as applicable).”

(Response 540) We have revised the regulatory text to refer to records of “testing (e.g., product testing, environmental monitoring).”

(Comment 541) Some comments refer to our request for comment on whether the regulatory text should specify the verification activities that must be conducted for corrective actions (see the discussion in Comment 489 and Response 489). These comments assert that if we do not further specify verification activities for corrective actions then we should eliminate the proposed requirement to review records of corrective actions.

(Response 541) Records are necessary to document all verification activities (see § 117.155(b)). The fact that the rule provides flexibility for the facility to appropriately determine the verification activities for corrective actions, rather than prescribes these verification activities, has no bearing on the requirement to document the verification activities.

(Comment 542) Some comments state that records of calibration activities are reviewed at the time the calibration is performed. These comments assert that in most cases a formal scheduled review of calibration records is not required to ensure the effectiveness of the control and that records review of calibrations should be based upon the nature of the control being calibrated.

(Response 542) The purpose of reviewing records as a verification activity is to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.

Although records may be reviewed at the time they are made, the review of records as a verification activity includes oversight by a preventive controls qualified individual (see Response 538). Because the timeframe for review of calibration records is “within a reasonable time after the records are created,” the facility has flexibility over the frequency of conducting this review. However, depending on the nature of the control for which the instrument is being calibrated, a facility that reviews calibration records infrequently, and finds a problem with calibration of process monitoring instruments and

verification instruments, may be faced with recall decisions for a relatively large number of affected lots of product.

(Comment 543) Some comments emphasize the importance of calibrating those instruments and monitoring devices that are critical to the preventive control, and reviewing the associated records, before validation of a lethality step and as frequently as necessary thereafter. These comments question whether requiring review of calibration records “within a reasonable time” will be adequate.

(Response 543) We agree that instruments and monitoring devices that are critical to a preventive control should be calibrated, and calibration records should be reviewed, before conducting studies to validate a lethality step. However, the provision is directed at verification of implementation and effectiveness of preventive controls on an ongoing basis. This rule does not prescribe specific steps that a facility must take before conducting validation studies.

A facility has flexibility to appropriately determine the frequency of reviewing calibration records based on the facility, the food, and the nature of the preventive control. We agree that it would be prudent to review calibration records of those instruments and monitoring devices that are critical to the preventive control more frequently than of those instruments and monitoring devices that are not critical to the preventive control. As discussed in Response 542, depending on the nature of the control for which the instrument is being calibrated, a facility that reviews calibration records infrequently, and finds a problem with calibration of process monitoring instruments and verification instruments, may be faced with recall decisions for a relatively large number of affected lots of product.

#### *G. Proposed § 117.165(b)—Written Procedures*

##### 1. Proposed § 117.165(b)(1)—Frequency of Calibration

We proposed that you must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

(Comment 544) As discussed in Comment 519, some comments ask us to specify that an accuracy check may be used as a verification activity in lieu of calibration. These comments also ask us to specify that written procedures address the frequency of accuracy checks, as well as calibration.

(Response 544) Consistent with Response 519, we have revised the proposed requirement to specify that written procedures address the frequency of accuracy checks, as well as calibration.

2. Proposed § 117.165(b)(2) and (b)(3)—Product Testing and Environmental Monitoring

We proposed that you must establish and implement written procedures for product testing. We proposed that procedures for product testing must: (1) Be scientifically valid; (2) identify the test microorganism(s); (3) specify the procedures for identifying samples, including their relationship to specific lots of product; (4) include the procedures for sampling, including the number of samples and the sampling frequency; (5) identify the test(s) conducted, including the analytical method(s) used; (6) identify the laboratory conducting the testing; and (7) include the corrective action procedures required by § 117.150(a)(1).

Likewise, we proposed that you must establish and implement written procedures for environmental monitoring. Procedures for environmental monitoring must: (1) Be scientifically valid; (2) identify the test microorganism(s); (3) identify the locations from which the samples will be collected and the number of sites to be tested during routine environmental monitoring; (4) identify the timing and frequency for collecting and testing samples; (5) identify the test(s) conducted, including the analytical method(s) used; (6) identify the laboratory conducting the testing; and (7) include the corrective action procedures required by § 117.150(a)(1).

(Comment 545) Some comments express concern that the word “valid” in the phrase “scientifically valid” could be construed to mean “validated” because not all testing protocols can be validated within the traditional meaning of the term. These comments state their belief that what we intend is for these testing programs to be “technically sound.” Other comments express concern that “scientifically valid” may be interpreted to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices).

(Response 545) We are retaining the term “scientifically valid” in these provisions. We disagree that we would interpret “scientifically valid” to mean that facilities are required to develop or validate analytical methods. We discussed our interpretation of the term “scientifically valid” in the Appendix to the 2013 proposed preventive controls

rule (78 FR 3646 at 3812 to 3813), and noted that this interpretation was consistent with our previous discussion of the term “scientifically valid” (in place of “validated”) in the rulemaking to establish CGMP requirements for dietary supplements (68 FR 12158 at 12198, March 13, 2003). While validated methods are considered “scientifically valid,” methods that have not gone through formal validation processes but have been published in scientific journals, for example, may also be “scientifically valid.” We do expect methods used for testing to be adequate for their intended use.

We have had several years interpreting the term “scientifically valid” in the context of the requirement, in the dietary supplement CGMPs, that the manufacturer must ensure that the tests and examinations that it uses to determine whether the specifications are met are appropriate, scientifically valid methods (§ 117.75(h)(1)). Although we agree that methods that are “scientifically valid” would also be “technically sound,” we disagree that the hypothetical concern that we would construe “scientifically valid” to mean “validated” warrants changing “scientifically valid” to a new term (such as “technically sound”) in light of our previous statements regarding this term and experience in the context of CGMP requirements. See the final rule establishing the dietary supplement CGMPs for additional discussion on the terms “validated” and “scientifically valid” (72 FR 34752 at 34853).

(Comment 546) Some comments support the proposed requirements for written procedures for environmental monitoring, including providing flexibility to use indicator organisms and to design the timing, location, and frequency of environmental monitoring programs in a risk-based manner, and in not prescribing specific locations (*e.g.*, food-contact surfaces or “zone 1”) or sample quantities for testing. Other comments ask us to add details to the written procedures for product testing and environmental monitoring regarding when and where sampling is required and the number of samples to take. Some comments ask us to make sure the most current “sampling planning science” is used for environmental monitoring by specifying that procedures for environmental monitoring must employ “sample quality criteria objectives.” Other comments assert that the product testing procedure requirements are inadequate and ask us to require that procedures for product testing specify the procedures for identifying samples (including their relationship to specific lots of product);

describe how sampling was conducted (to establish that the sample obtained adequately represents the lot of product the sample is intended to represent); and include the procedures for sample quality control from field to lab. Other comments assert that the frequency of environmental monitoring and product testing is unclear and express concern that frequent swabbing and frequent testing could cause cheeses to be held past their optimum ripeness if they are fresh or soft ripened.

(Response 546) We decline the request to prescribe additional details, such as those described in these comments, in the requirements for written procedures for product testing and environmental monitoring. As with other procedures required by the rule, those relating to environmental monitoring and product testing must be adequate for their intended purpose. Further, procedures will not be identical in all circumstances. For example, a facility that produces products with a short shelf life may choose a different frequency of swabbing and testing than a facility that produces products with a long shelf life.

(Comment 547) Some comments ask us to provide more flexibility in product testing by not requiring establishments to provide written procedures for product testing and corrective action procedures.

(Response 547) These comments are unclear. By requiring that a facility establish its own procedures, the rule provides facilities with flexibility to develop a product testing program that works best for its facility and its products. We are retaining the requirements for written procedures for product testing, as well as for corrective action procedures.

(Comment 548) Some comments ask us to add a provision requiring that all positive results must result in corrective action being taken.

(Response 548) We decline this request. The rule requires that a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate, the presence of a pathogen or appropriate indicator organism in an RTE product detected as a result of product testing and the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring (see § 117.150(a)(1)). However, the rule does not pre-determine what corrective actions a facility must take when presented with positive results from product testing or environmental

monitoring. The corrective action procedures that a facility would develop, and the actual corrective actions that the facility would take, will depend on the nature of the hazard and the nature of the preventive control, as well as information relevant to the positive result (e.g., pathogen or indicator organism, product or environment, food-contact surface or non-food-contact surface).

**XXXV. Subpart C: Comments on Proposed § 117.170—Reanalysis**

We proposed to establish requirements for reanalysis of the food safety plan. Some comments support the proposed requirements without change. For example, comments agree that a preventive controls qualified individual must perform (or oversee) the reanalysis (see section XXXV.D). Some comments that support the proposed provisions suggest alternative or additional

regulatory text (see, e.g., Comment 549, Comment 550, Comment 552, Comment 553, Comment 557, and Comment 558).

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 39, with editorial and conforming changes as shown in table 52.

TABLE 39—REVISIONS TO THE PROPOSED REQUIREMENTS FOR REANALYSIS

Section	Description	Revision
117.170(b) .....	Circumstances that require reanalysis	Provide for reanalysis of an applicable portion of the food safety plan (rather than the complete food safety plan) in specified circumstances.
117.170(b)(4) .....	Circumstances that require reanalysis	Require reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, whenever a preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective.
117.170(c) .....	Timeframe to complete the reanalysis	Clarify that the requirement applies to completing the reanalysis and <i>validating</i> any additional preventive controls (as appropriate to the nature of the preventive control and its role in the facility's food safety system), rather than to completing the reanalysis and <i>implementing</i> any additional preventive controls (emphasis added).

**A. Proposed § 117.170(a)—Circumstances Requiring Reanalysis**

We proposed that you must conduct a reanalysis of the food safety plan: (1) At least once every 3 years; (2) whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard; (3) whenever you become aware of new information about potential hazards associated with the food; (4) whenever appropriate after an unanticipated food safety problem; and (5) whenever you find that a preventive control is ineffective.

(Comment 549) Some comments assert that the need to reanalyze the food safety plan will depend on the nature of the preventive control and its role in the food safety system. These comments also assert that if a specific preventive control is found to be ineffective, only the applicable portion of the food safety plan would need to be reanalyzed.

(Response 549) We agree and have revised the regulatory text, with associated editorial changes and redesignation, to separate the requirement to reanalyze the food safety plan as a whole every 3 years from all other circumstances when reanalysis is required “for cause.” When reanalysis is “for cause,” the regulatory text provides that reanalysis is of the food safety plan as a whole, or the applicable portion of the food safety plan.

(Comment 550) Some comments ask us to recognize other terminologies already used by some facilities (e.g., “reassess”).

(Response 550) We have acknowledged that the terminology used in relation to the concept of “reanalysis” varies in current regulations and guidelines for systems such as HACCP (78 FR 3646 at 3759). A facility may choose to use a term such as “reassessment” in its records—e.g., if it relies on existing records that use the term “reassessment” to satisfy some or all of the requirements of this rule for reanalysis. However, the human preventive controls rule will use a single term (i.e., reanalyze) to minimize the potential for confusion about whether different terms have a different meaning for the purposes of the rule.

(Comment 551) Some comments ask us to define “reanalysis” to mean “a reassessment of the validity of a preventive control or food safety plan to control a hazard. Reanalysis may include a system review and, where necessary, activities to revalidate a control measure or combination of control measures.”

(Response 551) We decline this request. Reanalysis goes beyond assessing the validity of a preventive control or food safety plan to control a hazard. Reanalysis can also include assessing whether all hazards have been identified, whether established procedures are practical and effective, and other factors.

(Comment 552) Some comments ask us to require reanalysis on an annual basis, noting that annual reanalysis is required by Federal HACCP regulations for seafood, juice, and meat and poultry.

(Response 552) We decline this request. We proposed to require reanalysis at least once every 3 years as a minimum requirement in the event that there is no other circumstance warranting reanalysis (see proposed § 117.170(a)(1)). That 3-year minimum is consistent with the statute (see section 418(i) of the FD&C Act). As a practical matter, we expect that reanalysis will occur more frequently as a result of changes in the activities conducted at a facility (see final § 117.170(b)(1) through (4)).

(Comment 553) Some comments suggest editorial changes to improve the readability of the requirement to conduct reanalysis when there is a change in a preventive control.

(Response 553) We are including these editorial changes in the regulatory text, which now reads whenever “a significant change in the activities conducted at your facility creates a reasonable potential . . .”

(Comment 554) Some comments assert that the proposed requirement to conduct reanalysis whenever you become aware of new information about potential hazards associated with the food does not align with FSMA statutory language, is ambiguous, and would establish vague compliance obligations.

(Response 554) We disagree. See our previous discussion regarding the emergence of the pathogen *L. monocytogenes* in the mid-1980's and the first outbreak of foodborne illness in the United States, in 2006–2007, caused by consumption of peanut butter contaminated with *Salmonella* (78 FR 3646 at 3759). Although we acknowledge that the proposed requirement is not explicit in section 418(i) of the FD&C Act, we disagree it is not in alignment with FSMA as a whole. FSMA directs the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility and identify and implement preventive controls to significantly minimize or prevent the occurrence of those hazards (see section 418(a) of the FD&C Act). In other words, FSMA focuses on a system to prevent food safety problems rather than a system to react to problems after they occur. Requiring that a facility reanalyze its food safety plan, or the applicable portion of the food safety plan, in response to information such as the emergence of a new foodborne pathogen, or an outbreak of foodborne illness from consumption of a food product not previously associated with foodborne illness from a well-known pathogen, aligns very well with the statutory direction in FSMA.

(Comment 555) Some comments ask us to specify that reanalysis is required when a preventive control “fails to be” properly implemented rather than when a preventive control “is not” properly implemented.

(Response 555) We decline this request. We see no meaningful difference between “fails to be” and “is not” in this context, except that “fails to be” could lead to questions about the meaning of the term “fails” in this context.

(Comment 556) Some comments ask us to add a requirement to conduct reanalysis whenever a preventive control is found to be “missing” in addition to whenever a preventive control is found to be “ineffective.”

(Response 556) We have revised the regulatory text to require reanalysis whenever a preventive control, a combination of preventive controls, or the food safety plan as a whole, is ineffective. (See § 117.170(b)(4).) A “missing” preventive control could be discovered during verification to establish the validity of the food safety plan as a whole or as a result of an unanticipated problem. (See Response 482.) If circumstances lead a facility to conclude that an additional (or different) preventive control is

necessary, the facility would include that preventive control in its food safety plan along with associated preventive control management components, including verification to establish the validity of the food safety plan.

#### *B. Proposed § 117.170(b)—Timeframe To Complete Reanalysis*

We proposed that you must complete the reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. We have clarified that the requirement is to complete the reanalysis and validate (rather than implement) any additional preventive controls as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(Comment 557) As discussed in Comment 501, some comments question whether 6 weeks is enough time to perform all applicable validation studies that would address the execution element of validation. Likewise, some comments question whether 6 weeks is enough time to complete reanalysis.

(Response 557) Consistent with revisions we have made to the timeframe to complete validation (see Response 501), we have revised the timeframe to complete the reanalysis and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls to be within 90 days after production of the applicable food first begins or within a reasonable timeframe, provided that the preventive controls qualified individual provides (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable food first begins. We made a conforming change to the list of responsibilities of the preventive controls qualified individual (see § 117.180(a)).

(Comment 558) Some comments state that the phrase “before the change in activities at the facility is operative” is ambiguous in that it is unclear if the phrase is referencing the initial change in activities that triggered the reanalysis or a change in activities subsequent to the reanalysis. These comments ask us to clarify the requirement by substituting the phrase “before the relevant process is operative.”

(Response 558) We agree that there was ambiguity in this phrase, because changes in activities could result in the need for reanalysis and reanalysis could result in the need for changes in activities, both of which can result in a

new preventive control. We have made several revisions to the regulatory text, with associated editorial changes, to clarify the requirements for reanalysis. First, we have clarified that reanalysis can be routine (at least every 3 years) or “for cause” (*i.e.*, a significant change that creates the potential for a new hazard or an increase in a previously identified hazard; when you become aware of new information about potential hazards associated with the food; when there is an unanticipated food safety problem; or whenever a preventive control, combination of preventive controls or the food safety plan as a whole is ineffective). Second, we have specified that the reanalysis “for cause” may be for the entire food safety plan or only for an applicable portion.

In addition, as discussed in Response 557, we have clarified that the reanalysis and the validation, as appropriate to the nature of the preventive control and its role in the facility's food safety system, of any additional preventive controls needed to address an identified hazard would need to be completed before any change in activities (including any change in preventive controls) is operative. When additional time is necessary, we have provided for a timeframe within 90 days after production of the applicable food first begins or within a reasonable timeframe, provided that the preventive controls qualified individual provides (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable food first begins. In other words, if you decide to make a change, you should conduct a reanalysis before you make that change if there is potential for that change to create or increase a hazard; a reanalysis that results in changes to preventive controls should be completed and the preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, before changes in activities to produce food using a new preventive control are put into operation. However, we acknowledge that it may be necessary to produce product to demonstrate a revised preventive control can be implemented appropriately, and provide for an extended timeframe to make this assessment.

#### *C. Proposed § 117.170(c)—Requirement To Revise the Written Food Safety Plan or Document Why Revisions Are Not Needed*

We proposed that you must revise the written food safety plan if a significant change is made or document the basis



for the conclusion that no revisions are needed. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

*D. Proposed § 117.170(d)—Requirement for Oversight of Reanalysis by a Preventive Controls Qualified Individual*

We proposed that a preventive controls qualified individual must perform (or oversee) the reanalysis. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed. See section XXXVI.B.1 for comments on the qualifications for a preventive controls qualified individual who would perform or oversee the reanalysis.

*E. Proposed § 117.170(e)—Reanalysis on the Initiative of FDA*

We proposed that you must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

(Comment 559) Some comments ask us to issue formal, written communications about new hazards and developments in scientific understanding. These comments express concern that communications of this type could be inconsistent if they are communicated by individual investigators. Other comments ask us to specify in the regulatory text that it is the Commissioner of Food and Drugs who makes the determination that it is necessary to conduct a reanalysis of the food safety plan.

(Response 559) We agree that a communication from FDA about the need to reanalyze the food safety plan should be issued in a formal written manner but disagree that it is necessary to specify that it is the Commissioner of Food and Drugs who makes the determination that it is necessary to conduct a reanalysis of the food safety plan. The comment provides no basis for precluding such a determination by an organizational component (such as CFSAN or a component of FDA's Office of Regulatory Affairs) that has operational responsibility for food safety and subject matter experts to advise the managers in those organizational components.

**XXXVI. Subpart C: Comments on Proposed § 117.180—Requirements Applicable to a Preventive Controls Qualified Individual and a Qualified Auditor**

We proposed to establish requirements for the qualifications of a preventive controls qualified individual

and a qualified auditor. Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 563 and Comment 568) or ask us to clarify how we will interpret the provisions (see, e.g., Comment 560, Comment 564, and Comment 571).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the provisions as proposed with conforming changes as shown in table 52.

*A. Proposed § 117.180(a) and (b)—What a Preventive Controls Qualified Individual or Qualified Auditor Must Do or Oversee*

We proposed to list the functions that must be performed by one or more preventive controls qualified individuals (i.e., preparation of the food safety plan; validation of the preventive controls; review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions; and reanalysis of the food safety plan) or by a qualified auditor (i.e., conduct an onsite audit). We proposed to list these functions for simplicity (i.e., to make it easy to see all of the requirements in a single place). We specified that this list of functions already proposed to be established in applicable sections of the rule did not in itself impose any additional requirements.

(Comment 560) Some comments ask us to clarify whether the preventive controls qualified individual must be on the premises during operating hours. Other comments ask us to clarify that the preventive controls qualified individual is not responsible for performing laboratory testing, because the preventive controls qualified individual may not be appropriately educated and trained for laboratory testing.

(Response 560) The rule does not require that the preventive controls qualified individual be onsite during operating hours. The rule also does not require that the preventive controls qualified individual be responsible for performing laboratory testing, although review of testing records (e.g., records of product testing or environmental testing) must be conducted or overseen by a preventive controls qualified individual.

(Comment 561) Some comments ask us to consider the implication of having

the preventive controls qualified individual serve as the process authority, serve as the auditor, and offer final sign off on a validation and corrective actions, and suggest that a third party may be necessary to ensure that uniform standards are applied.

(Response 561) To the extent that the comment suggests that the functions of the preventive controls qualified individual create a conflict of interest, we disagree. The rule focuses on the need for applicable training and experience to perform certain functions. The preventive controls qualified individual must develop (or oversee the development of) the food safety plan that controls the identified hazards and then ensure through review of records that the plan is being implemented as designed. The rule does not require that a facility engage a third party to provide oversight of any individual, including a preventive controls qualified individual, but does not preclude a facility from doing so if it chooses.

*B. Proposed § 117.180(c)—Qualification Requirements*

1. Proposed § 180(c)(1)—Preventive Controls Qualified Individual

We proposed that to be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. We also proposed that this individual may be, but is not required to be, an employee of the facility.

(Comment 562) Some comments ask us to work with industry to establish a national training curriculum and standards for knowledge requirements before the final rule is issued. Comments recommend that curriculum and training requirements be consistent with already existing standards, including Better Process Control School, International HACCP, GFSI, Seafood HACCP, and those trainings offered by Cooperative Extension or State Agriculture departments. Some comments ask us to allow flexibility for industry to continue current training programs without receiving express approval from the FSPCA. Other comments ask that a standardized curriculum for training a preventive controls qualified individual be harmonized with the GFSI requirement.

(Response 562) As discussed in Response 2, the FSPCA is establishing a

standardized curriculum. The curriculum will focus on the specific requirements of the human preventive controls rule. Training providers do not need approval from the FSPCA to use the curriculum.

(Comment 563) Some comments ask who will assess the qualifications of a particular preventive controls qualified individual or determine whether particular individuals are in fact “qualified.” Some comments ask us to use an outcome-based demonstration of competency. Some comments ask us to specify that all work experience must be comparable or that a preventive controls qualified individual must pass a proficiency test. Some comments ask us to establish minimum standards for competency. Some comments ask us to clarify what job experiences would be sufficient. Some comments ask how we will verify that reported training and experience are true.

(Response 563) We are not establishing minimum standards for competency and do not intend routinely to directly assess the qualifications of persons who function as the preventive controls qualified individual, whether by their training or by their job experience. Instead, we intend to focus our inspections on the adequacy of the food safety plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate training or experience to carry out the assigned functions, including whether reported training and experience is accurately represented.

(Comment 564) Some comments ask us to provide for competency requirements to be met through on-the-job experience in lieu of traditional classroom training. Some comments ask us to clarify what we mean by training that is “at least equivalent” to that received under a standardized curriculum recognized as adequate by FDA. Some comments ask us to clarify whether individuals who have successfully completed training in the development and application of risk-based preventive controls through programs delivered and recognized under the International HACCP Alliance would be considered to have completed training “equivalent” to that recognized by FDA for the development and application of risk-based preventive controls.

(Response 564) The requirements do provide for qualification through appropriate job experience, such as experience with successfully implementing HACCP systems or other preventive-based food safety systems. It

is the responsibility of the owner, operator, or agent in charge of the facility to determine whether any individual who prepares (or oversees the preparation of) the food safety plan has appropriate qualifications to do so, whether by on-the-job experience or by training.

There are some differences in the requirements of the human preventive controls rule compared to the requirements of HACCP regulations for seafood, juice, and meat and poultry such that training provided by the International HACCP Alliance may not be equivalent. Such an individual may need to obtain supplemental training specific to the rule. Alternatively, a person who has received the International HACCP Alliance training and has implemented a HACCP plan may be qualified through job experience.

(Comment 565) Some comments ask us to emphasize that a standardized curriculum in the development and application of risk-based preventive controls may not provide a preventive controls qualified individual with sufficient expertise to design and conduct robust, scientific validation studies to support the adequacy of control measures.

(Response 565) We acknowledge that a single training course may not provide adequate training for every function of the preventive controls qualified individual for the foods produced by a facility. In some cases an individual may gain the full complement of knowledge and experience through multiple, specific training courses; in other cases an individual may gain the full complement of knowledge and experience through job experience or through a combination of training and job experience.

(Comment 566) Some comments ask us not to establish requirements that are overly strict because there is a finite supply of food safety experts in the country and many facilities will need multiple preventive controls qualified individuals.

(Response 566) We disagree that the requirements applicable to the preventive controls qualified individual should be designed to match any current limitations in the number of individuals who have the knowledge and skill to prepare (or oversee the preparation of) a food safety plan. We expect that market forces will act to increase the number of preventive controls qualified individuals to match the demand generated by this rule. In addition, as discussed in section LVI.A, we are staggering the compliance dates for the rule, so that only those

businesses that are not small or very small businesses will need to comply with the rule within one year, and very small businesses are not required to develop a food safety plan or conduct other activities that require oversight by a preventive controls qualified individual.

(Comment 567) Some comments ask us to develop training that emphasizes the need for appropriate equipment standards.

(Response 567) The training will focus on the specific requirements of the human preventive controls rule, which does not establish requirements for equipment standards.

(Comment 568) Some comments ask us to provide that the standardized curriculum can be recognized as adequate by the competent authority for food safety in each country rather than by FDA. One comment cited a requirement in one country for training that is consistent with Codex HACCP.

(Response 568) We decline this request. The standardized curriculum will be available to training providers, and we expect market forces will result in the development in foreign countries of training consistent with the standardized training curriculum. As noted previously (see Response 564), HACCP-based training may not be equivalent to the standardized curriculum because of the specific requirements of this rule. However, we believe that the flexibility provided by the alternative that a preventive controls qualified individual may be otherwise qualified through job experience to develop and apply a food safety system provides an approach to address the circumstances in a foreign country with respect to preventive controls qualified individuals until the training is available. In addition we will work with partners around the world—including the Alliances, regulatory counterparts, and multinational organizations—to promote training to the global community of food suppliers. We intend to meet both the letter and the spirit of our obligation to the World Trade Organization to facilitate training on the new regulations, particularly in developing nations.

## 2. Proposed § 117.180(c)(2)—Qualified Auditor

We proposed that to be a qualified auditor, a preventive controls qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(Comment 569) Some comments object to the proposed requirement that a qualified auditor must be a preventive

controls qualified individual with certain technical auditing expertise. One comment asserts that a qualified auditor should not be required to have the broader skills of a preventive controls qualified individual.

(Response 569) We have revised the definition of “qualified auditor,” and the requirements applicable to a “qualified auditor,” such that a “qualified auditor” means a person who is a “qualified individual” as that term is defined in this final rule, rather than a “preventive controls qualified individual,” because some auditors may be auditing businesses (such as produce farms) that are not subject to the requirements for hazard analysis and risk-based preventive controls, and it would not be necessary for such an auditor to be a “preventive controls qualified individual.”

(Comment 570) Some comments ask us to consider specifying training for qualified auditors. These comments also ask us to consider certain industry documents in any guidance we may issue regarding qualified auditors.

(Response 570) At this time, we are not planning to specify a training curriculum for qualified auditors. If we develop guidance related to qualified auditors, we will consider industry documents that are already available.

#### *C. Proposed § 117.180(d)—Records*

We proposed that all applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained. For clarity, we have revised the requirement to specify the type of training that must be documented—*i.e.*, applicable training in the development and application of risk-based preventive controls (see 78 FR 3646 at 3762).

(Comment 571) Some comments ask us to explain how job experience should be documented in records to prove qualifications.

(Response 571) The rule does not require documentation of job experience. A facility has flexibility to determine whether and how to document the job experience of a preventive controls qualified individual. For example, a facility could ask a preventive controls qualified individual to provide a resume documenting applicable experience. As discussed in Response 563, we intend to focus our inspections on the adequacy of the food safety plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate experience to carry out the assigned functions.

#### **XXXVII. Subpart C: Comments on Proposed § 117.190—Implementation Records**

We proposed to list all records documenting implementation of the food safety plan in § 117.190(a). We noted that proposed § 117.190(a) would not establish any new requirements but merely make it obvious at a glance what implementation records are required under proposed part 117, subpart C. We received no comments that disagreed with this proposed provision and are finalizing it as proposed.

We proposed that the records that you must establish and maintain are subject to the requirements of proposed subpart F (Requirements Applying to Records that Must be Established and Maintained). (Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 117.) We received no comments that disagreed with this proposed provision and are finalizing it as proposed.

#### **XXXVIII. Subpart D: Comments on Proposed § 117.201—Modified Requirements That Apply to a Qualified Facility**

As previously discussed (78 FR 3646 at 3769), sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility must submit two types of documentation to us. The first type of required documentation relates to food safety practices at the facility, with two options for satisfying this documentation requirement. Under the first option, the qualified facility may choose to submit documentation that demonstrates that it has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under the second option, the qualified facility may choose to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law. The second type of required documentation relates to whether the facility satisfies the definition of a qualified facility.

If a qualified facility does not prepare documentation demonstrating that it has identified potential hazards associated with the food being produced, is

implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective, it must provide notification to consumers of certain facility information by one of two procedures, depending on whether a food packaging label is required on the food.

Consistent with the statutory direction of section 418(l) of the FD&C Act, we proposed the following modified requirements for qualified facilities: (1) Submission of certain documentation (proposed § 117.201(a)); (2) procedures for submission of the documentation (proposed § 117.201(b)); (3) the frequency of the submissions (proposed § 117.201(c)); (4) notification to consumers in certain circumstances (proposed § 117.201(d)); and (5) applicable records that a qualified facility must maintain.

In the 2013 proposed human preventive controls rule, we tentatively concluded that a certified statement would be acceptable for the purposes of satisfying the submission requirements of proposed § 117.201(a). We also requested comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility.

Some comments support one or more of the proposed requirements without change. For example, some comments state that our proposed interpretation of the statutory term “business address” is consistent with our use of the term “business address” in our regulations regarding information that must be included in a prior notice for imported food (21 CFR 1.281). Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, *e.g.*, Comment 587 through Comment 589, Comment 591 through Comment 593, and Comment 596 through Comment 598) or ask us to clarify how we will interpret the provision (see, *e.g.*, Comment 572 and Comment 579 through Comment 585).

In this section, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. We also address comments discussing our tentative conclusion regarding the submission of certified statements to FDA, including submitting certified statements using the existing mechanism for registration of food facilities. After considering these comments, we have revised the proposed requirements as shown in

table 40, with editorial and conforming changes as shown in table 52.  
As discussed in Response 155, we have revised the definition of very small business to specify that it is based on an

average (of sales plus market value of human food held without sale) during the 3-year period preceding the applicable calendar year and, as a companion change, we are explicitly

requiring that a facility determine and document its status as a qualified facility on an annual basis (see § 117.201(c)(1)).

TABLE 40—REVISIONS TO THE PROPOSED MODIFIED REQUIREMENTS FOR QUALIFIED FACILITIES

Section	Description	Revision
117.201(a) .....	Documentation to be submitted.	<ul style="list-style-type: none"> <li>Specify that the submitted documentation is an “attestation.”</li> <li>Add “tribal” as an example of applicable non-Federal food safety law.</li> </ul>
117.201(b) .....	Procedure for submission ..	Update details regarding the electronic and paper submission of a form specific to the attestation requirement.
117.201(c) .....	Frequency of determination and submission.	<ul style="list-style-type: none"> <li>New requirement to determine and document status as a qualified facility on an annual basis no later than July 1 of each calendar year.</li> <li>Specify that a facility that begins manufacturing, processing, packing or holding food after September 17, 2018 must submit the attestation before beginning such operations.</li> <li>Specify that a facility must notify FDA of a change in status from “not a qualified facility” to “qualified facility” by July 31 of the applicable calendar year.</li> <li>Specify that when the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.</li> <li>Specify that the required biennial submissions of the attestations must be made during a timeframe that will coincide with the required biennial updates to facility registration.</li> </ul>
117.201(d) .....	Timeframe for compliance with the requirements of subparts C and G.	When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and G no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.
117.201(e) .....	Notification to consumers ...	Conforming changes associated with the term “attestation.”
117.201(f) .....	Records .....	Conforming changes associated with the term “attestation.”

*A. Comments on Submission of a Certification Statement*

(Comment 572) Some comments ask us to clarify the distinction between the documentation that would be submitted to FDA and the records that a qualified facility relies on to support the submitted documentation.

Some comments agree with our tentative conclusion to use certified statements to satisfy the proposed submission requirements, noting that it would save time and money and reduce the paperwork burden on qualified facilities. Some comments ask us to revise the proposed requirements to make this use of certified statements explicit in the regulatory text.

Other comments disagree with our tentative conclusion to use certified statements to satisfy the submission requirements. These comments focus on the importance of actual copies of documents in determining compliance with the documentation requirements and assert that proof of qualification requires more than a checked box in an on-line registration database. Some comments ask us to require that a qualified facility affirm that it has the original documents on file and available for FDA inspection. Other comments assert that requiring qualified facilities to submit copies of the actual

documentation would enable us to easily review food safety plans or inspection reports and to target our compliance and enforcement activities to those qualified facilities that pose a greater risk because of inadequate prevention measures or deficient inspections.

(Response 572) We are affirming our tentative decision that we will not require a qualified facility to submit to FDA, as part of its attestation, the underlying documentation that establishes its compliance. We agree that the underlying records are needed to determine compliance with the documentation requirements and that a qualified facility must retain the documents it is relying on to support its attestation and make them available to us during inspection. We also agree that the regulatory text needs to be explicit regarding the required documentation and that we need to clearly distinguish between the documentation that would be submitted to FDA and the records that a qualified facility relies on to support the submitted documentation. Therefore, we have made the following three revisions to the proposed regulatory text.

First, we have revised proposed § 117.201(a) to specify that the submitted documentation is an “attestation.” Second, we have revised

proposed § 117.201(b) to update details regarding the electronic and paper submission of a form specific to this attestation requirement. Third, we have revised proposed § 117.201(e) (final § 117.201(f)) to specify that you must maintain those records relied upon to support the “attestations” that are required by § 117.201(a).

We acknowledge that requiring submission of the actual documentation would enable us to easily review food safety plans or inspection reports and to target our compliance activities based on information that we see in those food safety plans or inspection reports. However, as discussed in Response 384, we are not requiring that other facilities submit a “facility profile” that would allow us to more broadly review food safety plans and target our compliance activities based on information that we see in those food safety plans and will instead explore other mechanisms to achieve the goals we described in the 2013 proposed human preventive controls rule for a facility profile.

*B. General Comments on Modified Requirements That Apply to a Qualified Facility*

(Comment 573) Some comments assert that the proposed modified requirements would create a costly burden for qualified facilities (e.g.,

registering and making submissions to FDA) that would not be imposed on other types of exempted facilities. Some of these comments question whether the exemption for qualified facilities is meaningful in light of the significant burden imposed by the proposed modified requirements. Some comments contrast the proposed modified requirement for qualified facilities to submit documentation to FDA with proposed requirements for all other facilities to simply establish and maintain applicable records.

(Response 573) The submission requirements that we are establishing in this rule for qualified facilities reflect the statutory framework for qualified facilities (section 418(l)(2)(B) of the FD&C Act). Although the submission requirements only apply to qualified facilities, the reporting burden associated with submission of an attestation is much lower than the recordkeeping burden for facilities that are subject to the requirements for hazard analysis and risk-based preventive controls (see section LXI).

(Comment 574) Some comments ask us to minimize setting different standards even though the modified requirements reflect express statutory provisions.

(Response 574) These comments appear to be referring to the statutory provisions of section 418(n)(3)(C) of the FD&C Act, which specify that the regulations we establish to implement section 418 of the FD&C Act acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods. We disagree that the statutory provisions of section 418(n)(3)(C) are directly relevant to the submission requirements of this rule for qualified facilities. The requirements for qualified facilities, but not other facilities, to submit documentation to FDA reflect different regulatory requirements. The different regulatory requirements are directed at different facilities, and do not set separate standards for particular foods. Regardless, even if the statutory provisions of section 418(n)(3)(C) were relevant to the submission requirements of qualified facilities, provisions of this rule that reflect express statutory provisions would not conflict with the statutory direction in section 418(n)(3)(C).

(Comment 575) Some comments ask us to implement the same labeling requirements that we proposed to establish for farms that would be eligible for a “qualified exemption” in the proposed produce safety rule, noting that such labeling requirements would allow us to trace food produced by the

facility back through the supply chain if there is a problem.

(Response 575) The rule does include a labeling requirement analogous to the applicable labeling requirement in the proposed produce safety rule (see § 117.201(e)). However, that labeling requirement only applies to one of the two options that a qualified facility has for satisfying the submission requirements (see § 117.201(a)(2) and (e)). Specifically, a labeling requirement applies if the qualified facility chooses to attest that it is in compliance with applicable non-Federal food safety laws (§ 117.201(a)(2)(ii) and (e)). However, the labeling requirement does not apply if the qualified facility chooses to attest that it has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective (§ 117.201(a)(2)(i)). The difference between the requirements of the human preventive controls rule and the proposed produce safety rule reflect differences in the distinct statutory provisions governing the two rules.

(Comment 576) Some comments emphasize that the modified requirements need to ensure adequate protection of public health and state that we should maintain and exercise oversight of qualified facilities. Some comments ask that we provide enough specificity so that qualified facilities know and understand their food safety responsibilities towards consumers.

(Response 576) A facility that satisfies criteria to be a qualified facility continues to be responsible to produce food that will not be adulterated under section 402 of the FD&C Act or misbranded under section 403 of the FD&C Act. Such a facility is also subject to the requirements of section 421 of the FD&C Act regarding frequency of inspection of all facilities and to the new administrative tools provided by FSMA, such as for suspension of registration (section 415 of the FD&C Act) and for mandatory recall (section 423 of the FD&C Act). As discussed in Response 151, we expect that most qualified facilities will be subject to the CGMP requirements of subpart B. As we do now, we will continue to inspect these facilities for compliance with those CGMP requirements.

(Comment 577) Some comments ask which exemption a farm mixed-type facility should follow if it satisfies criteria for a qualified facility (§ 117.5(a)), as well as criteria for a very small business that only conducts on-farm low-risk activity/food

combinations (specified in § 117.5(g) and (h)).

(Response 577) We describe these comments in more detail in Comment 202. As discussed in Response 202, a farm mixed-type facility that is a very small business and that only conducts the low-risk activity/food combinations listed in § 117.5(g) and (h) may find it advantageous to classify itself as a very small business eligible for the exemption in § 117.5(g) and (h) (which is not subject to the modified requirements in § 117.201) rather than as a qualified facility (which is subject to the modified requirements in § 117.201).

(Comment 578) Some comments express concern about State access to the records that a qualified facility maintains to support its attestations, particularly when a State would conduct an inspection for compliance with part 117 under contract to FDA. These comments express concern about the time and resources necessary to verify the status of a facility as a qualified facility and note that previous mechanisms whereby we provide information to States in advance of inspection have been slow. These comments also express concern that if the State must verify the “qualified facility” status of all firms, including those that are not FDA contracts, this could delay their ability to conduct timely inspections and increase inspection time, reducing the number of inspections conducted.

(Response 578) We are sensitive to the time required for various inspection activities and intend to communicate with States regarding our expectations for how to verify whether a facility is a qualified facility.

(Comment 579) Some comments point out that the proposed procedures for submission are silent on the process and timeframe for our review and approval of the submitted documentation and ask us to clarify this process and timeframe. Other comments ask us to clarify the consequences to a facility if its submission is found to be insufficient.

(Response 579) We will not be approving the submitted attestations. Instead, we intend to use the information to determine whether the facility should be inspected for compliance with the requirements for hazard analysis and risk-based preventive controls, or for compliance with the modified requirements. During the inspection, we would ask to see the records that the facility maintains to support any submitted attestations.

(Comment 580) Some comments ask us to clarify whether a foreign facility would need to submit documentation of

its status as qualified facility. These comments note that a foreign facility also would be required to provide information to an importer and assert that submitting information to both FDA and an importer would be a duplication of effort. These comments ask us to allow a foreign facility that is a qualified facility to submit information to either FDA or the importer, rather than to both FDA and the importer.

(Response 580) We decline this request. Documentation submitted to an importer would not reach FDA and, thus, could not satisfy the requirements of this rule. As discussed in Response 572, we are requiring submission of an attestation, on a form that can be submitted either electronically or on paper, rather than submission of the underlying information.

#### C. Proposed § 117.201(a)— Documentation To Be Submitted

##### 1. Proposed § 117.201(a)(1)— Documentation That the Facility Is a Qualified Facility

We proposed that a qualified facility must submit documentation that the facility is a qualified facility. We also proposed that for the purpose of determining whether a facility satisfies the definition of a qualified facility, the baseline year for calculating the adjustment for inflation is 2011. As discussed in Response 572, we have revised the provision to specify that the documentation that must be submitted is an attestation.

(Comment 581) Some comments ask us to clarify the documentation required to certify that an operation is a qualified facility. Some comments ask us to explicitly state that the documentation must include financial and sales records of the business and its subsidiaries or affiliates. Some comments ask us to clarify the types of records that would be required to be submitted by foreign establishments to support the classification of a foreign establishment as a “qualified facility.”

(Response 581) The submission to FDA will be an attestation rather than the records that the qualified facility relies on to support the attestation; however, you must maintain those records relied upon to support the “attestations” (see § 117.201(f)). As previously discussed, consistent with section 418(l)(2)(B)(ii) of the FD&C Act we intend to issue guidance on the records that a facility could retain to demonstrate that it is a qualified facility (78 FR 3646 at 3770). We intend to focus on records demonstrating that a facility is a very small business (*i.e.*, financial records demonstrating that a business

averages less than the \$1,000,000 threshold adjusted for inflation, during the 3-year period preceding the applicable calendar year) rather than records demonstrating that the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during a three-year period exceeded the average annual monetary value of the food sold by the facility to all other purchasers. We expect that financial records demonstrating that a business is a very small business will be less burdensome for a qualified facility to maintain and require fewer resources for FDA to review.

(Comment 582) Some comments ask whether documentation demonstrating that a facility is a qualified facility must be prepared by a “preventive controls qualified individual” as that term is defined in § 117.3.

(Response 582) The rule does not require that documentation demonstrating that a facility is a qualified facility be prepared by a “preventive controls qualified individual.”

(Comment 583) Some comments ask how the adjustment for inflation will be calculated and how regulators such as the States will get this information.

(Response 583) We intend to use the Federal calculation for the Gross Domestic Product price deflator, as provided by the Bureau of Economic Analysis, to adjust for inflation. We will make the inflation-adjusted dollar value to the baseline very small business sales cut-offs (*e.g.*, \$1,000,000 in 2011) available on our Internet site. We will update the values for the very small business exemptions and qualifications annually using this calculation.

##### 2. Proposed § 117.201(a)(2)(i)—First Option for Documentation: Food Safety Practices

We proposed two options for satisfying the statutory documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act. Under the first option (the food safety practices option), a qualified facility could submit documentation demonstrating that it has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective. As discussed in Response 572, we have revised the provision to specify that the submission is an attestation.

(Comment 584) Some comments assert that the rule is vague about what

the applicable documentation should include and how exhaustive it should be. Some comments ask whether documentation (such as a food safety plan) must address all operations at the establishment or only those that trigger the registration of the establishment as a facility. Some comments ask us to clarify the difference between having documentation to support food safety practices and attesting that the facility has such documentation. Other comments ask whether a qualified facility would need to have records documenting a risk analysis and monitoring.

(Response 584) If a qualified facility submits an attestation regarding its food safety practices, the documentation that the facility maintains for review during inspection must specify that the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective (see § 117.201(a)(2)(i)). For example, a qualified facility that produces one or more nut butters might have documentation specifying that it has determined that *Salmonella* is a hazard requiring a preventive control, describing the roasting process that will control *Salmonella*, describing sanitation controls to prevent contamination of the nut butters with *Salmonella*, and describing an environmental monitoring program to verify that its sanitation controls are effective. Likewise, a qualified facility that prepares cooked soups that require refrigeration for safety might have documentation specifying that it has determined that *Salmonella* is a hazard requiring a preventive control and supporting the temperature and time used in a thermal process to kill *Salmonella*, with temperature controls for safety and procedures for monitoring the temperature controls. A qualified facility that makes pickles might have documentation specifying that the hazard requiring a preventive control is *C. botulinum*, specifying the final equilibrium pH (of the pickled cucumbers) that is controlling the hazard, and demonstrating its monitoring of the pH during the production process.

As discussed in Response 572, a qualified facility that chooses the food safety practices option for complying with the submission requirements of this rule will attest to that by checking a statement on a form. In contrast, a food safety plan (or other documentation) that the qualified

facility relies on to support the attestation will be a record subject to the recordkeeping requirements of subpart F.

(Comment 585) Some comments ask us to clarify whether the submission requirement addresses compliance with the CGMP requirements of subpart B.

(Response 585) The submission requirement does not address compliance with the CGMP requirements of subpart B.

### 3. Proposed § 117.201(a)(2)(ii)—Second Option for Documentation: Compliance With Other Applicable Non-Federal Food Safety Law

Under the second option for satisfying the statutory documentation requirement, a qualified facility could submit documentation that it is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. As discussed in Response 572, we have revised the provision to specify that the submission is an attestation. We also have revised the provision to add “tribal” as an example of applicable non-Federal food safety law to clarify for purposes of this rule that a qualified facility could submit an attestation that it is in compliance with tribal food safety law.

(Comment 586) Some comments object to the proposed provision. These comments point out that State and local requirements are inconsistent and assert that such requirements are not sufficiently rigorous to substitute for the FSMA requirement to conduct a hazard analysis and establish and execute a documented food safety plan.

(Response 586) The provision reflects the express statutory direction of section 418(l)(2)(B)(i)(II) of the FD&C Act. See Response 576.

(Comment 587) Some comments ask us to specify that a qualified facility must document its compliance with the food safety laws of the State where its products are sold.

(Response 587) We decline this request. We interpret section 418(l)(2)(B)(i)(II) of the FD&C Act to apply to the State where a qualified facility is located. This is consistent with how States conduct inspections.

(Comment 588) Some comments ask us to specify that a qualified facility must document compliance with all applicable non-Federal food safety laws.

(Response 588) We decline this request. Section 418(l)(2)(B)(i)(II) of the FD&C Act refers to compliance with “State, local, county or other applicable non-Federal food safety law” (emphasis added).

(Comment 589) Some comments ask us to revise the proposed provision to make clear that a facility could submit an applicable attestation if the facility is subject to a State or local “cottage food” law (laws allowing sale of certain food from home kitchens). These comments explain that some cottage food laws do not require State or local authorities to inspect a facility or otherwise document that the facility is in compliance with the cottage food law. In addition, under some of these cottage food laws a facility would not have documentation such as a license to support its compliance with food safety requirements. Some of these comments ask us to revise the proposed provision to specify that a facility could rely on a copy of the relevant State law or regulation and a letter from the facility stating that it complies with that law or regulation, or certification by an appropriate agency (such as a State department of agriculture).

(Response 589) As discussed in Response 572, we have revised the regulatory text to provide for qualified facilities to submit an attestation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law. During an inspection, we expect the facility to be able to show us how the facility is complying with the applicable food safety regulation (including relevant licenses, inspection reports, certificates, permits, credentials, or certifications), and producing safe food.

(Comment 590) Some comments ask us to provide resources to the States to implement the proposed provision. These comments also ask us to develop and implement a strategic plan to provide resources (e.g., training, guidance) to State and local inspection agencies in advance of the anticipated increased burden on State and local inspection programs that will be created by the provision.

(Response 590) We do not believe that specific training for State or other government counterparts is necessary for the purposes of inspecting a qualified facility that attested to having documentation from a non-Federal regulatory authority. The State or other government counterpart would merely examine applicable documentation (such as a license, inspection report, certificate, permit, credentials, or certification by an appropriate agency (such as a State department of agriculture), which is specified in the provision. After inspecting such documentation, the State or other government counterpart would focus on inspection for compliance with CGMPs, as it has done in the past.

### D. Proposed § 117.201(b)—Procedure for Submission

We proposed that the documentation must be submitted to FDA either electronically or by mail. As discussed in Response 572, we have revised the regulatory text to update details regarding the electronic and paper submission of a specific form. We are developing paper and electronic versions of Form FDA 3942a, which is an information collection provision that is subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We intend to make the paper Form FDA 3942a available in the near future and invite comments consistent with procedures for approval of the form by OMB.

(Comment 591) Some comments recommend that any interface for electronic submission of certification statements post adequate notice of requirements the facility must meet and warnings detailing potential penalties (e.g., for fraudulent submission).

(Response 591) We intend that the electronic submission system will operate in a manner similar to the existing electronic submission system for registration of food facilities, including a certification statement advising the person signing the form that, under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. We intend to include a similar certification statement on paper forms that will be available for qualified facilities that choose to submit by paper rather than through the electronic system. The electronic and paper submission forms will focus on the attestation statements rather than on other requirements that the facility is subject to. The Small Entity Compliance Guide that we will issue in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public L. 104–121) will be better suited to helping qualified facilities understand the requirements of the rule than information presented on a submission form.

### E. Proposed § 117.201(c)—Frequency of Determination and Submission

We proposed that the documentation must be: (1) Submitted to FDA initially within 90 days of the applicable compliance date; and (2) resubmitted at least every 2 years, or whenever there is a material change to the information applicable to determining the status of a facility.

(Comment 592) Some comments assert that the proposed timeframe of 90

days to submit the required documentation would not provide sufficient time to gather and submit the required documentation and ask us to extend the timeframe—*e.g.*, to 120 or 180 days.

(Response 592) We are retaining the proposed timeframe for the initial submission (within 90 days of the applicable compliance date). The only documentation that the qualified facility will need to submit is an attestation, which does not need to be gathered. Importantly, however, documentation supporting the attestation must be available for inspection by September 17, 2018. As discussed in Response 155 the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016. As a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis by no later than July 1 of each calendar year (see § 117.201(c)(1)).

In addition, we have revised proposed § 117.201(c)(1) (which we are finalizing as § 117.201(c)(2)(i)(A), (B), and (C)) to specify the timeframe for the initial submission for three distinct circumstances: (1) By December 17, 2018, for a facility that begins manufacturing, processing, packing or holding food before September 17, 2018; (2) Before beginning operations, for a facility that begins manufacturing, processing, packing or holding food after September 17, 2018; or (3) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section. See the discussion in Response 155 regarding the approach we intend to take in a number of circumstances that could lead to a facility having records to support its status as a qualified facility for fewer than 3 preceding calendar years.

We have revised the provision to specify that the required biennial submissions of the attestations must be made during a timeframe that will coincide with the required biennial updates to facility registration (See section 102 of FSMA)—*i.e.*, during the period beginning on October 1 and ending on December 31, beginning in 2020. In determining that 2020 would be the first year for the required biennial submissions of the attestations, we first considered that the first submission of an attestation would be approximately December 2018 for qualified facilities that are operating as of the date of this final rule (*i.e.*, approximately 90 days after the date of publication of this rule).

For qualified facilities that do not begin operations until after December 2018, the first biennial submission will be required in a timeframe less than two years, but once the qualified facility has made its first submission the subsequent biennial submissions will all be at two-year intervals. Coordinating the biennial submissions of the required attestations with the biennial registration will reduce the cumulative economic impact on the food industry of complying with two separate requirements because qualified facilities that choose to submit electronically will be able to submit electronically while accessing the same electronic portal used for facility registration. This approach is consistent with our approach to food labeling requirements, where we establish a Uniform Compliance Date (see, *e.g.*, 79 FR 73201, December 10, 2014).

(Comment 593) Some comments ask us to include an option within the system to notify us when a facility’s status as a “qualified facility” changes—*e.g.*, because its business expands or changes.

(Response 593) Notifying us when there is a change in the facility’s status from “qualified facility” to “not a qualified facility” is a requirement rather than an option. We included this requirement in the proposed rule, and are establishing it in this final rule. We made editorial changes to the provision to make this clearer.

We also established a series of dates associated with the facility’s change in status from “qualified facility” to “not a qualified facility.” First, we are specifying that when the status of a facility changes from “qualified facility” to “not a qualified facility” based on the required annual determination, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year (see § 117.201(c)(3)). We have provided the facility with flexibility to wait until July 1 of a given calendar year to determine whether its status changes (see § 117.201(c)(1)); 30 days is an adequate timeframe to submit the form notifying us of the change in status.

Second, we are specifying that when the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and G no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility (see § 117.201(d)). In essence, this provision can provide a facility with up to a full year to comply with the full requirements for hazard analysis and risk-based preventive controls when the facility determines its change in status early in the calendar

year. A facility that does not determine that change in status until the required date of July 1 would still have 6 months to comply with the full requirements for hazard analysis and risk-based preventive controls. As we have done in the case of a qualified exemption being withdrawn (see § 117.257(d)(1)), we are providing flexibility for a facility to comply in an alternative timeframe if agreed to by FDA and the facility.

(Comment 594) Some comments ask us to specify that the required attestations be submitted annually rather than every 2 years. These comments assert that annual submission would be consistent with the statutory provisions that determine eligibility for status as a qualified facility based on sales, which will vary each year. These comments also assert that using the current mechanism for registration of food facilities would not be burdensome and would provide us with assurances that only facilities that satisfy criteria to be a qualified facility will operate under the modified requirements, thereby minimizing risk to public health.

Other comments ask us to specify that the required attestations be submitted every 5 years rather than every 2 years. These comments assert that doing so would be consistent with the statutory direction of section 201 of FSMA (Targeting of Inspection Resources) for non-high risk food facilities. These comments also assert that we did not provide specific reasons for the proposed 2 year timeframe and that re-submitting the attestations every two years will increase cost in time and labor.

(Response 594) We decline both of these requests. The rule already requires resubmission whenever there is a material change to the information that changes the status of a facility as a qualified facility. Therefore, if the facility’s sales change its status, so that it is no longer a qualified facility, the rule requires that facility to notify us when its status changes. (Note that the definition of very small business established in this rule is based on an average (of sales plus market value of human food held without sale) during the 3-year period preceding the applicable calendar year, rather than on annual sales plus market value. See Response 155.) A biennial submission is adequate to otherwise require a qualified facility to affirmatively attest that it continues to satisfy the criteria for being a qualified facility. A biennial submission is not overly burdensome, because a facility can coordinate its biennial submission with its biennial update to its facility registration. The suggested 5-year submission based on



the targeted inspection frequency for non-high risk food facilities implies that all qualified facilities produce such foods, which is not the case.

*F. Proposed § 117.201(d)—Notification to Consumers (Final § 117.201(e))*

We proposed that a qualified facility that does not submit documentation of its food safety practices must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities).

(Comment 595) Some comments assert that the proposed requirement exceeds what is already present for food in packaged form (21 CFR 101.5), and that these differences will create confusion for regulators and producers alike, with added costs but no food safety benefits. Some comments assert that the proposed requirement will likely cause consumer confusion at point of purchase and may discourage retail and food service buyers from receiving products from qualified facilities. Some comments ask us to specify that when a food packaging label is required, the required information must appear prominently and conspicuously on the label in compliance with § 101.5.

(Response 595) We decline these requests. The requirement for notification to consumers is mandated by section 418(l)(7)(A) of the FD&C Act. The labeling requirements applicable to packaged foods (§ 101.5) are established under a different statutory provision than the labeling requirements applicable to qualified facilities (*i.e.*, under section 403(e) of the FD&C Act (21 U.S.C. 343(e)) rather than section 418(l)(7) of the FD&C Act). The comments provide no explanation of the basis for their assertion that these differences will create confusion for consumers at point of purchase or discourage retail and food service buyers from receiving products from qualified facilities. As previously discussed (78 FR 3646 at 3771), the use of the term “business address” in section 418(l)(7) of the FD&C Act contrasts with Congress’ use of a different term, “place of business,” in section 403(e) of the FD&C Act. These comments do not address the reasons we previously discussed for our tentative conclusion that the use of the term “business address” in section 418(l)(7) demonstrates Congress’ intent to require the facility’s full address, including the street address or P.O. box,

to appear on labels or other required notifications when the facility has opted to not submit documentation directed to food safety practices. In this document, we are affirming that tentative conclusion. As discussed in section LVI.A, we are establishing January 1, 2020, as the date when a qualified facility that is subject to the notification requirements of § 117.201(e)(1) must notify consumers of the complete business address of the facility where the food was manufactured or processed.

*G. Proposed § 117.201(e)—Records (Final § 117.201(f))*

We proposed that a qualified facility must maintain those records relied upon to support the required documentation. We also proposed that the records that a qualified facility must maintain would be subject to the requirements that would be established in subpart F of this rule. As discussed in Response 572, after considering comments we have revised the rule to specify that a qualified facility must maintain those records relied upon to support the required attestations (rather than the required documentation).

(Comment 596) Some comments ask us to explicitly specify that we have access to documents that establish a facility as a qualified facility. Some comments assert that a facility may reasonably assume that records such as financial records would not be available to us because such records are excluded from the records that we have access to under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), as provided by § 1.362.

(Response 596) The rule explicitly specifies that we have access to records that are required by the rule (see § 117.320). If a facility relies on financial records to demonstrate its status as a qualified facility, we will have access to those financial records. The exemption referred to by the comments for financial records (§ 1.362) is narrowly targeted to records required by the section 414 recordkeeping regulations and does not apply to records required by this human preventive controls rule.

(Comment 597) Some comments ask us to revise the rule to define documentation as the actual records or true copies of the actual records.

(Response 597) The rule explicitly specifies that the records a qualified facility relies on to support the required attestations must be actual records, true copies, or electronic records. However, it does so by requiring that the records that a qualified facility must maintain

are subject to the requirements in subpart F (see § 117.305(a)), which specifies that these requirements apply to all records required by this rule, rather than by specifying these requirements within the provisions directed to modified requirements for qualified facilities.

(Comment 598) Some comments ask us to include a new section in subpart F to cover additional requirements applying to the records that a qualified facility must keep and make available to FDA upon request. These comments assert that such a section is necessary to ensure that qualified facilities understand their obligations. These comments also assert that clarity is needed in light of the nature of the financial records that would be required to support the facility’s status as a qualified facility.

(Response 598) We decline this request. As discussed in Response 581, consistent with section 418(l)(2)(B)(ii) of the FD&C Act we intend to issue guidance on the records that a facility could retain to demonstrate that it is a qualified facility rather than specify these records in the human preventive controls rule. Section 117.201(f) already specifies that a qualified facility must maintain those records relied upon to support the required attestations. There is no need to repeat this requirement in subpart F, which establishes general requirements for all records required by the rule but does not specify those records required to demonstrate compliance with particular requirements of the rule.

**XXXIX. Subpart D: Comments on Proposed § 117.206—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Unexposed Packaged Food**

We proposed that if your facility is solely engaged in the storage of unexposed packaged food, you must conduct certain activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. We requested comment on the proposed list of modified requirements. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, *e.g.*, Comment 599, Comment 600, Comment 604, Comment 606, Comment 608, and Comment 610) or ask us to clarify how we will interpret the provision (see, *e.g.*, Comment 601 and Comment 602).

In this section, we discuss comments that ask us to clarify the proposed

requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 41.

TABLE 41—REVISIONS TO THE PROPOSED MODIFIED REQUIREMENTS FOR UNEXPOSED, REFRIGERATED, PACKAGED FOOD

Section	Description	Revision
117.206(a)	Circumstances that make a facility subject to the modified requirements for unexposed, refrigerated packaged food.	Clarify that the requirements apply to a temperature control area in a facility that holds TCS food rather than to each product in the holding facility.
117.206(a)(3)	Modified requirements for corrective actions.	Clarify that corrective actions need only be taken when a loss of temperature control may impact the safety of the TCS food.
117.206(a)(4)(i)	Modified requirements for verification of temperature controls.	Provide additional flexibility for accuracy checks, in addition to calibration, to verify that temperature controls are consistently implemented.
117.206(a)(4)(iii)	Modified requirements for verification of temperature controls.	Provide additional flexibility for reviewing records of monitoring and corrective actions either within a week after the records are made or within a reasonable timeframe.
117.206(a)(5)(i)	Records documenting the monitoring of temperature controls.	Provide additional flexibility for records documenting the monitoring of temperature controls to be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control.
117.206(a)(5)(ii)	Records documenting corrective actions.	Conforming change associated with the modified requirements for corrective actions to clarify that records of corrective actions are required when there is a loss of temperature control that may impact the safety of the TCS food.

*A. Proposed § 117.206(a)—Modified Requirements for Unexposed Refrigerated Packaged Food That Requires Time/Temperature Controls*

1. Proposed § 117.206(a)(1)—Establish and Implement Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance.

We also tentatively concluded that it would be rare for a facility solely engaged in the storage of unexposed packaged food to not have information regarding whether a refrigerated packaged food is a TCS food and, if so, what specific temperature controls are necessary for safe storage of the food. We requested comment on this tentative conclusion.

(Comment 599) Some comments ask us to clarify that the requirement to establish and implement temperature controls applies to temperature control areas in a facility rather than to each product in a facility.

(Response 599) We agree that the requirement to establish and implement temperature controls applies to temperature control areas in a facility rather than to each product in a facility. To make this clearer, we have revised the proposed requirement to clarify that the facility must conduct activities as appropriate to ensure the effectiveness of the temperature controls rather than

conduct activities “for any such refrigerated packaged food.”

(Comment 600) Some comments disagree with our tentative conclusion that it would be rare for a facility solely engaged in the storage of unexposed packaged food to not have information regarding whether a refrigerated packaged food is a TCS food and, if so, what specific temperature controls are necessary for safe storage of the food. These comments ask us to specify that the responsibility for determining whether a food is a TCS food falls to the manufacturer of the food rather than the warehouse storing the food, because the warehouse merely provides a service. Other comments note that the food product owners determine the optimal conditions for storage of their products based on their own hazard analysis and preventive controls, and that the food product owners can simply communicate those requirements to the warehouses that will store the products.

(Response 600) In this type of circumstance, it is appropriate for the manufacturer of the food to share the responsibility with the warehouse for proper storage of the food. The various provisions of section 418 of the FD&C act explicitly place the responsibility for complying with the requirements for hazard analysis and risk-based preventive controls, including modified requirements, on the owner, operator, or agent in charge of a facility and, thus, a facility that is a warehouse is responsible for its own food safety plan. Regardless, the manufacturer also has responsibilities under section 418 of the

FD&C Act to determine the storage conditions necessary for food safety and to take steps to ensure that the food is stored under conditions that will ensure its safety.

It is not necessary to specify this joint responsibility for determining storage conditions in the rule, because the rule already clearly specifies that its provisions apply to persons who manufacture/process food, as well as to persons who hold food. Both the warehouse and the manufacturer have flexibility in determining how to comply with the rule, including the specific mechanism whereby the warehouse would receive information about storage of a food product from the manufacturer or owner of the product. Moreover, a citizen petition submitted to FDA [Docket No. FDA–2011–P–0561], in requesting an exemption or modified requirements for facilities solely engaged in the storage of unexposed packaged foods, asserts that such facilities work closely with food manufacturers to understand the conditions and controls needed to ensure the quality of the foods they store and distribute and that manufacturers appropriately instruct the warehouses to ensure packaged products are being properly stored (78 FR 3646 at 3712).

(Comment 601) Some comments ask us to clarify which facility—the shipping facility or the receiving facility—will be responsible for ensuring that temperature control is maintained during transportation of TCS foods.

(Response 601) See Response 423, which notes our intention to address comments regarding the responsibilities of shippers and receivers in the final sanitary transportation rule.

#### 2. Proposed § 117.206(a)(2)—Monitor the Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed. We requested comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

(Comment 602) Some comments ask us to explain in the preamble of the final rule that we will accept monitoring systems that provide exception reports to satisfy the modified requirements. The comments describe exception reporting as a structure where automated systems are designed to alert operators and management when the monitoring system observes a deviation from an established limit. These comments assert that monitoring of preventive controls by automated systems can be more efficient than monitoring by personnel, and can eliminate human error.

(Response 602) See also Response 468 and Response 610. We have revised the recordkeeping provisions of these modified requirements to provide that the temperature monitoring records for the modified requirements may be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control. Although the comments explicitly ask us to provide a clarification in the preamble of this rule, we decided the clarification within the regulatory text would be clearer to facilities that are subject to the requirements, as well as to investigators who will be inspecting facilities for compliance with the rule.

(Comment 603) Some comments state that written procedures for monitoring temperature are not necessary. One reason provided by the comments is that the required records (specified in proposed § 117.206 (a)(5)) would provide sufficient information on the type and frequency of monitoring. Another reason is that the specific activities we proposed to ensure the effectiveness of the temperature controls already address activities that a facility would include in a written procedure.

(Response 603) We agree with the comments that the rule does not need to require that a facility develop written procedures for monitoring temperature.

#### 3. Proposed § 117.206(a)(3)—Requirement to Take Corrective Actions

We proposed that if your facility is subject to the modified requirements, you must take appropriate corrective actions if there is a problem with the temperature controls for a TCS food.

(Comment 604) Some comments ask us to narrow the term “temperature controls” to more specifically focus it on temperature controls that are relevant to food safety because some problems with the controls may not impact the product temperature (and, thus, would not impact food safety).

(Response 604) We have revised the proposed requirement (and the applicable recordkeeping requirement) to specify that corrective actions are necessary only when there is a loss of temperature control that may impact the safety of a TCS food.

(Comment 605) Some comments assert that the responsibility for determining any corrective actions for a TCS food when there is a loss of temperature control falls to the manufacturer of the food rather than to the warehouse. These comments also assert that a warehouse is a third party who is not legally empowered to make independent decisions about when and where to ship the product, or not to ship it at all. These comments ask us to clarify that the responsibility of a warehouse for “preventing” affected food entering commerce ends when the product is returned to the manufacturer or processor.

(Response 605) Returning affected food to the manufacturer/processor or owner of the food is one way to satisfy the requirement to prevent food from entering commerce if the owner, operator, or agent in charge of a warehouse cannot ensure the affected food is not adulterated under section 402 of the FD&C Act, either on its own or after consultation with the manufacturer or processor of the food. It is not necessary to specify this specific action on the part of a warehouse in the regulatory text.

#### 4. Proposed § 117.206(a)(4)—Requirement To Verify Consistent Implementation of Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must verify that temperature controls are consistently implemented by: (1) Calibrating temperature monitoring and recording devices; (2) reviewing records of calibration within a reasonable time after the records are made; and (3) reviewing records of monitoring and corrective actions taken

to correct a problem with the control of temperature within a week after the records are made.

(Comment 606) Some comments assert that the proposed requirement to “calibrate” devices that monitor and record temperature is inconsistent with the requirement to test such devices for accuracy in the LACF regulations in part 113. These comments assert that “accuracy check” is a more appropriate term to use in the modified requirements because many instruments that monitor or record temperature have very low drift values and may seldom require calibration.

(Response 606) We have revised the proposed requirements to require verification that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices or checking them for accuracy. However, if the outcome of an accuracy check is that a temperature monitoring or recording device is not accurate, the facility must follow up by calibrating or replacing the device. See also Comment 519 and Response 519.

(Comment 607) Some comments assert that reviewing records of calibration or accuracy checks is only needed if a designated tolerance is exceeded.

(Response 607) Although we recognize that in most instances an out-of-calibration device will be identified and corrected at the time a calibration or accuracy check is performed, this is not always the case. The purpose of reviewing records of calibration or accuracy checks is to identify a problem that may have been missed or may not have been corrected rather than to react to a problem after the problem is identified. The records review is also a verification that the temperature controls were consistently implemented and that corrective actions were taken if needed.

(Comment 608) Some comments ask us to modify the frequency of checking monitoring records to specify that it be done with a frequency to demonstrate control rather than within a week after the records are made.

(Response 608) Consistent with Response 539, we have revised the proposed requirement to require review of records of monitoring (as well as records of corrective actions taken to correct a problem with the control of temperature) within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days.

(Comment 609) Some comments assert that the proposed verification and review activities are too prescriptive because they require reviews that are not necessary. However, these comments also assert that the proposed verification activities are too vague because they do not specify the reasons for reviewing the records. These comments ask us to focus the regulatory text on achieving the overall objective of the review (*i.e.*, ensuring the adequacy of the control) and to provide examples of meaningful review activities in guidance.

(Response 609) We disagree that the proposed verification activities would require reviews that are not necessary. As noted in Response 607, the purpose of the records review is both to identify a problem with a temperature monitoring device that may not have been detected or corrected, and to verify that the temperature controls were consistently implemented and that corrective actions were taken if needed. The requirement is consistent with requirement for records review in subpart C (§ 117.165(a)(4)), which specifies records review as a verification activity to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.

5. Proposed § 117.206(a)(5)—Establish and Maintain Records

We proposed that if your facility is subject to the modified requirements, you must establish and maintain records that document monitoring, corrective actions, and verification activities.

(Comment 610) Some comments state that temperature controls in refrigerated warehouses are extremely reliable and therefore extensive recordkeeping and

record review are not value-added. These comments ask us to revise the proposed provision to require a record only if a deviation in the environmental temperature from the prescribed limits was noted.

(Response 610) See also Response 468 and Response 602. We have revised the regulatory text to provide that temperature monitoring records may be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control. The revised provision is consistent with the more general requirement for monitoring records of refrigeration temperature during storage of TCS food (see § 117.145(c)(2)).

B. Proposed § 117.206(b)—Records

We proposed that the records that a facility must establish and maintain for the proposed modified requirements are subject to the requirements that would be established in proposed subpart F. We received no comments that disagreed with our proposal, and are finalizing proposed § 117.206(b) without change.

**XL. Subpart E: Comments on Proposed New Provisions for Withdrawal of a Qualified Facility Exemption**

In the 2013 proposed human preventive controls rule, we proposed to establish procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart E; the withdrawal provisions). In the 2014 supplemental human preventive controls notice, we discussed several comments we received on these withdrawal provisions, and proposed modifications and additions to them. Some of the proposed provisions would modify the provisions that we included in the 2013 proposed human preventive controls

rule (such as the timeframe for compliance with an order withdrawing an exemption), whereas others would be new provisions (such as a procedure to reinstate an exemption that had been withdrawn). In this section of this document we discuss comments that we received on the withdrawal provisions in the 2013 proposed human preventive controls rule, but did not address in the 2014 supplemental human preventive controls notice. We also discuss comments that we received on the re-proposed withdrawal provisions in the 2014 supplemental human preventive controls notice.

Most of the comments that support the proposed provisions suggest alternative or additional regulatory text (see, *e.g.*, Comment 612 through Comment 614, Comment 620 through Comment 626, Comment 628, Comment 629, and Comment 631 through Comment 633) or ask us to clarify how we will interpret the provision (see, *e.g.*, Comment 617).

For several provisions, we received no comments that disagreed with our proposal, and are finalizing the provisions without change. These provisions are § 117.274 (Presiding officer for an appeal and for an informal hearing); § 117.277 (Timeframe for issuing a decision on an appeal); § 117.280 (Revocation of an order to withdraw a qualified facility exemption); and § 117.284 (Final agency action).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 42, with editorial and conforming changes as shown in table 52.

TABLE 42—REVISIONS TO THE PROPOSED PROVISIONS FOR WITHDRAWAL OF A QUALIFIED FACILITY EXEMPTION

Section	Description	Revision
117.251(b)(2) .....	Timeframe for a qualified facility to respond to a notification from FDA about circumstances that may lead FDA to withdraw the facility's exemption.	Allow 15 calendar days, rather than 10 calendar days, for the facility to respond.
117.257(c) .....	Contents of an order to withdraw a qualified facility exemption.	Editorial changes to clarify that the order will specify which of two circumstances that may lead FDA to withdraw a qualified facility exemption apply, or whether both of these two circumstances apply.
117.257(d)(1) .....	Contents of an order to withdraw a qualified facility exemption.	Specify that the timeframe for the qualified facility to comply with the order is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order.
117.257(e) .....	Contents of an order to withdraw a qualified facility exemption.	Include a statement informing the facility that it may ask us to reinstate an exemption that was withdrawn by following the procedures in § 117.287.

TABLE 42—REVISIONS TO THE PROPOSED PROVISIONS FOR WITHDRAWAL OF A QUALIFIED FACILITY EXEMPTION—  
Continued

Section	Description	Revision
117.257(d)(2) .....	Timeframe for a qualified facility to appeal an order withdrawing the facility's exemption.	Allow 15 calendar days, rather than 10 calendar days, for the facility to appeal the order.
117.260 .....	Compliance with, or appeal of, an order to withdraw a qualified facility exemption.	Specifies that a qualified facility that loses its exemption would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption.
117.260(a)(1) and (c)(1) .....	Compliance with, or appeal of, an order to withdraw a qualified facility exemption.	Specify that the timeframe for the qualified facility to comply with the order is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order.

*A. Proposed § 117.251—Circumstances That May Lead FDA To Withdraw a Qualified Facility Exemption*

We proposed that we may withdraw the exemption that would apply to a qualified facility in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility, or if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. We also proposed that before we issue an order to withdraw an exemption, we: (1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak; (2) must notify you, in writing, of circumstances that may lead us to withdraw the exemption, and provide an opportunity for you to respond in writing, within 10 calendar days of the date of receipt of the notification, to our notification; and (3) must consider your actions to address the circumstances that may lead us to withdraw the exemption.

(Comment 611) Some comments agree with the proposed provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified facility exemption. For example, some comments agree that other regulatory actions should be considered before withdrawing a qualified facility exemption, and some comments agree that it is appropriate to assess corrective actions taken by a qualified facility in response to a food safety problem when considering whether to withdraw its exemption. Other comments agree that these provisions are reasonable and will provide qualified facilities due process and greater clarity on the withdrawal

process, but suggest that we could issue guidance rather than include these provisions in the rule to allow us greater flexibility should we have to act quickly to protect the public health.

Other comments disagree with these proposed provisions and ask us to delete them from the final rule. These comments assert that FSMA does not require us to describe the actions that we may take prior to withdrawing a qualified facility exemption and that it is not necessary to do so because it is customary for us to work with a food facility to address problems before taking enforcement actions. These comments also express concern that listing possible regulatory actions before we would issue an order to withdraw a qualified facility exemption could create an expectation that we will always exercise such regulatory actions before issuing the order. These comments also express concern that being bound by these provisions could prevent us from acting quickly to protect public health.

(Response 611) We are retaining the provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified facility exemption. We agree that it is customary for us to work with a food facility to address problems before taking enforcement actions but disagree that specifying this customary practice in the rule would prevent us from acting quickly to protect public health. As previously discussed, we consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions such as those described in these provisions may provide a more expeditious approach to correcting a problem than withdrawing an exemption (79 FR 58524 at 58553). We also disagree that the rule binds us to take alternative regulatory action before issuing an order to withdraw a

qualified facility exemption, other than to notify the facility in writing of circumstances that may lead us to withdraw the exemption, provide an opportunity for the facility to respond in writing, and consider the actions taken by the facility to address the circumstances we describe. The rule clearly specifies that regulatory actions such as a warning letter, recall, administrative detention, suspension of registration, refusal of food offered for import, seizure, and injunction are actions that we “may” (not “must”) take before issuing an order to withdraw a qualified facility exemption. Providing the facility with an opportunity to correct the problems before we take steps to withdraw an exemption has the potential to save agency resources associated with preparing an order, responding to an appeal of the order and request for a hearing, and administering a hearing. Directing resources to help a facility correct problems, rather than to administer a withdrawal process that could be resolved by the time of a hearing, is appropriate public health policy.

(Comment 612) Some comments ask us to specify that the notification of circumstances that may lead FDA to withdraw the exemption must include facts specific to the situation and information about how the facility can remedy the situation.

(Response 612) By specifying that we must notify the facility of circumstances that may lead us to withdraw an exemption, we mean that we would include facts specific to the situation. It is the responsibility of the facility, not FDA, to remedy the situation.

(Comment 613) Some comments ask us to state affirmatively that we must not withdraw the exemption if the facility has satisfactorily addressed the problematic conditions or conduct at the facility. These comments assert that,

without this affirmative statement, the requirement that we “consider the actions taken by the facility” remains unclear.

(Response 613) We decline this request. If the facility has satisfactorily addressed the problematic conditions or conduct, there would be no problematic circumstances for us to describe in the order withdrawing the qualified facility exemption.

(Comment 614) Some comments ask us to provide additional time for a qualified facility to respond, in writing, to a notification of circumstances that may lead us to withdraw its exemption. Comments suggest timeframes of 60, 90, and 120 days as a reasonable or appropriate period of time for a qualified facility to compile information and documentation of facts and to respond to a notification of circumstances that may cause us to withdraw its exemption. Some of these comments express concern that the proposed deadline is too short, and that the short timeframe violates the intent of the exemption. Some comments ask us to establish graduated response times, with less response time allowed for more serious food safety concerns.

(Response 614) We have revised the provision to provide for 15 calendar days, rather than 10 calendar days, for a facility to respond in writing to our notification. The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 615) Some comments ask us to clarify how an exemption can be revoked (and restored) on diversified farms that produce both exempt and non-exempt products.

(Response 615) We assume that this comment is referring to a farm mixed-type facility that produces some products (such as juice or dietary supplements) that are exempt from the requirements for hazard analysis and risk-based preventive controls, as well as some products that are not exempt from these requirements. Neither withdrawing nor reinstating a qualified facility exemption would have any impact on products that are not subject to the requirements for hazard analysis and risk-based preventive controls. In contrast, administrative procedures such as injunction and suspension of registration likely would apply to all food production by the facility.

(Comment 616) Some comments ask us to consistently use either “calendar

days” or “working days” throughout the provisions directed to withdrawal of an exemption. Some comments ask us to use “business days” rather than “calendar days” or “working days.”

(Response 616) We have expressed the timeframes for all of the withdrawal provisions in calendar days.

(Comment 617) Some comments ask us to clarify that the decision to withdraw a qualified exemption is an individualized determination and will not be applied to a class of farmers by stating this clearly in the preamble.

(Response 617) The decision to withdraw a qualified exemption is an individualized determination and will not be applied to a class of facilities or farmers.

(Comment 618) Some comments assert that the timeframes for responding to a notification that an exemption may be withdrawn should be the same regardless of whether the notification is sent to a qualified facility subject to the human preventive controls rule or a farm subject to the produce safety rule. These comments state that many small farms do value-added processing and will be subject to both rules.

(Response 618) Although the produce safety rule is not yet final, we intend to make the administrative procedures associated with withdrawal of an exemption consistent to the extent practicable, including the timeframe for responding to a notification.

(Comment 619) Some comments ask us to expand the scope of the withdrawal provisions to include facilities that would satisfy criteria for an exemption from the requirements for hazard analysis and risk-based preventive controls for low-risk activity/food combinations (*i.e.*, the exemptions in proposed § 117.5(g) and (h)).

(Response 619) We decline this request. Section 418 of the FD&C Act does not provide for withdrawal of the exemptions established in § 117.5(g) and (h). The withdrawal provision in section 418(l)(3) of the FD&C Act is limited to qualified facilities.

#### *B. Proposed § 117.254—Issuance of an Order To Withdraw a Qualified Facility Exemption*

We proposed procedures for the steps we would take to issue an order to withdraw an exemption applicable to a qualified facility, including procedures that would: (1) Emphasize that a senior FDA official (such as an FDA District Director, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition, or a more senior FDA official) must approve an order to withdraw the exemption before

the order is issued; (2) provide that any officer or qualified employee of FDA may issue the order after it has been approved; (3) specify that we would issue the order to the owner, operator, or agent in charge of the facility; and (4) require that the order be in writing and be signed and dated by the officer or qualified employee of FDA who is issuing the order.

(Comment 620) Some comments ask us to include in the procedures timeframes for: (1) Submitting an order after an initial determination that criteria for withdrawing an exemption are met; (2) approval or denial by the FDA District Director; (3) issuing the withdrawal (with automatic revocation of order if FDA does not issue the order within the specified timeframe); and (4) delivery of the order to the owner, operator, or agent in charge of the facility. Other comments recommend that the procedures for issuing an order specify that we send the order in a way that ensures its receipt, such as through certified mail with confirmation of delivery to ensure the facility operator receives the order.

(Response 620) We are not establishing timeframes for the steps we take before a facility receives an order for withdrawal of an exemption. The timeframes surrounding our internal process for developing an order have no bearing on the time that a facility will need to respond to the order or on the information it will need to do so. We agree that it is appropriate to specify timeframes for the procedural steps that follow a facility’s receipt of an order, and the withdrawal procedures include such timeframes.

We are not specifying that we send an order in a way that ensures its receipt. Although certified mail with confirmation of delivery is one way to ensure receipt, other methods are available, including delivery through private carriers that provide mechanisms to document receipt. In light of the provision (which we included in the 2014 supplemental human preventive controls notice) linking the timeframes for a facility to comply with, or appeal, an order to the date of receipt of the order (rather than to the date of the order), it will be up to us to deliver the order in a way that provides us with evidence of receipt.

#### *C. Proposed § 117.257—Contents of an Order To Withdraw a Qualified Facility Exemption*

We proposed specific information that would be included in an order to withdraw an exemption, including: (1) The date of the order and the name, address, and location of the qualified

facility; (2) a brief, general statement of the reasons for the order, including information relevant to the circumstances that led us to issue the order; (3) a statement that the facility must either comply with subpart C within 120 calendar days of receipt, or appeal the order within 10 calendar days of receipt; (4) the text of section 418(l) of the FD&C Act and of the withdrawal provisions in part 117, subpart E; (5) information about an informal hearing on an appeal of the order; and (6) contact information for appropriate senior FDA officials, as well as the name and the title of the FDA representative who approved the order.

(Comment 621) Some comments recommend that the order specify which of the two circumstances that could lead us to issue the order apply.

(Response 621) We have made editorial changes to the regulatory text to make it more clear that the provision requires us to specify which circumstance applies (*i.e.*, an active investigation of foodborne illness, or conduct or conditions associated with the qualified facility), or whether both of these two circumstances apply. See the revised regulatory text for § 117.257(c).

(Comment 622) Some comments ask us to add more specific requirements for the content of an order to withdraw an exemption, including specific evidence about the circumstances leading to the order. The comments maintain that doing so would help the facility respond with particularity to the facts and issues contained in the order if the facility appeals the order. The comments also recommend that the order include the evidence on which the order is based including, as applicable, evidence linking the active investigation of a foodborne illness outbreak directly to the facility or measurable evidence (collected using generally accepted scientific standards) indicating the presence in the facility of pathogens that pose an imminent threat to public health, or conduct or conditions that are material to the safety of food. The comments also recommend that the order include, when applicable, a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

(Response 622) We agree that the order must provide sufficient information to enable a facility to respond with particularity to specific evidence about the circumstances leading to the order. However, we disagree that the order must do so by including the specific information recommended by the comments, and we have not revised the proposed

withdrawal provisions to incorporate the suggestions of these comments. The comments appear to be more focused on whether the circumstances that lead us to issue an order meet an evidentiary standard than on explaining the problem so that a facility can both understand the problem and respond with particularity to the facts and issues contained in the order. The withdrawal provisions that we are establishing in this provision require the order to include a brief, general statement of the reasons for the order, including information relevant to: (1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or (2) conditions or conduct associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at the facility. The requirements that we are establishing in this provision would enable a qualified facility to both understand the problem and respond to it. In addition, because other requirements in these withdrawal provisions specify that we must notify a qualified facility of circumstances that may lead us to withdraw its exemption before we issue the actual order, the order withdrawing the exemption would be the second time that the facility hears about the problems (see § 117.251(b)(2)). We intend that the process of responding to the notification that we must send before issuing an order to withdraw an exemption, including discussing the problems with FDA as warranted, would provide additional information to the facility to enable the facility to both understand the problem and respond to it.

(Comment 623) Some comments ask us to provide 15 “business days” from date of receipt of the order, rather than the proposed 10 calendar days from date of receipt of the order, for the facility to appeal the order.

(Response 623) We have revised the provision to provide for 15 calendar days, rather than 15 business days, for a facility to appeal the order. We also have made conforming changes to establish the same 15 calendar timeframe in all provisions that specify the timeframe to appeal the order (*i.e.*, §§ 117.260(a)(2), 117.264(a)(1), and 117.267(a)(2)). We also extended the timeframe for the hearing to be held to be within 15 calendar days, rather than the proposed 10 calendar days, after the date the appeal is filed to provide more time for the facility to prepare for the hearing (see § 117.270(a)). The timeframe for the hearing to be held continues to provide for an alternative timeframe agreed upon in writing by both the facility and FDA; a facility that

would have preferred the proposed timeframe of 10 calendar days could request that the hearing be held more quickly than 15 calendar days.

The 15-day timeframe is the same as the timeframe for responding to a warning letter. As discussed in Response 614, circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 624) Some comments support the proposed timeframe of 120 calendar days for a qualified facility whose exemption has been withdrawn to comply with the human preventive controls rule, but ask us to make the timeframe for complying with a FSMA rule the same regardless of whether the exemption is withdrawn from a qualified facility subject to the human preventive controls rule or from a farm subject to the produce safety rule. Other comments ask us to extend the timeframe to come into compliance—*e.g.*, to 1 or 2 years. Some of these comments suggest that qualified facilities should have 120 days to develop a plan of action, but 2 years to fully comply. Some of the comments argue that large farms and manufacturers are given a year to come into compliance, and that requiring small and very small businesses to comply in a shorter time period would effectively drive them out of business. Other comments ask us to consider provisions that would require compliance with only those portions of the rule that formed the basis for the revocation.

(Response 624) We continue to believe that the 120-day timeframe is adequate, but we have added flexibility such that a facility may request, with a justification in writing to FDA, a reasonable timeframe for compliance that exceeds 120 calendar days from the receipt of the order. FDA must grant the request for the facility to receive the extended timeframe. We are not generally extending the timeframe because circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility. A qualified facility that receives an order to withdraw its exemption would have received advance notification of the circumstances leading to the order and would have had an opportunity to correct the problems rather than have us proceed to issue the order (see § 117.251(b)). If the facility requests a hearing, more than 40 days could elapse between the date that the facility receives the order and the date that the

presiding officer for the hearing confirms the order to withdraw the exemption. Given that the circumstances that would lead us to issue the order involve either: (1) An active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or (2) a determination that withdrawal of the exemption is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at the facility, a delay of 1 to 2 years to comply with the rule is not warranted. We also do not believe that it would be appropriate to require a facility to come into compliance with only those provisions that formed the basis of the revocation. The provisions of subparts C and G are interrelated and operate as a system and therefore are not optimized through piecemeal implementation. However, FDA may consider staggered implementation as an option in granting a request for an extension of the timeframe to comply with an order to withdraw the exemption for a qualified facility.

As already discussed, the new requirements for hazard analysis and risk-based preventive controls are not “one-size-fits-all.” Although each facility subject to the rule must prepare and implement a food safety plan, the preventive controls that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility’s hazard analysis. In addition, the preventive control management components that a facility would establish and implement for its preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system. (See Response 222.)

Although the produce safety rule is not yet final, we intend to make the administrative procedures associated with withdrawal of an exemption consistent to the extent practicable, including the timeframe to comply with the applicable rule if an exemption is withdrawn.

(Comment 625) Some comments ask us include in the order a statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 117.287.

(Response 625) We have revised the requirements for the contents of an order as requested by these comments.

*D. Proposed § 117.260—Compliance With, or Appeal of, an Order To Withdraw a Qualified Facility Exemption*

We proposed that: (1) You must either comply with applicable requirements of part 117 within 120 calendar days of receipt, or appeal the order within 10 calendar days of receipt; (2) submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action unless the Commissioner of FDA, as a matter of discretion, determines that delay or a stay is in the public interest; and (3) if you appeal the order, and we confirm the order, you must comply with applicable requirements of part 117 within 120 calendar days of confirmation of receipt of the order.

(Comment 626) Some comments ask us to specify that a qualified facility that loses its exemption from the requirements for hazard analysis and risk-based preventive controls would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption.

(Response 626) A qualified facility that loses its exemption from the requirements for hazard analysis and risk-based preventive controls would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption. To make this clearer, the final withdrawal procedures now include this information (see the regulatory text for § 117.260(c)).

*E. Proposed § 117.264—Procedure for Submitting an Appeal*

We proposed that: (1) To appeal an order, you must submit a written appeal to FDA within 10 calendar days of receipt and respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely; and (2) in your written appeal, you may include a written request for an informal hearing.

(Comment 627) Some comments ask us to rely on records kept in the normal course of business for documentation that will be sufficient to respond to an order to withdraw a qualified facility’s exemption, rather than requiring a facility to “respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.” These comments assert that we should not require a facility that submits a written appeal to provide

documents and records that they are not required to keep.

(Response 627) We decline this request. In a withdrawal action, FDA is providing a qualified facility multiple opportunities to persuade FDA that withdrawal is not appropriate. If the facility relies on documentation as part of its response, it is reasonable to require that this documentation be provided to FDA.

*F. Proposed § 117.267—Procedure for Requesting an Informal Hearing*

We proposed that if you appeal the order: (1) You may request an informal hearing, and must do so together with your written appeal (within 10 calendar days of the date of receipt of the order; and (2) a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted; you would receive written notice of the presiding officer’s determination, explaining the reason for the denial.

(Comment 628) Some comments ask us to guarantee a hearing so that a qualified facility can present its case in person before having its exemption revoked.

(Response 628) We decline this request. We agree that a qualified facility has a right to appeal an order to withdraw an exemption, and we have provided for a right to appeal.

*G. Proposed § 117.270—Requirements Applicable to an Informal Hearing*

We proposed that if you request an informal hearing, and we grant the request: (1) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and by us; (2) the presiding officer may require that the hearing be completed within 1 calendar day; and (3) we must conduct the hearing in accordance with part 16 (21 CFR part 16), with some specified modifications, including that no party shall have the right, under § 16.119, to petition FDA for reconsideration or a stay of the presiding officer’s final decision.

(Comment 629) Some comments object to our proposal that no party shall have the right, under § 16.119, to petition FDA for reconsideration or a stay of the presiding officer’s final decision. These comments assert that our justification (*i.e.*, that the circumstances that would lead to a withdrawal merit prompt action and that a facility has the opportunity for judicial review in accordance with 21



CFR 10.45) is not a sufficient argument for justifying the removal of the option to file a motion for reconsideration or stay. These comments ask us to revise proposed § 117.270(c)(6) to specify that the qualified facility shall have the right to file a motion for reconsideration or stay.

(Response 629) We decline this request. In the 2014 supplemental human preventive controls notice, we proposed an additional mechanism for a qualified facility to present its view that its exemption should not be withdrawn—*i.e.*, by providing advance written notification to a qualified facility if we are considering withdrawing an exemption and providing an opportunity for the facility to respond before we issue an order to withdraw an exemption. We also proposed to provide an opportunity for reinstatement of an exemption that had been withdrawn. We believe the multiple opportunities now available to a facility provide adequate opportunities for a facility's views to be considered, and further mechanisms are not warranted.

#### *H. Proposed § 117.287—Reinstatement of a Qualified Facility Exemption That Was Withdrawn*

We proposed four provisions for reinstating a withdrawn qualified facility exemption. First, we proposed that if the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or on the request of a facility, reinstate the exemption (proposed § 117.287(a)).

Second, we proposed that you may ask FDA to reinstate an exemption that has been withdrawn by following specific steps (§ 117.287(b)(1) and (2)). Third, we proposed that if your exemption was withdrawn in the event of an active investigation of a foodborne illness outbreak that is directly linked to your facility and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the

outbreak is not directly linked to your facility, FDA will reinstate your qualified facility exemption and will notify you in writing that your exempt status has been reinstated.

We proposed that if your exemption was withdrawn both in the event of an active investigation of a foodborne illness outbreak that is directly linked to your facility and because FDA had determined that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with your facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified facility exemption.

(Comment 630) Some comments agree with our tentative conclusion that the absence of a specific provision in section 418 of the FD&C Act for the reinstatement of an exemption that is withdrawn does not preclude us from providing for such a process (79 FR 58524 at 58553). Other comments disagree with that tentative conclusion and assert that Congress crafted the withdrawal provision as a “one strike, you're out” provision. These comments also assert that including the withdrawal provision as a “one strike, you're out” provision was an essential part of the legislative agreement that allowed for adoption of the qualified facility exemption. These comments also assert that reinstatement would undermine the intent of the withdrawal provision because it would reduce the incentive for small food processors to ensure that the products they sell are as safe as possible. These comments also assert that a recognized principle of statutory interpretation provides that exemptions to statutes should be strictly construed, particularly when the statute addresses public health and safety, and that we are giving the exemption an impermissibly broad construction.

Some comments ask why we believe that a business deserves a “second bite of the apple” in light of the understanding (under proposed § 117.251(b) and (c)) that we will first seek to correct problems before considering withdrawal. These comments also question at what point a facility would apply for reinstatement, and ask why we would allow a facility that has already come into compliance with FSMA's requirement to implement preventive controls to abandon those

controls in favor of reinstating its exempt status. These comments ask us to eliminate the proposed provisions allowing for reinstatement.

Some comments do not support the proposed reinstatement provisions when a food facility has been directly linked to a foodborne illness outbreak. Some comments support the proposed reinstatement provisions only when we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility that had its exemption withdrawn.

(Response 630) We disagree that the proposed reinstatement provisions would give the exemption an impermissibly broad construction. The express statutory language of section 418(l) of the FD&C Act does not support the comments' assertion that the withdrawal provision is a “one strike, you're out” provision. We also disagree that reinstatement would undermine the intent of the withdrawal provision because it would reduce the incentive for small food processors to ensure that the products they sell are as safe as possible. We expect that the withdrawal provision itself provides a big incentive for small food processors to ensure that the products they sell are as safe as possible because of the business disruption that would occur if they are subject to withdrawal of the exemption. We proposed that a facility would need to present data and information to demonstrate that it has adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

We disagree that we should categorically refuse to consider reinstating a qualified facility exemption if we had withdrawn the exemption because a food facility had been directly linked to a foodborne illness outbreak. First, if information later comes to light to raise considerable doubt that a qualified facility had, indeed, been directly linked to a foodborne illness outbreak, and conditions and conduct at the facility do not otherwise warrant withdrawing the facility's exemption, it would be appropriate for us to reinstate the facility's exemption. Second, we would only reinstate the exemption if we determined that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or

held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(Comment 631) Some comments that support the reinstatement of a withdrawn exemption ask us to establish a timeframe within which FDA will reinstate an exemption. Some comments ask us to specify in the regulatory text that the reinstatement would occur in a reasonable period of time, both in circumstances where FDA has decided on its own initiative to reinstate the exemption and in circumstances where a facility submits a request for reinstatement. Some comments suggest 10 days is a reasonable period of time within which FDA should reinstate an exemption.

(Response 631) We decline the requests to establish a timeframe for reinstatement in the regulatory text. If we determine on our own initiative to reinstate an exemption (e.g., because we later determine, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility), our determination would be effective immediately. If we receive a request to reinstate a withdrawn exemption, we intend to respond in a reasonable timeframe consistent with available resources. In some cases, we may respond that we need more information in order to evaluate your request.

(Comment 632) Some comments ask that the process for reinstatement include at least one level of administrative appeal if we deny a facility's request for reinstatement.

(Response 632) We have not revised the regulatory text to provide for an administrative appeal if we deny a facility's request for reinstatement. Existing procedures allow a facility to ask for a meeting with applicable FDA officials (see 21 CFR 10.65(c)) and appeal our decision if we deny the request (see 21 CFR 10.75).

(Comment 633) Some comments ask us to establish a 1-year probationary period before the withdrawn qualified facility exemption could be fully reinstated.

(Response 633) We decline this request. We intend to act on a request for reinstatement based on the merits of

the data and information presented in the request, not after a pre-determined timeframe.

*I. Conforming Amendment to 21 CFR Part 16*

We proposed to amend § 16.1(b)(2) to include part 117, subpart E, relating to the withdrawal of an exemption applicable to a qualified facility, in the list of regulatory provisions under which regulatory hearings are available. We received no comments that disagreed with this proposed provision, and are finalizing it as proposed.

*J. Other Comments on the Withdrawal Provisions*

(Comment 634) Several comments ask us to provide clarification through guidance, issued for public comment, on a variety of topics associated with the withdrawal provisions.

(Response 634) We will consider the need for guidance in the future. At this time, we consider that withdrawing an exemption would be both rare and dependent upon the circumstances. We need to direct our resources to developing guidance on issues that would apply more broadly, and more generally, than the withdrawal provisions.

(Comment 635) Some comments ask detailed questions about how we would coordinate the withdrawal process with the States.

(Response 635) In general, we work with our State partners and other government counterparts in dealing with enforcement actions, including coordinating actions or deferring to each other when one department has authority to swiftly act to protect the consumer. In the specific case of this rule, we are working through the PFP to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see Response 5 and section 209(b) of FSMA).

(Comment 636) Some comments ask us to add provisions regarding notification of the appropriate State regulatory agency when a qualified facility exemption is withdrawn and reinstated.

(Response 636) We decline this request. As previously noted, we are sensitive to the time required for various

inspection activities and intend to communicate with States regarding our expectations for how to verify whether a facility is a qualified facility. The status of a facility as a qualified facility principally affects the requirements that it is subject to, and will be most useful to FDA and our food safety partners when preparing for inspection. At this time we do not intend to establish a system notifying the applicable State authorities at a point in time when the status of a facility as a qualified facility changes, whether as a result of withdrawal or reinstatement of a qualified facility exemption or because the facility's business has grown to the point where it exceeds the financial threshold for very small business. See also Response 635.

**XLI. Subpart F: Comments on Proposed New Recordkeeping Requirements**

We proposed to establish in subpart F requirements that would apply to all records that would be required by the various provisions of proposed part 117, including general requirements related to the content and form of records; additional requirements specific to the food safety plan; requirements for record retention; requirements for official review of records by FDA; and public disclosure.

Some comments support the proposed requirements without change. For example, some comments state that the proposed 2-year retention period is consistent with the majority of food safety guidelines currently being used in the fresh produce industry. Some comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 639, Comment 642, and Comment 644 through Comment 646) or ask us to clarify how we will interpret the provision (see, e.g., Comment 643 and Comment 650).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 43, with editorial and conforming changes as shown in table 52.

TABLE 43—REVISIONS TO THE PROPOSED RECORDKEEPING REQUIREMENTS

Section	Description	Revision
117.305(c) .....	General requirements applying to records .....	Provide that the time of an activity being documented only include the time of the activity when appropriate.
117.305(g) .....	General requirements applying to records .....	Specify that electronic records are exempt from the requirements of 21 CFR part 11.

TABLE 43—REVISIONS TO THE PROPOSED RECORDKEEPING REQUIREMENTS—Continued

Section	Description	Revision
117.315(a)(2)	Requirements for record retention	Specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility for as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
117.315(c)	Requirements for record retention	Provide for offsite storage of all records other than the food safety plan, provided that the offsite records can be retrieved and provided onsite within 24 hours of request for official review.
117.315(d)	Requirements for record retention	Provide that the food safety plan may be transferred to some other reasonably accessible location if the plant or facility is closed for a prolonged period, provided that it is returned to the plant or facility within 24 hours of request for official review.
117.320	Requirements for official review	Clarify that FDA may copy records upon oral or written request by a duly authorized representative of the Secretary of Health and Human Services.
117.325	Requirements for public disclosure	Specify that the requirement applies to records “obtained by FDA”.
117.335	Special requirements applicable to a written assurance	<ul style="list-style-type: none"> <li>Establish requirements applicable to all written assurances required by the rule.</li> <li>Establish additional requirements applicable to written assurances that are required when a food product distributed by manufacturer/processor requires further processing for food safety by a subsequent manufacturer.</li> </ul>

*A. Proposed § 117.301—Records Subject to the Requirements of Subpart F*

We proposed that all records required by part 117 would be subject to all requirements of subpart F, except that certain specific requirements (proposed § 117.310) would apply only to the written food safety plan. We also proposed that certain proposed requirements (e.g., for records to contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities) would not apply to the records that would be kept by qualified facilities.

(Comment 637) Some comments disagree with the proposal to exempt the records that would be kept by qualified facilities from requirements to keep accurate, detailed records. The comments note that the proposed exemption would apply to qualified facilities regardless of whether they operate under the first option for documentation (i.e., food safety practices) or under the second option for documentation (i.e., compliance with non-Federal food safety laws). These comments assert that the proposed detailed recordkeeping requirements should apply to records relating to monitoring food safety practices and ask us to revise the proposed requirements so that this exemption would apply only to those

qualified facilities that operate under non-Federal food safety laws.

(Response 637) We decline this request. We based the proposed exemption on a statutory provision that a qualified facility is not subject to certain requirements, including the statutory recordkeeping requirements (see section 418(l)(2) of the FD&C Act). Although the modified requirements that apply to a qualified facility require submission of certain attestations to FDA (see § 117.201(a) and (b)), and these attestations must be supported by documentation (see § 117.201(f)), the rule does not require that records kept by a qualified facility to support its attestations be the same type of records that would be kept by a facility subject to subparts C and G. For example, if the facility attests that it has identified the potential hazards associated with the food being produced, implemented preventive controls to address the hazards, and is monitoring the performance of the preventive controls, the qualified facility might support its attestation by having a standard operating procedure for monitoring preventive controls rather than detailed records of actual monitoring.

*B. Proposed § 117.305—General Requirements Applying to Records*

We proposed that the records must: (1) Be kept as original records, true copies, or electronic records (and that electronic records must be kept in

accordance with part 11 (21 CFR part 11)); (2) contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities; (3) be accurate, indelible, and legible; (4) be created concurrently with performance of the activity documented; (5) be as detailed as necessary to provide history of work performed; and (6) include the name and location of the plant or facility, the date and time of the activity documented, the signature or initials of the person performing the activity, and, where appropriate, the identity of the product and the production code, if any.

We have revised the provision to require information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility) rather than to always require both the name and location of the plant or facility (see § 117.305(f)(1)). In some cases, the name of the plant or facility will be adequate to identify it—e.g., when a plant or facility is not part of a larger corporation that has facilities at more than one location. In other cases, the name of the plant or facility may not, by itself, be adequate to identify the plant or facility—e.g., when a plant or facility is part of a larger corporation with more than one location and the “name” of each plant or facility is the same.

(Comment 638) Some comments assert that compliance with part 11 for the secure operation of many systems

currently in use is unnecessary and would create the need to redesign and recreate existing systems, thus leading to considerable cost and complexity. These comments identify the requirement for hardware and software to be validated as a key cost concern and assert that validation activities would be difficult to maintain and would not deliver added value. As an example, these comments explain that an expectation for validation of electronic recordkeeping software and hardware would be particularly problematic because software patches and security updates are distributed on a nearly weekly basis, and express the view that validation procedures are most appropriately applied before use of a new system and after major software changes or updates. These comments also assert that it would be costly, burdensome, and require specialized resources to modify or replace existing electronic systems to comply with part 11. These comments provide an example in which a facility needed more than nine months to upgrade one system alone to comply with part 11, and note that it would not be unusual for companies to employ multiple systems, so the burden and cost would exponentially increase. These comments ask us to instead require facilities that use electronic records to use a secure system that ensures records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Other comments express concern about the financial burden for small facilities such as farm mixed-type facilities and ask us to either modify requirements for farm mixed-type facilities, very small businesses, and small businesses or provide that such facilities be fully exempt from part 11 requirements for electronic records. Other comments state that, as with the recordkeeping requirements under the Bioterrorism Act, such requirements are disproportionate to the regulatory need. Other comments state that many operators that use electronic data records in the produce industry use open software and would not meet part 11 requirements.

Some comments state that major advances in software technology have been made since part 11 published in 1997, and such advances must be carefully considered in evaluating any potential expansion or new applications of part 11. These comments also state that we already are in the process of reevaluating part 11 for the regulations for which it currently applies, citing industry guidance issued more than 10

years ago in which we acknowledged that part 11 is unworkable in many respects and decided to exercise enforcement discretion for part of the regulations and announced plans to reexamine part 11 as a whole.

Some comments recommend that we develop guidance, with input from key stakeholders, to describe the kinds of systems and steps that can be used to assure records meet the required standard. This guidance should clearly establish that specific security needs will depend on the circumstances, including the system at issue, its intended use, the criticality of the preventive control or other food safety measure it is used to manage, and other relevant factors. For example, these comments explain that a quality system used to manage CCP documentation would have greater security needs than a review of a Certificate of Analysis for a non-sensitive ingredient.

(Response 638) In light of the substantial burden that could be created by the need to redesign large numbers of already existing electronic records and recordkeeping, we are providing in new § 117.305(g) that records that are established or maintained to satisfy the requirements of part 117 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. As we did in the section 414 recordkeeping regulations, we also are specifying that records that satisfy the requirements of part 117, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. The rule provides that a facility may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. As we did in the rulemaking to establish the section 414 recordkeeping regulations, we are establishing a conforming change in part 11 to specify in new § 11.1(i) that part 11 does not apply to records required to be established or maintained under part 117, and that records that satisfy the requirements of part 117, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

Although we are not specifying that part 11 applies, facilities should take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(Comment 639) Some comments assert that certain production and associated activities are not time-

sensitive and would not require documentation of the time the activity is performed. These comments ask us to modify the proposed requirements so that the records would only require the time of the activity documented where appropriate for food safety.

(Response 639) We agree that certain activities (e.g., record review and verification activities) are not time-sensitive and, thus, would not need to include the time that the activity was performed. The final rule provides flexibility for the facility to determine when to document the time by specifying that the time be documented “when appropriate” (see § 117.305(f)(2)).

(Comment 640) Some comments assert that concurrent record creation will prove difficult in many food-processing environments. These comments ask us to modify the proposed requirement that records be created concurrently with the performance of the activity documented to qualify that the requirement only applies where feasible, and that the records could be created as soon as possible thereafter under circumstances where concurrent record creation is not feasible.

(Response 640) We decline this request. The comments did not provide any examples of activities where concurrent record creation in food manufacturing, processing, packing, or holding environments would prove difficult, and we are not aware of any such example. For example, we are not aware of any difficulty complying with long-standing similar requirements associated with our HACCP regulations for seafood and juice (see §§ 123.9(a)(4) and 120.12(b)(4), respectively).

(Comment 641) Some comments express concern about “apparent mandates” that we will require records to be kept in the English language and assert that the language of food factory documents should not be dictated as a precondition for food exports. These comments ask us to limit the documents that must be written in English to reduce translation and records duplication. These comments also ask us to focus the requirements for English language on those documents that must be submitted to FDA.

(Response 641) We did not propose to require that any “factory records” (such as the written food safety plan (§ 117.126) and the implementation records listed in § 117.190) be kept in the English language. Consistent with other regulations for submissions to FDA (such as for registration of a food facility), the form we will use for a qualified facility to submit its required

attestations (§ 117.201(b) and (c)) will be in the English language.

*C. Proposed § 117.310—Additional Requirements Applying to the Food Safety Plan*

We proposed that the food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

(Comment 642) Some comments state that the provision would exclude the preventive controls qualified individual from signing and dating the food safety plan unless the preventive controls qualified individual is the owner, operator, or agent in charge of the facility. These comments ask us to revise the rule to allow the preventive controls qualified individual to sign and date the food safety plan (e.g., because it is the preventive controls qualified individual who prepares (or oversees the preparation of) the food safety plan). Some comments ask us to require that any preventive controls qualified individuals who prepare (or oversee the preparation of) specific sections of the food safety plan sign and date the applicable sections.

(Response 642) We decline these requests. The statute expressly directs the owner, operator, or agent in charge of a facility to prepare the food safety plan (see section 418(h) of the FD&C Act). As previously discussed, such a signature would provide direct evidence of the owner, operator or agent's acceptance of the plan and commitment to implementation of the plan (78 FR 3646 at 3782). A facility has flexibility to require the signature of one or more preventive controls qualified individuals who prepared, or oversaw the preparation of, its food safety plan in addition to the minimum signature requirement specified in the rule. Likewise, a facility also has flexibility to require the signature of one or more members of its food safety team who contributed to the preparation of the food safety plan, even if those individuals are not serving as the preventive controls qualified individual for the facility. (See also Response 377.)

*D. Proposed § 117.315—Requirements for Record Retention*

We proposed that: (1) All required records must be retained at the plant or facility for at least 2 years after the date they were prepared; (2) records relating to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued; (3)

except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the records were made if such records can be retrieved and provided onsite within 24 hours of request for official review; and (4) if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

(Comment 643) Some comments ask us to clarify that the 2-year record retention requirement only applies to records created after the compliance date for the final rule.

(Response 643) The retention requirements only apply to records created after the applicable compliance date for the final rule. See Response 155 and section LVI.A, which explain that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016. See also Response 646, which explains that we have revised the record retention provisions to specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(Comment 644) Some comments ask us to delete the proposed requirement to keep records on site for 6 months or 2 years (depending on the record) and assert that it should suffice to require that records be available within 24 hours of request or within a reasonable period of time. Some comments assert that a facility should be able to keep records in the location where they are created, which may be at corporate headquarters. Comments also assert that specifying the location for record storage will increase costs but will not contribute to improvements in public health. Some comments ask us to permit off-site storage for all records more than 6 months old, in contrast to the 2-year retention period we proposed for records relating to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations.

(Response 644) We have revised the provisions to provide for offsite storage of all records (except the food safety plan), provided that the records can be retrieved and made available to us within 24 hours of request for official review. We expect that many records will be electronic records that are accessible from an onsite location and, thus, would be classified as being onsite

(see § 117.315(c)). As a companion change, we have revised the proposed provision directed to the special circumstance of storing records when a facility is closed for prolonged periods of time so that it only relates to the offsite storage of the food safety plan in such circumstances (see § 117.315(d)).

(Comment 645) Some comments assert that a two year retention period for records is much longer than needed for a product with a short shelf life (such as milk) and may not be long enough for products with very long shelf lives (such as oils). These comments ask us to establish a retention period that is risk-based and related to the shelf life of the product rather than “one-size-fits-all.” As an example, these comments suggest that we could set the retention requirement as 2 years past the date of manufacture or 1 year past an “expiration” date, whichever is longer. These comments also suggest that documentation on raw materials could be maintained for two years after final product lot is manufactured.

(Response 645) We decline these requests. The proposed 2-year retention period is authorized by the statute (see section 418(g) of the FD&C Act). Moreover, the reasons discussed by the comments for linking the retention period to shelf life are more relevant to the record retention requirements for the purpose of tracking potentially contaminated food (21 CFR part 1, subpart J; see § 1.360) than to the record retention requirements for the purpose of evaluating compliance with this rule.

(Comment 646) Some comments ask us to require that qualified facilities keep financial and sales records for 3 or 4 years, because a qualified facility must document that the average value of food it sold during the prior 3 years did not exceed \$500,000 annually.

(Response 646) We have revised the record retention provisions to specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year. As discussed in Response 155, the definition of very small business established in this rule is based on an average (of sales plus market value of human food held without sale) during the 3-year period preceding the applicable calendar year. Thus, both of the criteria for the qualified facility exemption are based on financial records associated with the preceding 3-year period. The actual retention time necessary to support the status of a qualified facility during the

applicable calendar year could be as long as 4 years. For example, if we inspect a facility on May 1, 2024, the facility would have retained the records from 2021–2023 for 3 years and 4 months. If we inspect the facility on December 28, 2024, the facility would have retained the records from 2021–2023 for nearly 4 years.

*E. Proposed § 117.320—Requirements for Official Review*

We proposed that all records required by proposed part 117 be made promptly available to a duly authorized representative of the Secretary of HHS upon oral or written request. We asked for comment on whether we should require a facility to send records to us rather than make the records available for review at a facility's place of business and, if so, whether we should require that the records be submitted electronically.

(Comment 647) Some comments assert that we should not copy documents as part of routine investigations so as to prevent critical documents from release under the Freedom of Information Act (FOIA). These comments are particularly concerned that our ability to copy verification records (such as testing records) and potentially release these records under the FOIA would discourage facilities from testing as a verification activity. These comments also express concern that some facilities would include in their food safety plans elements, not required by the proposed rule, that address food defense as well food safety, and that disclosure of such a food safety plan without proper redaction could provide useful information to persons seeking to defeat the facility's food defense strategies. In addition, these comments express concern that the task of reviewing all of these records and redacting trade secrets and confidential information would further set back FDA's already overburdened FOIA offices and create even longer delays in responding to FOIA requests.

As discussed in Comment 649, some comments suggest that we revise the proposed public disclosure requirements (proposed § 117.325) to be analogous to the public disclosure requirements in our HACCP regulations for seafood and juice (see §§ 123.9(d) and 120.12(f), respectively).

(Response 647) We have revised the proposed requirement to specify that all required records must be made promptly available "for official review and copying" to increase the alignment of the recordkeeping requirements of this rule with those of our HACCP

regulations for seafood and juice. The issues raised by these comments are similar to some of the issues raised by comments during the rulemaking to establish our HACCP regulations for seafood (see the discussion at 60 FR 65096 at 65137–65140, December 18, 1995) and our regulations in part 118 for the prevention of *Salmonella* Enteritidis in shell eggs. We intend to copy records on a case-by-case basis as necessary and appropriate. We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow-up regulatory actions. We primarily intend to copy records such as the results of product testing or environmental monitoring when we conduct an inspection for cause—*e.g.*, as a result of an outbreak investigation, violative sample results, or follow up to a consumer complaint. See Response 650 for a discussion of how the FOIA would apply to records, such as records of testing as a verification activity, that we copy during an inspection and maintain in our system.

See also Response 649 for a discussion of how the public disclosure requirements of this rule align with those of our HACCP regulations for seafood and juice.

(Comment 648) Some comments strongly oppose any requirement for submission of records to FDA remotely and assert that there is no basis in FSMA for such a requirement. Some comments express concern about our ability to protect confidential information (such as supplier and customer records received by a facility under the protection of confidentiality agreements) that is transmitted electronically (*e.g.*, the information might be released through computer hacking or leaks). Some comments note that inadvertent disclosure of information related to specific products, hazards, and preventive controls implemented at food facilities could both prove harmful from a commercial or competitive standpoint and expose existing vulnerabilities in the U.S. food supply, thus potentially rendering food facilities susceptible to malicious attack.

Some comments oppose the concept of a "desk audit" whereby our investigators conduct their inspections from a remote office without actually visiting the facility and assert that our access to company records must be conducted on-site in the course of an

authorized inspection so that we may understand the full context of what the records show. Some comments point out that there would be challenges associated with credential validation when we asked for records to be sent remotely, such as in an email request. Some comments ask that we modify the proposed requirement to specify that records would only be made available to us during a facility inspection.

(Response 648) We have decided not to establish any requirements for a facility to send records to us. We will review records when we are onsite in the course of an authorized inspection, and copy records as necessary and appropriate. (See also Response 647.)

We are not modifying the proposed requirement to specify that records would only be made available to us during a facility inspection because it is not necessary to do so. The regulatory text specifying that the records be made available to a duly authorized representative of the Secretary of Health and Human Services provides the context that the records would be made available during inspection.

*F. Proposed § 117.325—Public Disclosure*

We proposed that records required by proposed part 117 are subject to the disclosure requirements under part 20 (21 CFR part 20).

(Comment 649) Some comments assert that the proposed requirements governing public disclosure are not aligned with other risk-based preventive controls programs, such as HACCP programs. These comments argue that the proposed requirements should be realigned with other risk-based preventive controls programs to preserve the privacy of information maintained in required records unless that information has been otherwise made publicly available. Some comments suggest that we revise the proposed requirements to be analogous to the public disclosure requirements in our HACCP regulations for seafood and juice (see §§ 123.9(d) and 120.12(f), respectively). One comment acknowledged our statements that the proposed requirements governing public disclosure are consistent with, but framed differently than, the disclosure provisions of our HACCP regulations for seafood and juice (79 FR 3646 at 3783), but nonetheless asks us to provide a more detailed explanation of how our proposed approach is consistent with the disclosure provisions in our HACCP regulations for seafood and juice.

(Response 649) We disagree that the proposed provisions governing public disclosure are not aligned with the

public disclosure provisions of our HACCP regulations for seafood and juice. Our regulations in part 20 regarding public information apply to all agency records, regardless of whether a particular recordkeeping requirement says so. In the case of the recordkeeping requirements for our HACCP regulations for seafood and juice, we framed the provisions regarding public disclosure by providing specific details about how particular provisions in part 20 (*i.e.*, § 20.61 (Trade secrets and commercial or financial information which is privileged or confidential) and § 20.81 (Data and information previously disclosed to the public)) would apply to the applicable records, because we recognized that such details were of particular interest to the regulated industries. In the case of the recordkeeping requirements for this rule, we framed the provisions regarding public disclosure by more broadly referring to all the requirements of part 20, consistent with our more recent approach for framing the provisions regarding public disclosure in the rule “Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation” (part 118; see § 118.10(f)). For example, provisions such as § 20.20 (Policy on disclosure of Food and Drug Administration records) apply to all records that we have in our system, including HACCP records, even though the HACCP regulations do not specify that this is the case.

As discussed in Response 647, to increase the alignment between this rule and our HACCP regulations for seafood and juice, we have revised the proposed requirement regarding our access to records to specify that all required records must be made promptly available “for official review and copying.”

(Comment 650) Some comments ask us to clarify that the disclosure requirements of part 20 include protections for trade secrets and privileged or confidential commercial information and financial information. Other comments ask us to clarify that written food safety plans and associated records are not subject to public disclosure because they represent trade secret or confidential commercial information. Other comments ask us to clarify how the disclosure requirements of part 20 would apply to verification records (such as testing records).

(Response 650) The questions raised in these comments are similar to some of the questions raised during the rulemaking to establish our HACCP regulation for seafood (see the discussion at 60 FR 65096 at 65137–65140). Our experience in conducting

CGMP inspections in processing plants, our experience with enforcing our HACCP regulations for seafood and juice, and our understanding from the FRIA for this rule make it clear that food safety plans will take each facility some time and money to develop. Thus, we conclude that food safety plans generally will meet the definition of trade secret, including the court’s definition in *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983). Plans that incorporate unique regimens or parameters to achieve product safety, which are the result of considerable research and effort, will surely meet this definition.

Moreover, there is value in a plan to a company that produces it for no other reason than that it took work to write. The equity in such a product is not readily given away to competitors. We expect that plant configurations will be unique to individual processors, or at least have unique features, as was the case in the seafood industry (Ref. 88). While generic plans will have great utility in many circumstances, they serve primarily as starting points for processors to develop their own plans. Facilities will still need to expend time and money to tailor a generic plan to their individual circumstances.

We would establish the status of verification records, such as the results of product testing and environmental monitoring, as available for, or protected from, public disclosure on a case-by-case basis. As discussed in Response 647, we primarily intend to copy such records when we conduct an inspection for cause. We also intend to copy such records if the preliminary assessment by our investigator during a routine inspection is that regulatory follow-up may be appropriate (*e.g.*, if these records demonstrate that an environmental pathogen has become established in a niche environment in a food processing plant).

(Comment 651) Some comments assert that our regulations in §§ 20.47 and 20.48 require us to consult with the entity providing information prior to disclosing such information. These comments ask us to provide a small business compliance guide that would allow smaller entities to understand our procedures for publicly disclosing information, including information maintained in records required by this rule, to allow opportunity for redaction of “confidential” information prior to disclosure.

(Response 651) We disagree with the comments’ interpretation of §§ 20.47 and 20.48. Section 20.47 requires consultation with the person providing data or information only when the

confidentiality of data or information is uncertain. During any such consultation FDA would provide any necessary information to the person who provided the data or information at issue.

(Comment 652) Some comments ask us to modify the proposed requirement to clarify that it is “records required by this part and provided to the Agency,” rather than “records obtained by the Agency” that are subject to public disclosure.

(Response 652) We agree that it is appropriate to specify that the disclosure requirements of this rule apply to information that we maintain as a record (see the description of “record” in § 20.20(e)). (See also the discussion (in the proposed rule to establish our seafood HACCP regulation, 59 FR 4142 at 4160, January 28, 1994) that there are significant legal and practical questions as to whether FDA has the authority to require disclosure of industry records that are not in FDA’s possession.) However, we see no meaningful distinction between records “provided to FDA” and records “obtained by FDA,” and have revised the provision to specify that records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20. The revised regulatory text makes clear that the requirements of Part 20 attach to those documents obtained by FDA. To the extent that these comments are addressing the difference between records provided during inspection and records submitted to us, as already discussed we have decided not to require submission of certain records to us (see Response 648).

#### *G. Proposed § 117.330—Use of Existing Records*

We proposed that existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of subpart F. We also proposed that the information required by part 117 does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by part 117 may be kept either separately or combined with the existing records.

Comments that address this proposed requirement support it. For example, some comments state that this provision would provide flexibility to facilities to

comply with the record requirements in an efficient manner. Other comments state that this provision would prevent companies from having to duplicate records or create new records solely to satisfy recordkeeping requirements.

(Comment 653) Some comments state that food safety plan records are a “web of related documents” that may be used in other programs and cannot be collected or “reduced to a binder.”

(Response 653) We agree that food safety plan records could be considered a “web of related documents”—*i.e.*, a set of records that could include documents used in other programs. We also agree that the food safety plan records need not be collected in a single location or “reduced to a binder.” See the discussion in Response 215 about how a food safety plan could consist of one or more existing HACCP plans, one or more prerequisite programs that include food safety controls, and other components required by the rule, and be dated and signed even if its components are not kept in a single location.

Likewise, the records documenting implementation of the plan could be a “web of related documents.” For example, a facility that collects samples of product and sends them to a laboratory for testing would have records documenting its collection of samples, as well as records documenting the laboratory’s test results. Consistent with the requirements of the rule for written procedures for product testing (§ 117.165(b)(2)) and the general recordkeeping requirements of subpart F (§ 117.305), the sampling records would contain information such as the name and location of the facility, the date when the samples were collected, the signature or initials of the person collecting the samples, and the identity and lot code of the sampled product. Likewise, the laboratory report would contain information identifying the laboratory, the product tested (and associated lot code), the test analyte, the test(s) conducted (including the analytical method(s) used), the date of the test(s), the test results, and the signature or initials of the person who conducted the test. Alternatively, it would be acceptable to have the signature or initials of the person who approved the release of the test results from the laboratory. Together, these records contain all the required information to associate them with a facility, a specific lot of product, and the results of laboratory testing on that product.

Although the provisions for use of existing records provide flexibility, there are some limitations. For example,

monitoring records must be created concurrently with the monitoring activity and contain the signature or initials of the person conducting the monitoring. If the facility has an existing form that it uses to document the monitoring activity, and that form does not provide (or have space to add) information adequate to identify the plant or facility (*e.g.*, the name and, when necessary, the location of the facility), and does have (or have space to add) a place for the signature of the person performing the activity, we expect the facility to modify the form rather than use the existing form. The provisions for “supplementing” existing records do not extend to providing information identifying the facility, or signatures, on separate pages.

(Comment 654) Some comments state that our review of records should be limited to issues under our jurisdiction, regardless of the other information that may be contained in the record. Other comments ask us to ensure that inspectors are adequately trained on how to review facility records for the requisite information across multiple sets of documents, as needed.

(Response 654) Section 418(h) of the FD&C Act requires that the written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418, together with the documentation of monitoring of preventive controls, instances of nonconformance material to food safety, the results of testing and other means of verification, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions, be made available to FDA. Our inspectors will be trained to focus on the written food safety plan and the records documenting implementation of the plan during inspections. Our inspectors have experience in the review of records that a food business establishes and maintains for more than one purpose—*e.g.*, during the review of records kept under the section 414 recordkeeping regulations during the investigation of an outbreak of foodborne illness.

#### *H. Final § 117.335—Special Requirements Applicable to a Written Assurance*

As discussed in section XXVII, new § 117.335 establishes requirements applicable to the written assurance a manufacturer/processor obtains from its customer. New § 117.335(a) applies to all written assurances required by the rule—*i.e.*, the assurance must contain the effective date; printed names and

signatures of authorized officials; and the applicable assurance.

The provisions of § 117.335(b), together with another new provision (§ 117.137), establish legal responsibilities under the rule for a facility that provides a written assurance regarding a food product that a manufacturer/processor distributes without application of a preventive control that is needed to control a hazard. This responsibility exists even for a facility that is not itself a manufacturer/processor, such as for a facility that is a distributor. We are establishing legal responsibilities for the facilities that provide these written assurances because following these assurances is critical to ensuring that required preventive controls are applied to the food by an entity in the distribution chain before the food reaches consumers.

#### *I. Other Comments on the Recordkeeping Requirements of Subpart F*

(Comment 655) Some comments assert that the extensive recordkeeping requirements of every aspect of farm and food production would be crushing to small and mid-sized businesses. These comments ask us to replace the proposed recordkeeping requirements with a brief farm plan that outlines perceived risks and how the farmer plans to address those risks.

(Response 655) We decline this request, which is largely moot in light of the changes we have made to the “farm” definition and to the classification of activities on-farm and off-farm (see the discussion in section IV of this document and table 1 in the Appendix to the 2014 supplemental human preventive controls notice (79 FR 58524 at 58571–58572)). None of the activities within the “farm” definition (*i.e.*, packing and holding RACs, and certain processing activities (such as drying grapes to produce raisins, and packaging RACs such as strawberries, without additional manufacturing/processing), will be subject to this rule if performed on a farm.

#### **XLII. Subpart G: General Comments on Proposed Requirements for a Supply-Chain Program**

In the 2014 supplemental human preventive controls notice, we provided an opportunity for public comment on potential requirements for a supplier program as a preventive control. The supplier program for a receiving facility would be limited to those raw materials and other ingredients for which the receiving facility has identified a significant hazard (which we now refer



to as “hazard requiring a preventive control”). Under the definitions established in this rule, “supplier” means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature; “receiving facility” means a facility that is subject to subparts C and G and that manufactures/processes a raw material or other ingredient that it receives from a supplier (see § 117.3).

We previously explained our understanding that, particularly for RACs, there may be multiple establishments, including cooperatives, packinghouses, and distributors, between a receiving facility and the establishment that would be considered the supplier, which would make supplier verification very challenging under certain circumstances (79 FR 58524 at 58548). We requested comment on what verification activities would be appropriate for receiving facilities to conduct when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors. We discussed an example in which a receiving facility is a fresh-cut processing facility that receives produce from a distributor, who receives produce from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms where the hazards are being controlled, and we asked what supplier controls should be applied for the produce coming from the farms. We requested comment on whether and how the requirements for supplier verification should address such situations. We also requested comment

regarding whether (and, if so, how) the final human preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain (e.g., by Supplier A, a farm), and Point B in the supply chain is a facility (such as Warehouse B, Distributor B, or Packing Shed B) that only packs or holds food, but does not manufacture/process food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain, which also would not be required to have a supplier program (e.g., Retail Food Establishment C or Consumer C). We discussed an example in which Packing Shed B distributes produce it packs after receiving the produce from Farm A directly to retail facilities (which would not be subject to the requirements of the human preventive controls rule); under the proposed supplier control program no supplier controls would be applied to Farm A. We requested comment on whether verification activities should be required in circumstances in which a RAC such as fresh produce will not be sent to any facilities that would be required to have preventive controls before reaching consumers.

In the remainder of this section, we discuss comments that address our request for comment on complex supply-chain scenarios such as those described in the 2014 supplemental human preventive controls notice. We also describe our reasons for revising the proposed requirements for a supplier program to provide additional flexibility for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities. When an entity other than the receiving facility determines, conducts, or both determines and conducts the appropriate supplier verification activities, the receiving facility must review and assess that entity’s

applicable documentation, and document the receiving facility’s review and assessment. Providing this additional flexibility required a series of changes to multiple proposed provisions. To improve clarity and readability we redesignated proposed § 117.136 into eight distinct sections of regulatory text in a newly established subpart G (Supply-Chain Program), with editorial changes associated with the new structure of the redesignated regulations. See table 44 for the section numbers and titles in subpart G. See table 45 for an overview of the major revisions to the proposed requirements for a supplier program. See sections XLIII through XLIX for a discussion of the specific provisions of the final requirements for a supplier program, and table 46, table 47, table 48, table 49, table 50, and table 51 for more detailed summaries of revisions to these specific provisions. Because table 45 is an overview, the changes identified in table 45 appear again in table 46, table 47, table 48, table 49, table 50, and table 51. Because the editorial changes associated with the redesignation are extensive, we do not list them in table 52.

The title of subpart G is “Supply-Chain Program” rather than “Supplier Program.” As shown in table 45 and discussed in more detail in section XLIII.D, we have added one requirement applicable to non-suppliers. “Supply-chain program” is a more appropriate term to reflect a subpart that includes a requirement applicable to non-suppliers in addition to the requirements applicable to suppliers. In the remainder of this document, we use the phrase “supply-chain program” in section headings and when referring to the provisions of the final rule. We continue to use the term “supplier program” when describing the proposed provisions and the comments regarding the proposed provisions.

TABLE 44—REDESIGNATION OF THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM IN SUBPART G  
[Supply-chain program]

Section	Description
117.405 .....	Requirement to establish and implement a supply-chain program.
117.410 .....	General requirements applicable to a supply-chain program.
117.415 .....	Responsibilities of the receiving facility.
117.420 .....	Using approved suppliers.
117.425 .....	Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).
117.430 .....	Conducting supplier verification activities for raw materials and other ingredients.
117.435 .....	Onsite audit.
117.475 .....	Records documenting the supply-chain program.

TABLE 45—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
Throughout .....	Throughout .....	The type of preventive control applicable to the supply-chain program.	Refer to “supply-chain-applied control” rather than “preventive control” or variations such as “hazard requiring a preventive control when the hazard is controlled before receipt of the raw material or other ingredient.”
117.136(a)(2) ..... (in subpart C) .....	117.136(a)(1)(ii) .....	A supply-chain program is not required when the hazard will be controlled by the receiving facility’s customer in the distribution chain.	Shifted to be in provisions outside the framework of the supply-chain program in subpart G.
117.405(a)(2) .....	N/A .....	Circumstances that do not require a supply-chain program.	The receiving facility does not need a supply-chain program when the receiving facility is an importer, is in compliance with the forthcoming FSVP requirements, and has documentation of verification activities conducted under the forthcoming FSVP program.
117.405(a)(3) .....	N/A .....	Exemption from the requirements for a supply-chain program.	Exemption for food supplied for research or evaluation.
117.405(c) .....	N/A .....	Requirements applicable to non-suppliers.	When a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce that will be subject to the forthcoming produce safety rule), because growing, harvesting, and packing activities are under different management), the receiving facility must (1) verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity, review and assess the entity’s applicable documentation, and document that review and assessment.
117.410(c) .....	117.136(a)(3)(ii) .....	Purpose of the supply-chain program.	Specify only that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.
117.410(d) .....	117.136(b) .....	Factors that must be considered in determining appropriate supplier verification activities.	<ul style="list-style-type: none"> <li>• Clarification that these factors must be considered in approving suppliers, as well as in determining appropriate supplier verification activities.</li> <li>• Flexibility in the factors that must be considered if a supplier is a qualified facility, a produce farm that will not be subject to the forthcoming produce safety rule on the basis of size and/or direct farm marketing, or a shell egg producer that is not subject to the requirements of 21 CFR part 118 (production, storage, and transportation of shell eggs) because it has less than 3,000 laying hens.</li> </ul>
117.415(a) .....	N/A .....	Responsibilities of the receiving facility.	Provide flexibility for an entity other than the receiving facility to determine, conduct, and document supplier verification activities, provided that the receiving facility reviews and assesses applicable documentation from that entity and documents the receiving facility’s review and assessment.
117.415(b) .....	N/A .....	Responsibilities of the receiving facility.	Specify documentation that a receiving facility may not accept from a supplier to satisfy the receiving facility’s responsibilities for its supply-chain program.
117.420(a) .....	117.136(a)(3)(i) .....	Approval of suppliers .....	Explicit requirement for a receiving facility to approve its suppliers.
117.420(b) .....	117.136(a)(3)(i) .....	Approval of suppliers .....	Explicit requirement for a receiving facility to establish and follow written procedures for receiving raw materials and other ingredients.
117.430(e) .....	N/A .....	Alternative supplier verification activity.	Provide for an alternative supplier verification activity when the supplier is a shell egg producer with less than 3,000 laying hens.
117.430(f) .....	N/A .....	Independence of the supplier .....	Specify that there must not be any financial conflicts of interests that influence the results of the verification activities listed in §117.410(b) and payment must not be related to the results of the activity.
117.435(c)(1) .....	117.136(e) .....	Substitution of an inspection for an audit.	Provide additional flexibility for domestic inspection by representatives of other Federal agencies (such as USDA), or by representatives of State, local, tribal, or territorial agencies.
117.475 .....	117.136(g) .....	Records documenting the supply-chain program.	List additional records associated with the revised provisions.

(Comment 656) Several comments ask us to issue guidance rather than establish requirements for a supplier program in the rule. Some comments assert that the benefits of a supplier verification program do not outweigh

the costs, that we did not consider the effects of such a requirement on farms and small businesses, and that FSMA does not actually contain a requirement for a supplier verification program.

Conversely, other comments support including a mandatory supplier program in the rule for hazards that are controlled in raw materials and other ingredients before receipt by the receiving facility, although many comments assert that a supplier verification program should be viewed as a verification activity rather than a preventive control. Some comments assert that a mandatory domestic supplier program is necessary to provide parity with the requirements of the FSVP rule authorized by FSMA, while other comments assert that FSMA's authorization of foreign supplier verification should not be used to justify a domestic supplier program. Some of these comments single out our request for comment, in the proposed FSVP rule, on whether to allow an entity that would be both an importer (under the FSVP rule) and a receiving facility (under the human preventive controls rule) to be deemed in compliance with the FSVP rule if it was in compliance with the supplier verification provisions of the human preventive controls rule, and agree with such an approach (78 FR 47730 at 45748).

(Response 656) We agree that it is necessary to include a mandatory supply-chain program in the rule to ensure the safety of food where hazards are controlled in raw materials and other ingredients before receipt by a receiving facility, and we are finalizing such a requirement in this rule. The statute specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act). Further, we believe a supply-chain program is a measure that a person knowledgeable about food safety would establish and implement in order to significantly minimize or prevent hazards requiring a preventive control in an incoming raw material or other ingredient.

Supplier verification is sufficiently important for the control of hazards in both domestic and imported foods that FSMA contains provisions for both domestic and foreign supplier verification (sections 418(o)(3) and 805 of the FD&C Act). Because we have aligned the provisions for supplier verification in the FSVP rule with the provisions for a supply-chain program in this rule, we are allowing importers and receiving facilities to take advantage of that fact in considering compliance with both part 117 and our forthcoming

FSVP regulations that we proposed to establish in part 1, subpart L, so that they do not have to duplicate verification activities (see § 117.405(a)(2)).

(Comment 657) Some comments that addressed questions we asked in the 2013 proposed human preventive controls rule and the 2014 supplemental human preventive controls notice recommend that we add flexibility to the requirements for a supplier program such that any entity in the supply chain between the supplier and the receiving facility can perform supplier verification activities. Some comments ask us to allow a receiving facility to have a supplier program established for it by another entity. Other comments assert that it would be too burdensome for a receiving facility to consider any information related to the supplier's supplier or to go further back in the supply chain beyond the entity that is one back from the receiving facility. Other comments assert that we should eliminate any requirements for a supplier program from the rule because a supplier program involving more entities than just the receiving facility and the supplier would become too complex. Some comments express concern that we would be creating "an environment where our supply chain is required to be disclosed to our customers via product testing, audits and supplier verification," asserting that this would discourage customers from buying from entities such as re-packers when they could go to the source. Some comments state that we have not taken into account the low-risk nature of specific industries such as those that re-pack already processed foods. Other comments ask us to confirm that distributors and warehouses are not included in the requirements for a supplier program because they would not likely meet the definition of a receiving facility or a supplier.

(Response 657) We agree with comments recommending additional flexibility in the supply-chain program with regard to who can perform certain activities and have added this flexibility to the final rule (see § 117.415). Because the receiving facility and the supplier may be separated by several entities in a supply chain, we are allowing such entities (e.g., distributors, brokers, aggregators) to determine, conduct, and document supplier verification activities as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. However, because the approval of suppliers is ultimately the

responsibility of the receiving facility, the rule specifies that only a receiving facility can approve suppliers (see §§ 117.415(a)(1) and 117.420(a) and Response 658).

We disagree that complex supply chains make a supply-chain program too difficult and that a receiving facility cannot be expected to reach further back in a supply chain than the entity immediately before it in the supply chain. Supply-chain programs are currently used by facilities as a standard business practice and we understand that some of those supply chains are complex, with entities between the receiving facility and the supplier. We acknowledge that complex supply chains present a challenge because information will need to flow through several entities to allow the link between the receiving facility and the supplier. However, we believe a supply-chain program is a critical preventive control for receiving facilities that will rely on suppliers to control hazards in raw materials and other ingredients. Although distributors, brokers, and other entities in the supply chain between a receiving facility and its supplier are not required to have a role in supplier verification, they have the option to determine, conduct, and document supplier verification activities as a service to the receiving facility if they so choose. If these entities choose not to participate in supplier verification, the receiving facility will need to reach back in the supply chain past them. In such situations, it may be necessary for the entities between the receiving facility and the supplier to provide the identity of the supplier to the receiving facility, if that identity is not available on the raw material or other ingredient or otherwise apparent. In such cases, the role that distributors, brokers, aggregators, and similar entities would play in supplier verification would be minimal. We cannot determine whether having to provide the identity of the supplier to the receiving facility would change buying practices. However, we believe that manufacturers consider a number of factors in determining who they will purchase from, including the services provided, and that there will continue to be a role for aggregators, re-packers, brokers, and others. We have provided flexibility for these entities to play a role in supplier verification if the receiving facility and the business entity determine there is a benefit to do so.

See also the discussion in section XLV regarding the specific provisions of § 117.415. Although comments focus on flexibility for an entity in the supply chain between the supplier and the

receiving facility to perform supplier verification activities, and such entities are the most likely entities to be the entities determining, conducting, and documenting supplier verification activities, the flexibility provided by the rule is not limited to such entities.

(Comment 658) Some comments ask us to establish a general requirement for a supplier program without specifying roles and responsibilities for the various entities involved. Other comments ask us to define “supplier” as the entity with which the receiving facility has a commercial relationship.

(Response 658) We disagree that we should establish a general requirement for a supply-chain program without specifying roles and responsibilities for the various entities involved. Although we have added flexibility to provide that an entity other than the receiving facility may determine, conduct, and document supplier verification activities (see § 117.415), we continue to believe it is important to clearly define two roles in the supply chain that share the primary responsibility in the supplier verification process—*i.e.*, the receiving facility and the supplier. In all cases where we have added flexibility for participation by an entity other than the receiving facility, the responsibility for the supply-chain program is clearly lodged with the receiving facility, and linked to the supplier (see § 117.415). To emphasize the responsibility of the receiving facility and its link to the supplier, the final rule clearly states that the receiving facility must approve its suppliers before receiving raw materials and other ingredients (see § 117.420(a)).

For the supply-chain program to be meaningful and robust, there must be an exchange of information between these two entities—the entity receiving the food and the entity that controlled the hazard—even when an entity other than the receiving facility participates by determining, conducting, and documenting some supplier verification activities. The ultimate responsibility for supplier verification rests with the receiving facility through its determination in approving suppliers and in reviewing and assessing applicable documentation provided by another entity. Therefore, we also disagree that the definition of “supplier” should be revised to be the next entity back in a supply chain (*e.g.*, the entity with which a receiving facility has a commercial relationship). The entity with which a receiving facility has a commercial relationship might be a distributor, broker, or aggregator. A distributor, broker, or aggregator does not control an identified hazard and, therefore, cannot assume

the same role as an establishment that manufactures/processes the food, raises the animal, or grows the food.

(Comment 659) Some comments ask us to provide flexibility in the content of the supplier program. Some comments assert that specifying the content of the supplier program would result in duplicative requirements on suppliers, who must first comply with certain regulations and then demonstrate that compliance in order to comply with a different regulation.

(Response 659) We disagree that a requirement for a supply-chain program in which compliance with an underlying regulation is demonstrated is duplicative with the need to comply with the underlying regulation. The requirement for a supply-chain program is not mandating that the facility or farm comply twice with the human preventive controls rule or the produce safety rule; it is merely requiring that the compliance by the facility or the farm with the applicable regulation be verified to ensure that hazards requiring a preventive control are being controlled.

We are continuing to specify the basic content of a supply-chain program—*i.e.*, using approved suppliers; determining appropriate supplier verification activities; conducting supplier verification activities; and establishing records documenting these activities (see § 117.410(a)). However, the rule provides flexibility in the choice of supplier verification activities and how often such activities must be performed. (See §§ 117.410(b)(4) and 117.430(b)(2), (c), (d), and (e)). In addition, the rule provides for an alternative supplier verification activity for certain entities (see § 117.430(c), (d), and (e)) regarding alternative supplier verification activities for qualified facilities, certain produce farms, and certain shell egg producers, respectively).

(Comment 660) As already noted in this section, in the 2014 supplemental human preventive controls notice we asked for comment on whether verification activities should be required in circumstances in which a RAC such as fresh produce will not be sent to any facilities that would be required to have preventive controls before reaching consumers. In response, we received comments both in support of, and in opposition to, a requirement that verification activities be conducted in circumstances in which produce would go directly from an establishment that would not be required to have supplier controls (*e.g.*, farm, warehouse, distributor) to another establishment not required to have supplier controls (*e.g.*, retail food establishment) or to a

consumer. Some comments assert that any firm that sells directly to retail food establishments or consumers should have a supplier program in place, while other comments assert that this is not necessary, particularly in the case of RACs.

Some comments maintain that the produce safety rule will provide adequate assurances of safety for covered produce and that covering such products with the supplier verification requirements of the human food preventive controls rule would be subjecting this produce to duplicative requirements. These comments recommend that, if some verification is required in these “gaps” on which we asked for comment, entities in these categories be allowed to voluntarily apply certain supplier verification best practices rather than be subject to the supplier program requirements of this rule.

(Response 660) As previously discussed (79 FR 58524 at 58548), fresh produce often goes directly from the farm to a distributor and then on to retail food establishments and/or consumers. We are not requiring any of the entities in this supply chain to do supplier verification under part 117, so the farm’s compliance with the produce safety rule, if applicable, will not be verified unless done voluntarily. In contrast, we are requiring that a manufacturer/processor that uses covered produce to make a processed product such as fresh-cut produce establish and implement a supply-chain program. As we have previously discussed, processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination (Ref. 89). This has the potential to increase the exposure to pathogens, because contamination of a few pieces of raw produce can be spread to many servings of processed fresh-cut produce. Disturbing the physical barriers of produce (*e.g.*, by cutting the produce) and inadequate temperature control of fresh-cut produce can enhance bacterial growth (including growth of pathogens, if present). The increased risk presented by processing of fresh produce makes it appropriate to subject this processed food to the full requirements of the human preventive controls rule in addition to the requirements of the forthcoming produce safety rule for the RACs that are used to make this processed food.

#### **XLIII. Subpart G: Comments on Requirement To Establish and Implement a Supply-Chain Program**

We proposed that the receiving facility must establish and implement a

risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient (proposed

§ 117.136(a)). We also proposed circumstances when a receiving facility would not be required to have a supplier program. In the following sections, we discuss comments that ask us to clarify the proposed requirement to establish and

implement a written supplier program or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the regulatory text as shown in table 46.

TABLE 46—REVISIONS TO THE PROPOSED REQUIREMENTS TO ESTABLISH AND IMPLEMENT A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
N/A	117.136(a)(2)(i)	A supplier program is not required when there are no hazards requiring a preventive control.	Deleted as unnecessary.
N/A	117.136(a)(2)(i)	A supplier program is not required when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards requiring a preventive control.	Deleted as unnecessary.
117.136(a)(2)	117.136(a)(2)(iii)	A supplier program is not required when the hazard will be controlled by the receiving facility's customer in the distribution chain.	Shifted to be in provisions outside the framework of the supply-chain program in subpart G.
117.405(a)(2)	N/A	Circumstances that do not require a supply-chain program even though the receiving facility's hazard analysis determines that a hazard requires a supply-chain-applied control.	A receiving facility is an importer, is in compliance with the forthcoming FSVP requirements, and has documentation of verification activities conducted under the forthcoming FSVP program.
117.405(a)(3)	N/A	Exemption from the requirements for a supply-chain program.	Exemption for food supplied for research or evaluation.
117.405(c)	N/A	Requirements applicable to non-suppliers	When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce that will be subject to the forthcoming produce safety rule), because growing, harvesting, and packing activities are under different management), the receiving facility must (1) verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

*A. Requirement for a Written Supply-Chain Program (Final § 117.405(a)(1) and (b))*

We proposed that the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. We also proposed that the supplier program must be written. (See proposed § 117.136(a)(1)(i) and (2).) To improve clarity, we have revised the revision to substitute the phrase “hazard requiring a supply-chain-applied control” for the phrase “significant hazard when the hazard is controlled before receipt of the raw material or ingredient.” We have added a definition for the term “supply-chain-applied control” to mean a preventive control for a hazard in a raw material or other ingredient when the

hazard in the raw material or other ingredient is controlled before its receipt (see § 117.3) and use the more specific term “supply-chain-applied control,” rather than the broader term “preventive control,” throughout the provisions for a supply-chain program.

(Comment 661) As discussed in Comment 656, several comments ask us to issue guidance rather than establish requirements for a supplier program in the rule.

(Response 661) See Response 656 for a discussion of our reasons for declining this request and establishing requirements for a supply-chain program in the rule.

(Comment 662) Some comments ask us to revise the regulatory text to remove the condition that all hazards be foreseeable so that the supplier program can address economically motivated adulteration.

(Response 662) This comment is unclear. The requirement for a supply-

chain program applies when the outcome of a hazard analysis is that a known or reasonably foreseeable hazard requires a preventive control, and the hazard would be controlled by the receiving facility's supplier. The requirement applies regardless of whether the hazard requiring a preventive control is, or is not, a hazard that would be introduced into a food for the purposes of economic gain.

(Comment 663) Some comments ask us to specify that a Certificate of Analysis or other documentation of the existence and/or level of a hazard could be provided to the receiving facility to indicate the potential for an actual existence of a hazard so that the receiving facility could evaluate whether the hazard requires a preventive control. One comment explains that chemical contaminants such as lead are not controlled through easily described “procedures” but are instead controlled through factors such

as product formulation (e.g., controlling the levels of contaminants in each ingredient depending on the proportion of the ingredient in the finished food) and serving size. These comments explain that chemical contaminants such as lead may require control in one context (e.g., if children are the target consumers) but not in another context (e.g., if adults are the target consumers and the product is unlikely to be consumed by children). This comment expresses concern about whether customers would be willing to provide the receiving facility with confidential information about the customer's own hazard analysis with respect to sensitive topics (e.g., how much lead it has decided to allow in its finished products, or how its product formulation controls the level of lead in its finished food). Furthermore, in such cases the receiving facility will not even know whether the chemical contaminant constitutes an actual "hazard" for the purposes of the customer's finished food. This comment also asserts that a Certificate of Analysis provided to a receiving facility constitutes "control before receipt of the raw material or ingredient."

(Response 663) We do not understand the concern of this comment. A receiving facility and a supplier do not need to share all of the details of product formulation for a receiving facility to communicate its requirements to a supplier. In the example provided by the comment, the receiving facility could provide the supplier with a written specification for a contaminant such as lead, and the supplier could demonstrate that it satisfied the receiving facility's specification by providing a Certificate of Analysis showing the results of laboratory testing for lead. Neither the written specification provided by the receiving facility, nor the Certificate of Analysis provided by the supplier, would disclose confidential information about the formulations or procedures of either entity.

This comment also appears to misunderstand the applicability of the supply-chain program. The rule requires a supply-chain program when the receiving facility has identified, through its hazard analysis, that there is a hazard requiring a supply-chain-applied control. In the circumstances described by the comment, a Certificate of Analysis or other documentation of test results from the supplier to the receiving facility could demonstrate that the supplier has controlled the hazard to the receiving facility's specifications, but would not overturn the outcome of the receiving facility's hazard analysis

that there is a hazard requiring a preventive control, and that the appropriate control is applied by the supplier. On the contrary, the Certificate of Analysis simply demonstrates that the supply-chain-applied control functioned as intended.

(Comment 664) One comment asks us to specify in the regulatory text that the supplier program must be written "if required" because there are specified circumstances when a supplier program is not required.

(Response 664) We decline this request. Although the rule provides circumstances when a supply-chain program is not required (see § 117.405(a)(2)), it is not necessary to specify, for all other provisions of the supply-chain program, that the provision only applies "if required."

*B. Circumstances That Do Not Require a Written Supply-Chain Program (Final § 117.405(a)(2))*

We proposed that the receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which there are no significant hazards; the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. (See proposed § 117.136(a)(1)(ii)(A), (B), and (C).)

We are deleting the proposed provision that a supplier program is not required for raw materials and ingredients for which there are no "significant hazards" (which we now refer to as "hazards requiring a preventive control") because it is unnecessary. The supply-chain program is required when a hazard identified in the receiving facility's hazard analysis identifies a hazard requiring a supply-chain-applied control; it is not necessary to also state the converse. Likewise, we are deleting the proposed provision that a supplier program is not required if the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards. In such a case, the outcome of the hazard analysis would not be that the hazard requires a supply-chain-applied control.

As discussed in section XXVII, after considering comments, we are shifting the provision in which the receiving facility relies on its customer to control

the hazard from the requirements for a supply-chain program to a series of provisions that apply when a manufacturer/processor identifies a hazard requiring a preventive control, but can demonstrate and document that the hazard will be controlled by an entity in its distribution chain (see §§ 117.136 and 117.137). However, as discussed in Response 665 and section XLIII.C, we also are establishing two additional circumstances when a supply-chain program is not required (see § 117.405(a)(2) and (3)).

(Comment 665) As noted in Comment 656, some comments single out our request for comment, in the proposed FSVP rule, on whether to allow an entity that would be both an importer (under the FSVP rule) and a receiving facility (under the human preventive controls rule) to be deemed in compliance with the FSVP rule if it was in compliance with the supplier verification provisions of the human preventive controls rule, and agree with such an approach (78 FR 47730 at 45748).

(Response 665) As noted in Response 656, we have aligned the provisions for supplier verification in the FSVP rule with the provisions for a supply-chain program in this rule, and we are allowing importers that are receiving facilities to take advantage of that fact in considering compliance with our forthcoming FSVP regulations that we proposed to establish in part 1, subpart L, so that they do not have to duplicate verification activities (see § 117.405(a)(2)).

(Comment 666) Some comments support the specified criteria for when a receiving facility would not be required to establish and implement a supplier program. Other comments express concern that these criteria suggest no supplier verification is needed at all in some circumstances despite supplier verification activities being potentially informative about a particular supplier. These comments ask us to establish some general requirement to perform verification activities for all suppliers.

(Response 666) We decline this request because it is neither risk-based nor consistent with the nature and purpose of the supply-chain program, which is to provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented (see the regulatory text of § 117.410(c)). We agree that some degree of verification of all suppliers may prove useful to a receiving facility for various purposes, and the rule would not prevent a receiving facility from establishing a

supply-chain program for all of its suppliers regardless of risk and regardless of whether the applicable hazard in a raw material or other ingredient is controlled before its receipt.

(Comment 667) Some comments ask us to specify that a “kill step” would be an adequate indicator to significantly minimize or prevent significant hazards identified by the receiving facility when the receiving facility controls the hazard.

(Response 667) These comments appear to misunderstand the applicability of the supply-chain program. The rule requires a supply-chain program when the receiving facility has identified, through its hazard analysis, that there is a hazard requiring a preventive control and the receiving facility’s manufacturing/processing will not control the hazard. In the circumstances described by the comment, the receiving facility is controlling the hazard and a supply-chain program for the raw material or other ingredient is not required. It is not necessary to specify the types of controls that the receiving facility may use to control the hazard.

(Comment 668) Some comments ask us to specify that a receiving facility need not establish and implement a supplier program for raw materials and ingredients if those raw materials or ingredients were received from an affiliated party within the same corporate or controlling entity.

(Response 668) We decline this request. With the revisions we have made to the proposed requirements for a supplier program, the supply-chain program that we are establishing in this rule provides ample opportunities for an affiliated party within the same corporate or controlling entity to establish and implement a supply-chain program that is suited to its relationship to these entities. For example, as discussed in Response 687, a receiving facility might be able to determine and document a justification for a supplier verification activity other than an annual audit when a supplier is an affiliated party based on the receiving facility’s knowledge of the corporate policies regarding food safety practices (see § 117.430(b)(2)). In addition, as discussed in Response 690, we have agreed that the corporate parent of a facility can be active in developing and implementing the facility’s food safety plan (see section XXIV.A). If, for example, a corporate headquarters establishes and implements a supply-chain program for use company-wide, a receiving facility could rely on supplier verification activities conducted by its

corporate headquarters, with applicable documentation available during inspection.

*C. Exemption for Food Supplied for Research or Evaluation (Final § 117.405(a)(3))*

We are establishing an exemption from the requirement for a receiving facility to establish and implement a supply-chain program when it receives food for the purposes of research or evaluation, provided that certain conditions are met (see § 117.405(a)(3)). Those conditions are that the food: (1) Is not intended for retail sale and is not sold or distributed to the public; (2) is labeled with the statement “Food for research or evaluation use”; (3) is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and (4) is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public. The exemption is analogous to an exemption we proposed for the FSVF rule under section 805(f) of the FD&C Act. (See proposed § 1.501(c), 78 FR 45730 at 45745). We believe it is not necessary to conduct supplier verification activities when food is obtained in this limited circumstance.

*D. Additional Requirements for Non-Suppliers (Final § 117.405(c))*

As discussed in section IV.B, the final rule includes several revisions to the “farm” definition in response to comments. For example, as discussed in Comment 23 comments emphasize that farming operations can have complex business structures, and ask us to revise the “farm” definition to provide for these business models. In response to these comments, we have added a new definition for a “secondary activities farm,” which provides for practices such as packing by cooperatives and packinghouses under the ownership of multiple growers to remain within the “farm” definition (See Response 25). Another change to the “farm” definition accommodates business models in which one operation grows crops but does not harvest them, and another operation, not under the same management, harvests crops but does not grow them (see Response 32). As discussed in Response 32, this revision is a change from the “farm” definition established in the section 415 registration regulations in 2003, and the proposed revisions to the “farm” definition in the 2013 proposed human

preventive controls rule and the 2014 supplemental human preventive controls notice, which all describe a “farm” as an entity “devoted to the growing and harvesting of crops” (emphasis added).

We proposed the requirements for a supplier program in the context of a single business entity “devoted to the growing and harvesting of crops” (emphasis added), in which packing operations were often done by that same business entity. The final “farm” definition accommodates business models where growing, harvesting, and packing operations will be done by different business entities. Harvesting and packing operations include some supply-chain-applied controls, such as controls on worker hygiene, quality of water used during harvesting and packing operations, and establishing and following water-change schedules for recirculated water, even though the harvesting and packing operations do not fall within the definition of “supplier.”

A receiving facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (see section 418(c) of the FD&C Act and § 117.135(a)). That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier. An example of such a situation is when produce that will be covered by the forthcoming produce safety rule is grown, harvested, and packed under different management. To clarify the receiving facility’s responsibilities when a supply-chain-applied control is applied by a non-supplier, we are establishing a requirement specifying that when a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce that will be subject to the forthcoming produce safety rule), because growing, harvesting, and packing activities are under different management), the receiving facility must: (1) Verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity, review and assess the entity’s applicable documentation, and document that review and assessment. See

§ 117.405(c). Because § 117.405(c) refers to provisions in a future produce safety rule, we will publish a document in the **Federal Register** announcing the effective date of that provision once we finalize the produce safety rule.

We do not expect the receiving facility to follow all of the requirements of subpart G applicable to “suppliers” when verifying control by a “non-supplier,” as required by § 117.405(c). Instead, we expect the receiving facility will take steps such as a review of the non-supplier’s applicable food safety records. For example, if a receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer, the grower is the supplier and the requirements of subpart G applicable to “suppliers” apply to the grower. To verify controls applied by the harvester, the receiving facility could review the harvester’s records, such as records of training for harvest workers and records of agricultural water quality used in harvest operations. To verify controls applied by the packer, the receiving facility could review the packer’s records, such as records of agricultural water quality used in packing operations. As discussed in Response 657, we are allowing entities such as distributors, brokers, and aggregators to determine, conduct, and document verification activities that apply to

suppliers as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. Likewise, under § 117.405(c)(2) a receiving facility could obtain documentation of review of applicable records maintained by the harvester or packer from another entity, review and assess the entity’s applicable documentation, and document that review and assessment.

*E. Proposed General Requirements for the Supply-Chain Program That We Are Not Including in the Final Rule (Proposed § 117.136(a)(4) and (5))*

We proposed that when supplier verification activities are required for more than one type of hazard in a food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards. We also proposed that for some hazards, in some situations it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented. We have concluded that these provisions are largely self-evident and need not be included in the regulatory text. Therefore, we are not finalizing these proposed provisions.

We will consider whether it will add value to discuss the principles in these proposed provisions in guidance that we intend to develop for the supply-chain program.

**XLIV. Subpart G: Comments on General Requirements Applicable to a Supply-Chain Program**

We proposed several requirements generally applicable to the supplier program (such as factors to consider in determining appropriate supplier verification activities (proposed § 117.136(b)), as well as several requirements more narrowly targeted to specific aspects of the supplier program (such as requirements applicable to onsite audits). As part of the redesignation of proposed § 117.136 into subpart G, with eight distinct sections, we are establishing the more general requirements in § 117.410 (see table 47).

Most comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 671, Comment 672, Comment 675, Comment 676, and Comment 678). In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the regulatory text as shown in table 47.

TABLE 47—REVISIONS TO THE PROPOSED GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
117.410(a) .....	117.136(a)(3) .....	What the supply-chain program must include.	Add that the supply-chain program includes, when applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility’s supplier and documenting that verification, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment.
117.410(b) .....	117.136(c)(1) .....	Appropriate supplier verification activities.	N/A.
117.410(c) .....	117.136(a)(3)(ii) .....	Purpose of supplier verification activities for raw materials and other ingredients.	Specify only that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.
117.410(d) .....	117.136(b) .....	Factors that must be considered when approving suppliers and determining appropriate supplier verification activities for raw materials and other ingredients.	Clarify that the factors apply in approving suppliers, as well as in determining appropriate supplier verification activities.
117.410(d) .....	117.136(b) .....	Factors that must be considered when approving suppliers and determining appropriate supplier verification activities for raw materials and other ingredients; Supplier performance.	<ul style="list-style-type: none"> <li>Specify that three of the factors relate to “supplier performance.”</li> <li>Specify “The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control” rather than “Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier’s supplier.”</li> <li>Add “other FDA compliance actions related to food safety” as an example of information relevant to the supplier’s compliance with applicable FDA food safety regulations</li> </ul>



TABLE 47—REVISIONS TO THE PROPOSED GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Revision
117.410(e) .....	117.136(f) .....	Supplier non-conformance .....	<ul style="list-style-type: none"> <li>• Clarify that consideration of supplier performance includes, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States and information relevant to the supplier's compliance with those laws and regulations</li> <li>• Provide flexibility in the factors that must be considered if a supplier is a qualified facility, a produce farm that will not be subject to the forthcoming produce safety rule on the basis of size and/or direct farm marketing, or a shell egg producer that is not subject to the requirements of 21 CFR part 118 (production, storage, and transportation of shell eggs) because it has less than 3,000 laying hens</li> </ul> N/A.

*A. Description of What the Supply-Chain Program Must Include (Final § 117.410(a))*

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers) (proposed § 117.136(a)(3)(i)). We also proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities. We also proposed requirements applicable to the determination and documentation of appropriate supplier verification activities (proposed § 117.136(b)). We also proposed specific documentation requirements for records associated with the supplier program (proposed § 117.136(g)).

The final rule specifies that the supply-chain program must include: (1) Using approved suppliers; (2) determining appropriate supplier verification activities (including determining the frequency of conducting the activity); (3) conducting supplier verification activities; and (4) documenting supplier verification activities. For clarity, § 117.410(a) states this general requirement for the supply-chain program and §§ 117.420, 117.425, 117.430, 117.435, and 117.475 provide the specific requirements for using approved suppliers, determining appropriate supplier verification activities, conducting verification activities, specific requirements for onsite audits, and records, respectively. See the discussion of the specific requirements of §§ 117.420, 117.425,

117.430, 117.435, and 117.475 in sections XLVI, XLVII, XLVIII, and XLIX, respectively.

As discussed in section XLIII.D, the final rule establishes a verification requirement when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (see § 117.405(c)). For clarity, § 117.410(a) states this general requirement for the supply-chain program in § 117.405(a)(5), and § 117.405(c) provides the specific requirements that apply when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

*B. Appropriate Supplier Verification Activities (Final § 117.410(b))*

We proposed to require that appropriate supplier verification activities include: (1) Onsite audits; (2) sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; or (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier (proposed § 117.136(c)(1)).

(Comment 669) Some comments support the inclusion of onsite audits as an appropriate supplier verification activity. However, other comments oppose it, and ask us to remove the onsite audit requirement from the supplier verification program, stating that Congress prohibited FDA from requiring third parties to verify or audit compliance with the rules. These comments express concern that the supplier verification program effectively imposes an "entire second layer of regulation" on produce farms that are supplying ingredients to processors, and

claim this is an unnecessary burden that is not authorized by FSMA.

(Response 669) We are retaining onsite audits as an appropriate supplier verification activity. As noted in our memorandum on supplier programs, onsite audits are commonly used by industry in the verification of supplier performance (Ref. 83). Onsite audits provide the opportunity to review the food safety plan and written procedures and to observe the implementation of food safety procedures, as well as to review the records related to the past application of control measures, including laboratory test results. Audits also provide the opportunity to interview employees to assess their understanding of the food safety measures for which they are responsible. Thus, an audit can provide for a more comprehensive assessment of food safety implementation by a facility, and often is used in approving food suppliers. Comments that oppose including onsite audits as a verification activity are concerned that farms will be required to have audits to verify that they are in compliance with produce safety standards or facilities will be required to have audits to verify preventive controls. These comments apparently refer to the provision in section 419(c)(1)(E) of the FD&C Act that the regulation issuing standards for the safety of produce "not require a business to hire a consultant or other third party to identify, implement, certify compliance with these procedures, processes and practices," or the provision in section 418(n)(3)(D) of the FD&C Act that the preventive controls regulation "not require a facility to hire a consultant or other third party to identify, implement, certify or audit [preventive] controls." The regulations proposed under section 419 of the FD&C Act do not impose such

requirements. The requirements for supplier verification in this rule (under section 418 of the FD&C Act) provide for audits as one supplier verification activity. Although the rule does specify an annual onsite audit as the appropriate supplier verification activity when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the receiving facility is not required to hire a third party to conduct the audit. Any qualified auditor, other than the supplier, may conduct the audit, including an employee of the receiving facility or another entity, such as an entity in the supply chain between the supplier and the receiving facility. The rule also provides that a receiving facility may determine and document that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (see § 117.430(b)(1) and (2)). Audits already conducted on a supplier's facility or operation for other business purposes may meet the requirement for supplier verification. In addition, the rule provides alternative requirements for verification of suppliers that are farms that are not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5 (see § 117.430(d)). Finally, we have also provided that inspections may substitute for an audit under specified circumstances (see § 117.435(c)).

While we realize that some farms may receive audits under the supplier verification provisions of part 117, we note that farms that might receive an audit because they are suppliers to a receiving facility produce a limited subset of the total produce production that comes from farms. These are products such as leafy greens for fresh-cut processing operations and fruits and vegetables that are going into ready-to-eat products like deli salads. These are products for which there is a history of outbreaks and, therefore, good reason to do appropriate supplier verification activities.

(Comment 670) Some comments support the inclusion of sampling and testing of the raw material or other ingredient as an appropriate supplier verification activity, and note that verification testing is more effective when conducted by the supplier than the receiving facility because the supplier can control the lot of product tested. However, other comments oppose it, stating that sampling and

testing is not useful for products with short shelf life, such as fresh produce.

(Response 670) We are retaining sampling and testing as an appropriate supplier verification activity. As noted in our memorandum on supplier programs, sampling and testing are commonly used by industry in the verification of supplier performance (Ref. 83). We have previously discussed factors that impact the utility and frequency of raw material/ingredient testing (see the Appendix published in the 2013 proposed human preventive controls rule (78 FR 3646 at 3818–3820); republished in its entirety with corrected reference numbers on March 20, 2013, 78 FR 17142 at 17149–17151). We agree that there are benefits in having sampling and testing conducted by the supplier, because the supplier can then take appropriate action with respect to the findings, including not shipping contaminated product. However, because contamination with microbial pathogens is likely to be non-homogeneous and the numbers of pathogens are likely to be low, a negative does not guarantee the absence of contamination. This should be taken into account when deciding which verification activity (or activities) is appropriate. Because of the limitations of sampling and testing, the controls the supplier has in place to minimize contamination, and the management of those controls, are key in determining when sampling and testing is appropriate as a verification activity. For short shelf life products, where holding product pending test results can negatively impact product shelf life, an onsite audit to verify control of hazards may be more appropriate than sampling and testing.

(Comment 671) Some comments ask us to specify in the regulatory text that sampling and testing can be conducted by or on behalf of the supplier or the receiving facility.

(Response 671) The provisions of § 117.415 specify the responsibilities of the receiving facility, and allow a receiving facility to conduct all supplier verification activities, including sampling and testing. These provisions also provide that a supplier, or an entity other than the receiving facility (such as an entity in the supply chain between the supplier and the receiving facility), can conduct sampling and testing, provided that the receiving facility reviews and assesses the documentation provided by the supplier. The rule places no restrictions on when a receiving facility, a supplier, or an entity other than the receiving facility could have a business relationship with a third party (such as a contract

laboratory) to conduct sampling and testing.

(Comment 672) Some comments suggest that, for a facility regularly undergoing audits, reviewing a “supplier’s relevant food safety records” should allow for the receiving facility to review documentation related to pre-existing audits. These comments ask us to revise the provision to add “including, but not limited to, records related to audits previously performed on the supplier’s facility.”

(Response 672) We decline this request. The comment misinterprets what we mean by a “supplier’s relevant food safety records.” The rule provides for onsite audits as a verification activity, as well as reviewing a “supplier’s relevant food safety records.” When an annual audit is determined to be an appropriate verification activity (see § 117.430(b)(1)), the audit would be reviewed by the receiving facility, but a review of this audit is not what we meant by a “supplier’s relevant food safety records.” As described in our memorandum on supplier programs, food safety records are records documenting that the food safety procedures that have been established to control hazards are being followed and are adequately controlling such hazards (Ref. 83). Thus, a receiving facility may obtain documentation of a supplier’s control measures for a particular lot of a raw material or ingredient provided to the receiving facility, such as the records created when a process control measure was applied. The food safety records may also include supplier records that show that the supplier’s supplier has controlled a hazard. Such records may include audits, for example, when the supplier’s supplier controls the hazard and the supplier’s records include records of an audit conducted with respect to the hazard control activities of the supplier’s supplier. To emphasize that the review of a supplier’s relevant food safety records can include records other than records of audits, we have revised the documentation requirements applicable to review of a supplier’s food safety records to specify that the documentation must include the general nature of the records reviewed (see § 117.475(c)(9)). By “general nature of the records reviewed,” we mean information such as “records of process controls.”

(Comment 673) Some comments support the inclusion of other appropriate supplier verification activities based on the risks associated with the ingredient and the supplier, because it provides flexibility for

facilities to design risk-based programs that are appropriate for their operations. Comments suggest other verification activities may include receiving raw materials and other ingredients from a supplier without a full audit report if the supplier maintains certification to a standard recognized by GFSI; providing for documentary verification (such as fact-specific questionnaires and representations exchanged between the supplier and the receiving facility); and confirming that a facility, especially a small manufacturing facility, is licensed by the appropriate State or local regulatory authority.

(Response 673) We are retaining this provision to allow other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient. We have revised the regulatory text to refer to “supplier performance and the risk associated with the raw material or other ingredient” because “supplier performance” is more appropriate than “risk associated with the supplier.” We use the term “risk” as defined by the Codex Alimentarius Commission to be “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food” (Ref. 90). As discussed in section XLIV.D, the considerations for supplier performance, which can be related to the probability of a hazard in the raw material or ingredient and the severity of adverse health effects that can result, are broader than this.

We agree that a supplier’s certification to a GFSI scheme that considers FDA food safety regulations can be a consideration in the determination of the type and frequency of the verification activity conducted. Similarly, fact-specific questionnaires and representations exchanged between the supplier and the receiving facility can be a consideration in the determination of the type and frequency of the verification activity conducted. Confirming that a facility is licensed by the appropriate State or local regulatory authority should not serve as the only verification that a supplier is controlling the hazard, because the requirements for a license and the degree of inspectional oversight could vary greatly. We do provide for modified supplier verification activities for qualified facilities, which are very small businesses (§ 117.430(c)).

#### *C. Purpose of Supplier Verification Activities for Raw Materials and Other Ingredients (Final § 117.410(c))*

We proposed to require that a supplier program include verification

activities, as appropriate to the hazard, and documentation of these activities, to verify that: (1) The hazard is significantly minimized or prevented; (2) the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and (3) the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 117.136(a)(3)(ii)). We have revised the provision to specify that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. If the supply-chain program provides assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented, it is not necessary to also specify that the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. We also have deleted the requirement that the verification activities must verify that the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations and instead focused that requirement as a factor that must be considered in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted rather than as one of the stated purposes of the supply-chain program. See the regulatory text of § 117.410(d)(i)(iii)(B).

(Comment 674) Some comments ask us to revise this provision to state that the receiving facility’s use of the incoming raw material or ingredient will not cause the finished food to be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. These comments assert that FSMA does not mandate, nor is it reasonable to expect, that incoming raw materials and ingredients will not be adulterated under section 402, and that it is acceptable for a receiving facility to control the “adulterating hazard,” even if it relies on the supplier to control other hazards.

(Response 674) We decline this request. We acknowledge that in some circumstances a receiving facility may rely on the supplier to control certain hazards, while controlling other hazards itself. For example, a receiving facility that produces peanut-derived products could rely on its supplier for the control of the chemical hazard aflatoxin, but control the biological hazard *Salmonella* through its own roasting process.

However, the supply-chain program applies to hazards requiring a supply-chain-applied control, and the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. In the example where the receiving facility is relying on the supplier to control aflatoxin, the provision would require the receiving facility to verify that the hazard (aflatoxin) has been significantly minimized or prevented by the supplier.

#### *D. Factors That Must Be Considered When Approving Suppliers and Determining Appropriate Supplier Verification Activities for Raw Materials and Other Ingredients (Final § 117.410(d))*

We proposed that in determining and documenting the appropriate verification activities, the receiving facility must consider the following: (1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients; (2) where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier’s supplier; (3) the supplier’s procedures, processes, and practices related to the safety of the raw material and ingredients; (4) applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food; (5) the supplier’s food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation practices (proposed § 117.136(b)).

As discussed in Response 657, Response 658, and section XLVI.A, we have revised the regulatory text regarding use of approved suppliers to more explicitly state that the receiving facility must approve suppliers. The factors that must be considered in determining the appropriate supplier verification activities are equally relevant to approving suppliers, and the final rule requires that these factors must be considered in approving suppliers, as well as in determining appropriate supplier verification activities. For clarity and consistency with terms used throughout the final

provisions for a supply-chain program, the final rule specifies “the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control” rather than “Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier’s supplier.”

As discussed in Response 673, we are using the term “supplier performance,” rather than “risk of supplier,” when discussing factors associated with suppliers. The final rule groups three of the proposed factors as “supplier performance.” As a companion change to emphasize that “supplier performance” applies to all three of these factors, we refer to the supplier’s “food safety history” rather than “food safety performance history.”

We also have revised the regulatory text to clarify that consideration of supplier performance includes, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States and information relevant to the supplier’s compliance with those laws and regulations. We made this change because the final rule includes several provisions that acknowledge that some food establishments, including food establishments that are “suppliers” as that term is defined in this rule, operate in a foreign country. (See, e.g., the definition of “qualified auditor” in § 117.3 and §§ 117.201(a)(2)(ii), 117.201(e), 117.405(a)(2), 117.430(c), 117.435(c)(1)(ii), 117.435(c)(2), and 117.475(c)(15)). Some of these provisions (e.g., §§ 117.405(a)(2), 117.430(c), 117.435(c)(1)(ii), 117.435(c)(2), and 117.475(c)(15)) are in the requirements for a supply-chain program. When the supplier is in a foreign country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, a receiving facility may substitute the written results of an inspection by the applicable food safety authority for an audit, provided that certain conditions are met (see § 117.435(c)(1)(ii) and (2)).

The final rule provides flexibility for alternative verification requirements for certain entities (see § 117.430(c), (d), and (e)). We have revised the factors that must be considered regarding supplier performance to reflect the flexibility the rule provides for conducting supplier verification activities for these entities (see § 117.410(d)(2)).

(Comment 675) Some comments support the flexibility for receiving facilities to determine the appropriate supplier verification activities and frequency with which to conduct these activities. Some comments state that not all of the factors that we proposed a receiving facility consider are relevant for the process of selecting the verification activity. These comments suggest changing the regulatory text to require a receiving facility to consider “both food and supplier related risks, including the following, as appropriate” and then listing the factors as proposed. Other comments suggested similar changes to the regulatory text.

(Response 675) We disagree that some of the factors that we proposed a receiving facility must consider are not relevant to determining the appropriate verification activity. Every factor might not be determinative in all cases, and our requirement merely to consider each factor does not assume so. However, any one of these factors could be crucial depending on the food, the hazard, and the nature of the preventive control. We continue to consider it appropriate to require receiving facilities to consider each of these factors in making their determinations about the appropriate verification activities.

(Comment 676) Some comments ask us to clarify that the phrase “the nature of the hazard” means the nature of the hazard requiring control.

(Response 676) We have revised the regulatory text to specify “the nature of the hazard controlled before receipt of the raw material or other ingredient.” The revised regulatory text is consistent with regulatory text in the provisions for the preventive control management components (see § 117.140(b), which specifies “taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient”).

(Comment 677) Some comments agree that a receiving facility must consider where the preventive controls for hazards are applied for the raw materials and ingredients, such as at the supplier or the supplier’s supplier. Other comments assert that this consideration should not be used to determine if supplier oversight is needed. Other comments state that it may be hard to review the procedures used by a supplier’s supplier and beyond and ask us to provide clear flexibility regarding requirements for the content and performance of a receiving facility’s supplier program.

(Response 677) The purpose of the requirement to consider where the hazard is controlled is to assist a receiving facility in determining what

supplier verification activities are appropriate, not to determine whether supplier oversight is needed. Once a receiving facility has already determined that a hazard requiring a preventive control is controlled before receipt of a raw material or other ingredient, supplier oversight is needed.

We recognize that there is need for additional flexibility regarding conducting supplier verification activities. As discussed in Response 657, we are providing significant additional flexibility to address this situation in the final rule.

(Comment 678) Some comments object to the proposed requirement to consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food. These comments assert that it is difficult for a receiving facility to know a supplier’s compliance status, because it is not easy to obtain this kind of information in a timely fashion. Some comments ask us to develop an online database to house this information to help make it easier to find. Some comments ask us to replace the broad requirement to consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations with a narrower requirement to only consider any FDA warning letter or import alert relating to the safety of the food.

(Response 678) We are retaining the broad requirement to consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations. Such information is relevant to supplier performance regardless of whether there is an applicable warning letter or import alert. For example, if a receiving facility purchases canned green beans to use in making vegetable soup, it is appropriate for the receiving facility to verify that its supplier is producing the canned green beans in accordance with part 113.

We currently have a searchable online database for warning letters (Ref. 91) and another searchable online database for import alerts (Ref. 92). Both of these databases are available to the public from our homepage at <http://www.fda.gov>. We also publicize actions to suspend a facility’s registration, such as in our 2012 suspension of registration due to *Salmonella* contamination of nut butter and nut products manufactured, processed, packed, and held by the facility (Ref. 93). Under the requirement to consider supplier performance with respect to applicable food safety

regulations, a receiving facility cannot ignore published information relating to a supplier's compliance with applicable FDA food safety regulations in determining the appropriate verification activities, such as publicized information regarding suspension of registration. To emphasize this point, we have revised the regulatory text to specify that the applicable information includes "other FDA compliance actions related to food safety." We also have revised the regulatory text to specify that the compliance relates to an FDA warning letter or import alert relating to the "safety of food," rather than the "safety of the food," to provide flexibility for a receiving facility to identify information that may raise a question about a supplier's compliance history in a more general way, rather than only with respect to a particular food.

(Comment 679) Some comments state we should only require consideration of the supplier's food safety performance history relevant to the hazards requiring control in the raw materials or ingredients that the receiving facility receives from the supplier.

(Response 679) Consideration of the supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier will be focused on the hazard that the supplier is controlling because that is the food safety information the receiving facility will consider to be most relevant and for which the receiving facility would develop a history. The information could indicate that certain verification activities may be more appropriate than others for verifying the control of the hazard at that particular supplier or provide information useful in determining a frequency for the verification activity. However, we decline to revise the provision to specify that consideration should be limited to the hazards requiring control. Even though this is the most relevant information, a facility may become aware of information with respect to a raw material or other ingredient provided to another customer of the supplier that may suggest the need to conduct a different verification activity. For example, if the receiving facility is obtaining a cheese product from a supplier that is controlling pathogens such as *L. monocytogenes* and

*Salmonella*, and becomes aware that cheeses from this supplier have been associated with an undeclared allergen due to improper labeling, the receiving facility would determine that it should implement verification activities related to label control to prevent undeclared allergens.

(Comment 680) Some comments ask us to replace the phrase "examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation" with "such as storage and transportation."

(Response 680) We have made this editorial change.

#### *E. Supplier Non-Conformance (Final § 117.410(e))*

We proposed that if the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 117.136(f)).

(Comment 681) Some comments object to the use of the word "significant" in this proposed provision, recommending that we replace it with "requiring control by the supplier." These comments reason that these activities are only necessary if the receiving facility is relying on the supplier to control the specific hazards.

(Response 681) We have revised the regulatory text to state "a hazard requiring a supply-chain-applied control" rather than "significant."

#### **XLV. Subpart G: New Requirement Specifying the Responsibilities of the Receiving Facility (Final § 117.415)**

As discussed in Response 657, after considering comments we are providing flexibility for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents the receiving facility's

review and assessment. We are specifying that flexibility in § 117.415. We have titled this section "Responsibilities of the receiving facility" to emphasize the responsibility of the receiving facility for its supply-chain program. (See Response 657 and Response 658.) Although comments focus on flexibility for an entity in the supply chain between the supplier and the receiving facility to perform supplier verification activities, and such entities are the most likely entities to be the entities determining, conducting, and documenting supplier verification activities, the flexibility provided by the rule is not limited to such entities.

The rule does, however, set some bounds on the flexibility for determining, conducting, and documenting appropriate supplier verification activities. For example, as discussed in Response 657 and Response 658, only the receiving facility can approve its suppliers. As another example, although it would not be appropriate for a supplier to determine the appropriate supplier verification activities for itself, we had proposed that it would be appropriate for a supplier to conduct sampling and testing of raw materials and ingredients as a supplier verification activity (proposed § 117.136(c)(1)(ii)), and we are retaining that provision in the final rule (see § 117.415(a)(4)). Likewise, it is common industry practice for a supplier to arrange for an audit by a third party (Ref. 83), and the new flexibility provision does not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with the requirements of the rule applicable to audits (§ 117.435). See § 117.415 for the full text of this new flexibility provision.

#### **XLVI. Subpart G: Comments on Using Approved Suppliers and Determining Appropriate Supplier Verification Activities**

We proposed requirements for the use of approved suppliers (proposed § 117.136(a)(3)(i)) and for determining and documenting appropriate supplier verification activities (proposed § 117.136(b)). See table 48 for a description of the final provisions and the changes we have made to clarify the requirements.

TABLE 48—REVISIONS TO THE PROPOSED REQUIREMENTS FOR APPROVING SUPPLIERS AND FOR DETERMINING AND DOCUMENTING APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES

Final section designation	Proposed section designation	Description	Revision
117.420(a) .....	117.136(a)(3)(i) .....	The receiving facility must approve suppliers and document that approval.	Explicit statement of this requirement.
117.420(b)(1) .....	117.136(a)(3)(i) .....	Written procedures for receiving raw materials and other ingredients must be established and followed.	Explicit requirement for written procedures.
117.420(b)(2) .....	.....	The purpose of the written procedures is to ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients the receiving facility subjects to adequate verification activities before acceptance for use).	N/A.
117.420(b)(3) .....	117.136(a)(3)(i) .....	Use of the written procedures for receiving raw materials and other ingredients must be documented.	Conforming change associated with the explicit requirement to establish and follow written procedures.
117.425 .....	117.136(b) .....	Requirement to determine and document appropriate supplier verification activities.	N/A.

*A. Using Approved Suppliers (Final § 117.420)*

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 117.136(a)(i)).

This proposed requirement included an implicit requirement that a facility must approve suppliers. For clarity, we make that requirement, and documentation of that approval, explicit in the final rule. (See § 117.420(a)).

The rule continues to require that a receiving facility ensure raw materials and other ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or other ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to adequate verification activities before acceptance for use), but we revised the provision to specify that the receiving facility must do so by establishing and following written procedures, and require documentation that these procedures were followed. To simplify the provisions, we also established a definition for the term “written procedures for receiving raw materials and other ingredients” to

mean written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use), and use that term throughout subpart G. For example, a facility could design a checklist for employees to use when raw materials and other ingredients are delivered to the facility. We decided to specify use of written procedures for receiving raw materials and other ingredients in light of the flexibility the final rule provides for an entity other than the receiving facility (such as an entity in the supply chain between the supplier) to conduct this activity (see § 117.415(a)(2)). Although we agree that such an entity can do this as a service to the receiving facility, a written procedure is appropriate to ensure a robust and meaningful verification. As a companion change, we revised the associated documentation requirement to specify documentation of use of the written procedures.

(Comment 682) Some comments support the requirement to approve suppliers. Other comments ask us to provide guidance for use of unapproved suppliers on a temporary basis, because the use of unapproved suppliers could be a high risk situation. Other comments emphasize that if the final supplier approval process is significantly changed compared to the proposed supplier approval process, industry must have enough time to plan and

develop supplier verification plans and a process for unapproved sources.

(Response 682) We will consider including guidance for use of unapproved suppliers on a temporary basis in guidance that we intend to issue regarding the supply-chain program. We do not believe that the final requirements regarding the use of approved suppliers will require increased implementation time. The principal change is to allow flexibility for entities in the supply chain other than the receiving facility to establish written procedures for receiving raw materials and other ingredients and document that written procedures for receiving raw materials and other ingredients are being followed.

*B. Determining Appropriate Verification Activities (Final § 117.425)*

The rule requires that a supply-chain program include determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (see § 117.410(a)(2)). Comments that addressed the proposed provision for determining appropriate verification activities (which provides flexibility to the facility to determine the appropriate verification activities) did not disagree with it. (See Comment 675.) The rule also requires that certain factors must be considered in determining appropriate verification activities (§ 117.410(d)). We discuss those factors, and comments that addressed those factors, in section XLIV.D. Both of these provisions (*i.e.*, § 117.410(a)(2) and § 117.410(d)) derive from the proposed requirement regarding factors that must be

considered in determining appropriate supplier verification activities (proposed § 117.136(b)). To give prominence to both the responsibility and the flexibility to determine appropriate supplier verification activities, and emphasize the factors that must be considered in addressing this responsibility, new § 117.425 specifies that appropriate supplier verification activities (including the frequency of conducting the activity)

must be determined in accordance with the requirements of § 117.410(d).

**XLVII. Subpart G: Comments on Conducting Supplier Verification Activities for Raw Materials and Other Ingredients**

We proposed requirements applicable to conducting supplier verification activities (proposed § 117.136(c)). Most comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g.,

Comment 688, Comment 690, and Comment 695) or ask us to clarify how we will interpret the provision (see, e.g., Comment 684 and Comment 685). In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 49.

**TABLE 49—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS**

Final section designation	Proposed section designation	Description	Revision
117.430(a) .....	117.136(c)(1) .....	Requirement to conduct one or more appropriate supplier verification activities.	Add reference to an additional provision that provides for alternative supplier verification activities for shell egg producers that have less than 3,000 laying hens.
117.430(b)(1) .....	117.136(c)(2)(i) .....	Requirement to conduct an onsite audit as the supplier verification activity when the hazard being controlled by the supplier is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.	N/A.
117.430(b)(2) .....	117.136(c)(2)(ii) .....	Exception to the requirement to conduct an annual onsite audit with a written determination.	N/A.
117.430(c) .....	117.136(c)(3) .....	Alternative supplier verification activity when the supplier is a qualified facility.	<ul style="list-style-type: none"> <li>• Modify the regulatory text to better align with the responsibilities of a qualified facility to submit an attestation to FDA about its food safety practices or its compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.</li> <li>• Clarify that the date for a receiving facility to obtain written assurance that a supplier is a qualified facility is before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year for the following calendar year.</li> <li>• Provide for written assurance that, when applicable, the supplier is producing the raw material or other ingredient in compliance with relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.</li> </ul>
117.430(d) .....	117.136(c)(3) .....	Alternative supplier verification activity when the supplier is a farm that is not a “covered farm” under part 112 in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5.	<ul style="list-style-type: none"> <li>• Clarify that the applicable farms are “not covered farms” rather than “not subject to part 112” because some of these farms are subject to modified requirements in § 112.6.</li> <li>• Clarify that the date for a receiving facility to obtain written assurance from the farm about its status is before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year for the following calendar year.</li> </ul>

TABLE 49—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS—Continued

Final section designation	Proposed section designation	Description	Revision
117.430(e) .....	N/A .....	Alternative supplier verification activity when the supplier is a shell egg producer that has fewer than 3,000 laying hens.	<ul style="list-style-type: none"> <li>• Clarify that the written assurance from the farm is an acknowledgement that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). Specify an additional situation where the receiving facility can consider an alternative supplier verification activity.</li> </ul>

*A. Requirement To Conduct One or More Supplier Verification Activities (Final § 117.430(a))*

With two exceptions, we proposed that the receiving facility must conduct and document one or more specified supplier verification activities for each supplier before using the raw material or ingredient and periodically thereafter (proposed § 117.136(c)(1)). See section XLIV.B for a discussion of comments regarding the appropriate verification activities (*i.e.*, onsite audits, sampling and testing, records review, and other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient). See sections XLVII.C and XLVII.D for a discussion of the proposed exceptions to this requirement to conduct and document verification activities. As discussed in section XLVII.E, the final rule provides for an additional circumstance in which an alternative supplier verification activity may be conducted—*i.e.*, when the supplier is a shell egg producer that has fewer than 3,000 laying hens.

*B. Requirement for an Onsite Audit as a Verification Activity When a Hazard Has a Reasonable Probability of Resulting in Serious Adverse Health Consequences or Death to Humans (Final § 117.430(b))*

We proposed that when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. We also proposed that this requirement does not apply if the receiving facility

documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (Proposed § 117.136(c)(2)).

(Comment 683) Some comments support the provision for audits when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. Some of these comments state that audits should be the default verification activity in order to eliminate facilities choosing the lowest cost option regardless of whether it was best for food safety. Other comments state that audits would be the best option for facilities that cannot visit each supplier annually and that onsite inspection can identify problems in ways that paperwork reviews cannot.

However, other comments oppose this requirement. Some of these comments express concern that this requirement does not allow the necessary flexibility for a facility to tailor an effective supplier program based upon risk. Other comments state that annual audits are neither the preferred nor the most effective verification measure and express concern that the provision sets a precedent that annual audits are the preferred or most effective verification measure and that other verification activities often can help paint a more accurate picture of a supplier over time. Other comments express concern that audits only give a “snapshot” of a supplier’s performance at a given time and ask that we not overemphasize audits.

(Response 683) We are retaining this provision as proposed. As we indicated in the Appendix of our 2013 proposed preventive controls rule, an increasing number of establishments are requiring, as a condition of doing business, that their suppliers become certified to food safety management schemes that

involve third-party audits (78 FR 3646 at 3818–3820); republished in its entirety with corrected reference numbers on March 20, 2013, 78 FR 17142 at 17149–17151). An online survey of retail suppliers noted that such certification enhanced their ability to produce safe food (Ref. 94). We agree that onsite audits can identify problems in ways that paperwork reviews cannot. Because an audit involves more than simply observing the facility producing a food product, we believe it is more than just a “snapshot” of the supplier’s programs. As discussed in Response 669, onsite audits can include observations, records review and employee interviews.

The requirement to conduct an annual audit in specified circumstances is risk-based because the specified circumstances are limited to situations where there is a reasonable probability that exposure to the hazard in the raw material or other ingredient will result in serious adverse health consequences or death to humans. The food safety controls applied by suppliers of such raw materials or other ingredients are more important than for other types of hazards because of the serious adverse health consequences that can occur if the hazards are not controlled. Annual audits are required of certification schemes that are benchmarked to the Global Food Safety Initiative Guidance Document for GFSI recognition (Ref. 95). We disagree that this requirement does not provide flexibility in choosing verification activities; in recognition that other verification activities can help paint a more accurate picture of a supplier over time, we have provided for alternative verification activities or audit frequencies if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the



hazards are controlled (see § 117.430(b)(2)).

(Comment 684) Some comments ask us to define those products that may trigger the requirement for an audit, especially with respect to farms. These comments question how to assess whether a hazard could result in serious adverse health consequences or death to humans.

(Response 684) We decline this request. Any list of such products would be extensive and it is unlikely we could capture all the circumstances in which this could apply. Hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans are those for which a recall of a violative product posing such a hazard is designated as "Class 1" under 21 CFR 7.3(m)(1). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans include pathogens or their toxins in RTE foods and undeclared food allergens. Foods (other than dietary supplements or infant formula) containing a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals are considered reportable foods; examples of foods FDA has considered to present a reasonable probability of serious adverse health consequences or death can be found in our Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Ref. 32) and (Ref. 33).

(Comment 685) Some comments ask us to clarify the role of third-party audits and the GAP program and ask us to allow GAPs to be a voluntary mechanism to satisfy buyer demands for food safety certification.

(Response 685) Although the rule would not require a receiving facility to hire a third party to conduct an audit, onsite audits can include third-party audits. There are likely to be benefits for suppliers to have a third-party audit, because the same audit may be acceptable by multiple receiving facilities as an appropriate supplier verification activity. For farms, GAPs audits may be viewed as an appropriate supplier verification activity. GAPs audits and other third-party audits would need to comply with the requirements of this rule applicable to onsite audits (see § 117.435).

(Comment 686) Some comments assert that we should delete this provision entirely, stating that this

requirement for an audit is "outside the scope of FSMA." Other comments state that manufacturing or processing facilities should not require suppliers that are produce farms to conduct annual onsite audits in three specified circumstances: (1) If the farm is not subject to the produce safety standards (e.g., the produce is not eaten raw, or the farm is not covered because total annual sales exclude it, because these farms are so small as to pose minimal risk to the food supply and audits would be cost-prohibitive for them); (2) if the farm is subject to the produce safety standards (because these farms are already regulated); and (3) if the farm has been GAP certified (because this would mean they were undergoing duplicative requirements).

(Response 686) When a supplier farm is not subject to the produce safety standards because of low sales revenue, we have provided for modified verification requirements (see § 117.430(d)). For produce not subject to the produce safety standards because they are rarely consumed raw, we would not expect receiving facilities to identify hazards requiring a preventive control that would be controlled before receipt of the raw material or ingredient; thus such produce would not be subject to the supply-chain program.

We disagree that a farm should not be subject to the requirements of the supply-chain program in this rule simply because it is subject to the produce safety rule. The produce subject to the produce safety rule may contain hazards that could result in serious adverse health consequences or death to humans; unless such produce will receive a treatment that significantly minimizes these hazards, the controls for the hazards are those applied by the farm. GAP certification involves an audit of the farm; as noted in Response 685, GAPs audits that comply with the requirements of this rule may be viewed as an appropriate verification activity, and the certification audit could serve two purposes.

We disagree that a requirement for an audit is "outside the scope of FSMA." See the discussion in Response 669 regarding the provision in section 419(c)(1)(E) of the FD&C Act that the regulation issuing standards for the safety of produce "not require a business to hire a consultant or other third party to identify, implement, certify compliance with the procedures, processes and practices" and the provision in section 418(n)(3)(D) of the FD&C Act that the preventive controls regulation "not require a facility to hire a consultant or other third party to

identify, implement, certify or audit preventive controls." As noted in that response, a facility is not required to hire a third party to conduct an audit.

(Comment 687) Some comments support the flexibility to not conduct an annual onsite audit if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Other comments question how a facility would prove that alternative measures are equally effective as an annual audit, when it is not known how effective an annual audit is. Other comments assert that the provision is meaningless because a farm or facility would not take the legal risk of verifying it has received "adequate assurance," because this would be subject to an FDA inspector's interpretation.

(Response 687) This provision requires a facility to use a verification activity that provides adequate assurance that a hazard is controlled, not to determine how effective an audit is and assess whether alternative measures are equally effective.

As an example of using an alternative approach to an annual onsite audit, consider the situation in which a receiving facility is part of a larger corporation, is making trail mix, and obtains roasted peanuts from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as the receiving facility. The receiving facility could determine that the food safety requirements established by the parent company and applied at the subsidiary provide the needed assurance that *Salmonella* in raw peanuts is adequately controlled. The facility could support its decision by documenting this determination, including the procedures in effect at the supplier and the activities used by the corporation to verify that the subsidiary operates in accordance with corporate food safety policies and practices to ensure that hazards are adequately controlled.

We disagree that the provision is meaningless because a farm or facility would see a legal risk in using an alternative to annual onsite audits as a supplier verification activity. First, a farm would be a supplier and would not be the entity that would determine whether an onsite audit or some other supplier verification activity is appropriate. As established in § 117.415, determining the appropriate supplier verification activity would be the responsibility of a receiving facility, and although appropriate supplier verification activities could be

determined by another entity in the receiving facility's supply chain as a service, the supplier verification activities could not be determined by the supplier itself. Second, although there is always a potential for differences in interpretation between an FDA inspector and an inspected firm, we are establishing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance. For example, FDA intends to deploy specialized investigators, backed up by technical experts, to assess the soundness and performance of a facility's food safety system (Ref. 12). In addition, a central element of FDA's strategy to gain industry compliance is to help make available to farmers, food processors, and importers—especially small businesses—the education and technical assistance they need to understand and implement FSMA's new prevention-oriented standards (Ref. 6). The new inspection paradigm and the assistance and training for industry should help minimize different interpretations between industry and regulators.

(Comment 688) Some comments ask us to require facilities to notify us when they determine that an alternative to an audit is an appropriate supplier verification activity and be able to justify and document how an alternative verification activity provides the same level of assurance as an onsite audit.

(Response 688) We decline this request. We will assess a facility's supplier verification activities during a facility inspection, including the documentation that an alternative verification activity provides the same level of assurance as an onsite audit.

(Comment 689) Some comments ask us to specify the type of documentation required for our investigators to determine when the activities are "in compliance with the law and sufficient to protect public health."

(Response 689) We decline this request. The facility's approach to the determination, and the applicable documentation required to support that determination, would depend on the circumstances. For example, in Response 687 we discuss a possible approach in a situation in which a receiving facility is part of a corporation and obtains an ingredient from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as the receiving facility. Another situation could be when a receiving facility has many years of experience with the same supplier,

but the approach and documentation in that situation likely would be different from an approach and documentation used when the supplier and the receiving facility are part of the same corporation.

(Comment 690) Some comments ask that we not limit the determination for a supplier verification activity other than an onsite audit to a determination by the receiving facility. These comments explain that the corporate parent of a facility can be the entity that makes this determination. These comments suggest that we can account for the role of the corporation by specifying that a facility documents "the determination" (rather than "its" determination).

(Response 690) We have agreed that the corporate parent of a facility can be active in developing and implementing the facility's food safety plan (see section XXIV.A). However, the specific suggestion of these comments is not necessary to achieve the outcome requested by the comments because of editorial changes we made to provide for entities other than the receiving facility to determine and conduct the appropriate supplier verification activities.

#### *C. Alternative Verification Activity When the Supplier Is a Qualified Facility (Final § 117.430(c))*

We proposed that if a supplier is a qualified facility the receiving facility need not comply with the specified verification requirements if the receiving facility: (1) Documents, at the end of each calendar year, that the supplier is a qualified facility; and (2) obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

This rule has several provisions that require written assurances. We have established specific elements that each of these written assurances must include—*i.e.*, the effective date; printed names and signatures of authorized officials; and the applicable assurance (see § 117.335).

We have revised the provision to clarify that the receiving facility must have written assurance that a facility is a qualified facility: (1) Before first approving the supplier for an applicable

calendar year; and (2) by December 31 of each calendar year (rather than "at the end of the calendar year") and that the written assurance is regarding the status of the qualified facility for the following calendar year. By specifying "by December 31," a receiving facility can work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify the receiving facility about its status. See also Response 155, Response 592, and Response 593, the requirements in § 117.201(a) for an annual determination of the status of a facility as a qualified facility, and the requirements in § 117.201(d) that apply when the status of a facility changes from "qualified facility" to "not a qualified facility." A receiving facility and its suppliers have flexibility to approach the potential for the status of a facility to shift between "qualified facility" and "not a qualified facility" (or vice versa) in a way that works best for their specific business relationship.

As discussed in section XLIV.D, we have revised the requirements for considering supplier performance to provide that the receiving facility may, when applicable, consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations, rather than consider applicable FDA food safety regulations and information relevant to the supplier's compliance with applicable FDA food safety regulations. We have made a conforming change to the alternative verification activities for a qualified facility (see the regulatory text of § 117.430(c)(2)).

(Comment 691) Some comments support this alternative supplier verification activity because it provides flexibility. Other comments ask us to revise the provision so that it only requires that the supplier document its status as a qualified facility. Still other comments ask us to remove all provisions on qualified facilities because they view these provisions as effectively adding a second layer of regulations on produce farms, and claim this is not authorized by FSMA. Other comments ask us to delete the requirement that the written assurance include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

(Response 691) We have revised the provisions for an alternative verification activity for a qualified facility to better

align with the responsibilities of a qualified facility to submit an attestation to FDA about its food safety practices (§ 117.201(b)(2)(i)) or its compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries (§ 117.201(b)(2)(ii)) (see the regulatory text of § 117.430(c)). Importantly, a qualified facility is still subject to CGMPs and the FD&C Act, and if the qualified facility is a supplier controlling a hazard it is reasonable for a receiving facility to expect the qualified facility to provide to the receiving facility an assurance that reflects an attestation the facility has made to FDA. As modified, one possibility is for a qualified facility to provide a receiving facility with a brief description of the preventive controls it is implementing to control the applicable hazard, consistent with an attestation of its food safety practices in accordance with § 117.201(a)(2)(i). For example, the qualified facility could state that its manufacturing processes include a lethality step for microbial pathogens of concern. As required by § 117.201(f), a qualified facility that submits an attestation to FDA about its food safety practices would have documentation of those practices to support its attestation to FDA and, thus, would have documentation to support its written assurance to the receiving facility. Although a qualified facility that submits an attestation to FDA about its food safety practices also would have documentation of monitoring the performance of the preventive controls to ensure that such controls are effective as required by § 117.201(a)(2)(i), we are not requiring the qualified facility to describe its monitoring of the performance of preventive controls to ensure that they are effective. Alternatively, a qualified facility could provide a receiving facility with a statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

We disagree that the alternative verification activity for produce farms would add a second layer of regulations on produce farms and are retaining this provision. See Response 693.

(Comment 692) Some comments ask us to remove the requirement that the written assurance be obtained at least every 2 years. Other comments ask us to revise the purpose of the written assurance from “the raw material or ingredient is not adulterated” to “the receiving facility’s use of the raw material or ingredient will not cause the finished food to be adulterated.”

(Response 692) We decline these requests. A supplier verification activity needs to consider supplier performance on an ongoing basis. Procedures and practices evolve over time, and it is appropriate for a receiving facility that is obtaining written assurance from a supplier as an alternative verification activity to be aware of both procedures and practices that have changed, as well as procedures and practices that have stayed the same. The specified timeframe for updating the written assurance—*i.e.*, at least every two years—is reasonable.

A supplier can only provide assurance about raw materials and other ingredients that it supplies to the receiving facility, not about the food product that the receiving facility will produce using the supplier’s raw material or other ingredients.

*D. Alternative Verification Activity When the Supplier Is a Produce Farm That Is Not a “Covered Farm” for the Purposes of the Future Produce Safety Rule (Final § 117.430(d))*

We proposed that if a supplier is a farm that is not subject to the requirements that we have proposed to be established in the produce safety rule in accordance with proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with the verification requirements if the receiving facility: (1) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to the produce safety rule; and (2) obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. See also § 117.335, which establishes specific elements that this written assurance must include—*i.e.*, the effective date; printed names and signatures of authorized officials; and the applicable assurance.

Produce farms that are not “covered farms” under § 112.4 of the forthcoming produce safety rule have less than \$25,000 in annual sales averaged over the previous 3-year period, or satisfy the requirements for a qualified exemption in § 112.5 and associated modified requirements in § 112.6 based on average monetary value of all food sold (less than \$500,000) and direct farm marketing (during the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual

monetary value of the food sold to all other buyers). In the 2014 supplemental human preventive controls notice, we erroneously referred to these farms as farms “not subject to the requirements in part 112.” While produce farms that make less than \$25,000 are not subject to the requirements in part 112, produce farms that satisfy the requirements for a qualified exemption are not subject to the full requirements of part 112, but they do have certain modified requirements that they must meet, as described in § 112.6. We have corrected the description of these farms in § 117.430(d).

We have revised the provision to clarify that the receiving facility must have documentation that the raw material or other ingredient provided by the supplier is not subject to part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5: (1) Before first approving the supplier for an applicable calendar year; and (2) by December 31 of each calendar year (rather than “at the end of the calendar year”) and that the documentation is regarding the status of supplier for the following calendar year. By specifying “by December 31,” a receiving facility can work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify the receiving facility about its status. See also the discussion in section XLVII.C regarding a similar revision we made when the supplier is a qualified facility.

(Comment 693) Some comments support the proposed alternative supplier verification activity. Other comments support applying the proposed alternative supplier verification activity more broadly—*i.e.*, to any farm that will not be subject to part 112 (*e.g.*, a farm that grows wheat), stating that both small and large non-produce farms should have the same option as farms that are exempted under § 112.4. Some comments ask us to revise the alternative verification requirements to apply to raw materials from farms that do not grow and harvest “produce” as we proposed to define it in § 112.3(c) so that the alternative verification requirements would apply to grain. Some comments assert that it is not possible to receive “written assurances” of compliance from growers of grain because there is no safety standard for grain growers, and that any such documents would be essentially meaningless.

Some comments ask us to revise the requirement to obtain written assurance so that it does not apply to “food not subject to the requirements of part 112 of this chapter pursuant to part 112.2.”

Other comments assert that a documentation requirement for commodities that will be exempt from the produce safety rule would increase recordkeeping burdens without added benefit because produce that will be exempt from the produce safety rule is low-risk.

Some comments assert that farms should not have to provide written assurances because the requirement is ambiguous. These comments assert that exempt farmers are small-scale producers who are subject primarily to state and local laws and this provision would require them to provide written assurances that they are complying with unspecified Federal regulations. The comments claim that, without seeking legal counsel, many exempt farmers would be unable to provide such assurances, limiting the ability of these farmers to market their products to non-exempt facilities (the overwhelming majority of the food market).

(Response 693) We have revised the provision to specify that the written assurance from the farm must state that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). Any business that introduces food into interstate commerce is subject to the prohibited acts provisions in section 301 of the FD&C Act, and is accountable if it produces food that is adulterated.

As discussed in Response 444, new § 117.136(a) allows a manufacturer/processor to not implement a preventive control if it determines and documents that the type of food (e.g., RACs such as cocoa beans, coffee beans, and grains) could not be consumed without application of the appropriate control. We believe most receiving facilities will take advantage of this provision, and not establish supply-chain controls under the supply-chain program in subpart G for a number of RACs.

This alternative supplier verification activity is intended to minimize the burden on suppliers that are small farms. The amount of food produced by such farms is small, and the exposure to food from such farms therefore is low. We disagree that a written assurance from such a farm would be meaningless. Any business that distributes food in interstate commerce is subject to the FD&C Act, and must produce food that is in compliance with the FD&C Act, regardless of whether FDA has established a specific regulation governing the production of the food.

(Comment 694) Some comments ask us to delete this alternative supplier verification activity because they see it as a contradiction to the traceability provisions of the Bioterrorism Act and FSMA, because “traceback” is only required for “one step back” or for a single supplier for a particular shipment of food.

(Response 694) The supply-chain program that is being established in this rule is a preventive control for the ongoing production of safe food, not a “traceback” provision, established under the Bioterrorism Act, to help address credible threats relating to food that is reasonably believed to be adulterated and to present a threat of serious adverse health consequences or death to humans or animals.

(Comment 695) Some comments ask us to specify 3 options for verification if a supplier is a farm subject to the requirements of part 112: (1) Documentation at the end of each calendar year that the raw material or ingredient provided by the supplier is subject to part 112; (2) written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under the FD&C Act; or (3) evidence that the supplier is certified to a recognized third-party GAP/GHP/GMP/HACCP audit scheme. (We note that we are assuming that “GHP” is an abbreviation for “Good Hygienic Practice.”)

(Response 695) We decline this request. Documenting that a raw material or other ingredient is subject to the produce safety rule has no bearing on whether the farm is complying with that rule to control the hazards. With respect to all farms subject to the requirements of part 112 providing a written assurance, as discussed in Response 693, the amount of food produced by the small farms that could provide written assurance to a receiving facility is small, and the exposure to food from such farms therefore is low. We disagree that it is appropriate to extend this alternative supplier verification activity to larger farms because such farms provide a larger volume of produce.

A farm that has been subject to an audit that complies with the requirements of this rule can provide the results of the audit.

#### *E. Alternative Verification Activity When the Supplier Is a Shell Egg Producer That Has Less Than 3,000 Laying Hens (Final § 117.430(e))*

We are establishing an additional alternative supplier verification activity when a supplier is a shell egg producer that is not subject to the requirements of part 118 because it has less than 3,000 laying hens. See the regulatory text of § 117.430(e). The provision is analogous to the alternative supplier verification activity when a supplier is a farm that meets the criteria in § 117.430(d) and would account for a very small amount of eggs in the food supply. See also § 117.335, which establishes specific elements that the required written assurance must include—i.e., the effective date; printed names and signatures of authorized officials; and the applicable assurance.

#### *F. Independence of Persons Who Conduct Supplier Verification Activities (Final § 117.430(f))*

In the 2014 supplemental preventive controls notice, we requested comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements.

(Comment 696) Some comments ask that conflict of interest provisions not be written too broadly, and be limited to circumstances where the individual employee carrying out the verification activities has a direct personal financial interest in or financial ties to the supplier (e.g., owns a substantial amount of stock in the supplier or is personally paid directly by the supplier). Comments state that it would not be uncommon for a receiving facility to have a shared financial interest in the supplier (e.g., partial ownership of one by the other or both being owned by the same parent company). Thus, employees that have an indirect financial interest (e.g., owning stock in a supplier because they own stock in their own company, which in turn owns an interest in the supplier) should not be disqualified from performing verification activities. Comments also indicate that a laboratory analyst performing ingredient testing should not be precluded from testing ingredients from a supplier in which the analyst has a potential conflict of interest, as long as the analyst is not aware of the identity of the supplier at the time the test is performed.

(Response 696) We are establishing a requirement that there must not be any financial conflicts of interests that

influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity. This does not prohibit employees of a supplier from performing the functions specified in § 117.415 in accordance with § 117.415. For example, this provision would not prohibit an employee of a supplier from conducting sampling and testing so that the supplier could provide the results in documentation provided to the receiving facility. The provisions would not prevent a person who is employed by a receiving facility from having an indirect financial interest in a supplier (e.g., if a company in which the employee owns stock owns an interest in the supplier).

(Comment 697) Comments ask that we not preclude a supplier from hiring an outside party to perform onsite audits,

food certifications, or sampling and testing.

(Response 697) We have specified that the requirements do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor (see § 117.415(c)). We also have specified that a supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide the documentation to the receiving facility (see § 117.415(a)(4)). This acknowledges that it is common for suppliers to include Certificates of Analysis for tests conducted on specific lots of product along with the shipment to the receiving facility.

**XLVIII. Subpart G: Comments on Onsite Audit**

We proposed requirements that would apply to an onsite audit. Most comments that support the proposed provisions suggest alternative or additional regulatory text (see, e.g., Comment 698, Comment 701, and Comment 702) or ask us to clarify how we will interpret the provision (see, e.g., Comment 703 and Comment 704). In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 50.

TABLE 50—REVISIONS TO THE PROPOSED REQUIREMENTS FOR ONSITE AUDITS

Final section designation	Proposed section designation	Description	Revision
117.435(a) .....	117.136(d)(1) .....	An onsite audit of a supplier must be performed by a qualified auditor.	N/A.
117.435(b) .....	117.136(d)(2) .....	An onsite audit must consider applicable FDA regulations.	Clarify that, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.
117.435(c)(1)(i) .....	117.136(e)(1) .....	Substitution of inspection for domestic suppliers.	Broaden the list of applicable inspections to include inspections by representatives of other Federal agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies.
117.435(c)(1)(ii) and 117.435(c)(2).	117.136(e)(2) .....	Substitution of inspection for foreign suppliers.	N/A.
117.435(d) .....	N/A .....	Use of a third-party auditor that has been accredited in accordance with regulations that will be established in the forthcoming third-party certification rule.	If the onsite audit is solely conducted to meet the requirements of the human preventive controls rule by an audit agent of a certification body that is accredited in accordance with regulations that will be established in part 1, subpart M, the audit is not subject to the requirements in those regulations.

*A. Requirements Applicable to an Onsite Audit (Final § 117.435(a) and (b))*

We proposed that an onsite audit of a supplier must be performed by a qualified auditor. If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier’s written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited (proposed § 117.136(d)). We have revised “including its implementation” to “and its implementation” to emphasize that implementation of the plan is distinct from the plan itself (e.g., § 117.126(c) establishes the recordkeeping requirement for the food safety “plan,”

and § 117.190 lists implementation records).

As discussed in section XLIV.D, we have revised the requirements for considering supplier performance to provide that the receiving facility may, when applicable, consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier’s compliance with those laws and regulations, rather than consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with applicable FDA food safety regulations. We have made a conforming change to the requirements for an onsite audit to clarify that an onsite audit may consider relevant laws

and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(Comment 698) Comments support a requirement that an onsite audit be performed by a qualified auditor, provided that we finalize provisions (in proposed § 117.136(e)) whereby an inspection by certain authorities could substitute for an audit. Some comments ask us to specify that the rule permits the use of audits conducted by private third-party food safety auditing firms. Other comments ask us to provide a list of recognized private third-party food safety schemes and consider making third-party food safety certification to a recognized audit scheme mandatory for all food operations that grow, pack, hold, and manufacture/process food for

wholesale markets. Other comments ask us to further specify that FDA will audit all food facilities no less than once every 5 years to verify that private third-party audits are consistent with FDA audits and findings.

(Response 698) See our discussion in section XLVIII.B of the final provisions governing substitution of inspection for an audit. We agree that onsite audits may be conducted by third parties but disagree that it is necessary to specify this in the rule. Nothing in this rule prevents a facility from hiring a third party to conduct audits.

We decline the requests to provide a list of recognized private third-party food safety schemes or to make third-party food safety certification to a recognized audit scheme mandatory for all food operations that grow, pack, hold, and manufacture/process food for wholesale markets. The rule provides flexibility regarding use of third-party auditors and the information is easily obtained from other sources. Likewise, we decline the request to specify that FDA will “audit” all food facilities no less than once every 5 years to verify that private third-party audits are consistent with FDA audits and findings. We will inspect food facilities for compliance with this rule, not to verify the findings of a third-party audit, with a frequency consistent with our responsibilities under the FD&C Act.

(Comment 699) Some comments express concern about the multiple audits that facilities are subject to each year and ask us to encourage those subject to the rule to accept an audit performed by any of the “bona fide authorities” where it is warranted. Other comments note that food manufacturers conduct their own audits and have developed extensive expertise in doing so, and oppose any supplier verification requirement that would affect those audits. Other comments ask us to allow audits such as GFSI benchmark schemes to satisfy supplier verification requirements to avoid adding a new audit to audits currently being conducted. Some comments express concern that requiring a new audit in addition to audits already being conducted could lead to auditor shortages and unnecessary additional costs.

(Response 699) We expect that a facility will adopt an approach to audits that works best for the facility and minimizes the number of audits conducted for the same facility. An employee of a receiving facility may perform an audit, provided that the employee satisfies the criteria established in the rule for qualified auditors. Under § 117.3 and § 117.180, a

qualified auditor is a qualified individual (as defined in § 117.3) and has technical expertise obtained through education, training or experience (or a combination thereof) necessary to perform the auditing function. See Response 700, in which we discuss auditor qualifications with respect to the GFSI’s auditor competency model, noting that the provisions for auditor competency for GFSI are consistent with our definition of a qualified auditor. GFSI schemes that consider FDA food safety regulations and include a review of the supplier’s written HACCP plan (or other food safety plan), if any, and its implementation, with respect to the hazard being controlled are likely to satisfy the requirements for an onsite audit. We expect that audits being conducted for other purposes will also be used to satisfy supplier verification audit requirements and such audits will be adjusted as needed to conform to the requirements of this rule.

(Comment 700) Some comments assert that GFSI-benchmarked audits and other similarly accredited audits should be considered equivalent to onsite audits.

(Response 700) See our description of GFSI in Response 496. The GFSI guidance document requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization’s facility (Ref. 83), and a GFSI-compliant food safety scheme must include procedures for conducting internal audits (Ref. 95). To be used to satisfy the requirements of this rule, a GFSI-benchmarked audit, as with any audit, must address all requirements of this rule, including the requirement to consider applicable FDA food safety regulations and include a review of the supplier’s written plan (e.g., HACCP plan or other food safety plan), if any.

As discussed in our memorandum on supplier programs (Ref. 83), the GFSI guidance document also specifies that the person who performs the audit needs to be qualified to do so. As described in “GFSI Food Safety Auditor Competencies,” the GFSI’s auditor competency model lists three main components for auditor competencies: (1) Auditing skills and knowledge; (2) technical skills and knowledge; and (3) behavior and systems thinking (Ref. 96). Within each main component, GFSI provides details of specific tasks and the required auditor knowledge and skills to perform the specific tasks (Ref. 96). The provisions for auditor competency are consistent with our definition of a qualified auditor.

(Comment 701) Some comments ask us to delete the proposed requirement for a review of the supplier’s written plan as part of an audit because review of the supplier’s food safety plan should be part of an overall supplier verification program when the supplier is controlling a hazard that could cause serious adverse health consequences or death, but should not be tied to an audit. These comments state that receiving facilities may choose to use an unannounced audit program where the auditor spends time focusing on the actual conditions on the production floor, with a review of the supplier’s food safety plan being done as a separate verification activity.

(Response 701) We decline this request. We agree that review of an applicable food safety plan should be part of an overall supplier verification program and that the review of the food safety plan may be conducted separately from the observation of actual conditions on the production floor, provided that both are conducted within the annual timeframe. However, we believe it important that the audit address whether the food safety plan is being implemented as designed, and other comments to this rule support that view. For example, as discussed in Comment 648 regarding our inspection of a food facility, some comments assert that our access to company records must be conducted onsite in the course of an authorized inspection so that we may understand the full context of what the records show. Thus, the onsite observations and the food safety plan review cannot be entirely separated, as the comment seems to suggest.

We note that the requirement to include a review of the supplier’s food safety plan only applies when the supplier has a food safety plan. For example, we did not propose a requirement for a farm that would be subject to the forthcoming produce safety rule to have a food safety plan.

#### *B. Substitution of Inspection by FDA or an Officially Recognized or Equivalent Food Safety Authority*

We proposed that instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by the food

safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country (proposed § 117.136(e)).

(Comment 702) Some comments ask us to allow State or local inspection reports, as well as FDA inspection reports, to substitute for an onsite audit for small and very small facilities. Other comments ask us to create a “safe harbor” provision in which a supplier providing a copy of permits obtained from the most recent inspection done by Federal, State, or local health authorities satisfies the supplier verification requirement; if there are no permits, review of relevant records and/or sampling of raw material based on scale of production should be adequate.

(Response 702) We have revised the regulatory text to provide for an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal agencies (such as USDA), or by representatives of State, local, tribal, or territorial agencies. We are specifying that the inspection must be “appropriate” and be conducted for compliance “with applicable FDA regulations” to make clear that the inspection must be sufficiently relevant to an onsite audit or credibly substitute for an onsite audit. For example, inspection by USDA to determine whether a farm satisfies the requirements of the produce safety rule could constitute an appropriate inspection that could substitute for an audit, but an inspection by USDA to determine whether a farm satisfies the requirements of the National Organic Program could not.

We have not provided for substitution of a “permit obtained from the most recent inspection” for an onsite audit. We do not see how a “permit” could shed light on whether a business is complying with specific applicable FDA regulations. We have provided for an alternative verification activity to the annual onsite audit (such as a review of relevant records and/or sampling of raw material) with a written justification (see § 117.430(b)). The rule would not preclude an appropriate review of records, or sampling and testing of raw materials, by other Federal agencies, or by representatives of State, local, tribal, or territorial agencies, provided that the receiving facility satisfies the

requirements for an adequate written justification.

(Comment 703) Some comments ask us to clarify what we mean by “food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.” These comments also ask whether a specific country qualifies and whether HACCP certificates issued by a specific foreign government agency would replace an onsite audit.

(Response 703) A country whose food safety system FDA has officially recognized as “comparable” to that of the United States would be one for which there is a signed systems recognition arrangement or other agreement between FDA and the country establishing official recognition of the foreign food safety system. Information on FDA systems recognition can be found on the FDA Web site (Ref. 97). As of March 2015, FDA only has a signed systems recognition agreement with New Zealand, but agreements with other countries are under development. We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit, but a receiving facility could consider whether such a certificate could be part of its justification for conducting another supplier verification activity in lieu of an annual onsite audit, or for conducting an audit on a less frequent basis than annually.

(Comment 704) Some comments ask us to clarify that the applicable standards will be those applied by the food safety authority of a country with a food safety system recognized as comparable or equivalent rather than having to achieve compliance with the applicable U.S. FDA food safety regulations.

(Response 704) The applicable standards will be those applied by the food safety authority of a country with a food safety system recognized as comparable or equivalent to that of the United States.

#### *C. Onsite Audit by a Third-Party Auditor Accredited for the Purposes of Section 808 of the FD&C Act*

We have proposed to establish regulations (in part 1, subpart M) to provide for accreditation of third-party auditors/certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications (78 FR 45782, July 29, 2013). The purpose of the proposed third-party certification rule is to help us ensure the competence and

independence of third-party auditors/certification bodies who conduct foreign food safety audits and to help ensure the reliability of food and facility certifications, issued by third-party auditors/certification bodies, that we will use in making certain decisions relating to imported food, such as food certifications required by FDA as a condition of granting admission to a food determined to pose a safety risk.

(Comment 705) Comments support use of third-party auditors, but emphasize that such auditors need not be accredited under the requirements to be established under our forthcoming third-party certification rule.

(Response 705) We agree that a third-party auditor who conducts an audit as a supplier verification activity to satisfy the requirements of this rule need not be accredited under our forthcoming third-party certification rule. In addition, we see no reason that any requirements of our forthcoming third-party certification rule should apply to an audit merely because it was conducted by a person who had been accredited under that rule. To make this clear, we have added a provision to specify that if an onsite audit is solely conducted to meet the requirements of this rule by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, the audit is not subject to the requirements in those regulations. See § 117.435(d). Because § 117.435(d) refers to provisions in a future third-party certification rule, we will publish a document in the **Federal Register** announcing the effective date of § 117.435(d) once we finalize the third-party certification rule.

#### **XLIX. Subpart G: Comments on Records Documenting the Supply-Chain Program**

We proposed to require documentation of verification activities in records, including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier’s relevant food safety records. We also proposed that the receiving facility must review such records in accordance with the requirements applicable to review of records as a verification activity (*i.e.*, in accordance with § 117.165(a)(4)).

We did not receive comments on the documentation requirements associated with a written supplier program, determination of appropriate supplier verification activities, review of records, supplier verification activities other than an annual onsite audit when the

hazard being controlled by the supplier is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, alternative supplier verification activity when the supplier is a qualified facility, substitution of inspection for an audit, or supplier nonconformance (proposed § 117.136(g)(1), (2), (7), (9), (10), (12), and (13), respectively). We are finalizing these documentation requirements with editorial and conforming changes associated with the final requirements of the supply-chain program.

The supply-chain program includes two provisions that are explicit requirements of the final human preventive controls rule, but had been implicit requirements of the proposed human preventive controls rule. The first of these provisions is the explicit requirement that the receiving facility must approve suppliers in accordance with the requirements of § 117.410(d),

and document that approval, before receiving raw materials and other ingredients from those suppliers (see § 117.420(a)). The second of these requirements is that written procedures for receiving raw materials and other ingredients must be established and followed (see § 117.420(b)(1)). We are including in § 117.475 the documentation associated with these requirements (see § 117.475(c)(3) and (4)).

The supply-chain program includes four provisions that were not in the proposed human preventive controls rule: (1) A receiving facility that is an importer can comply with the foreign supplier verification requirements in the FSVP rule rather than conduct supplier verification activities for that raw material or other ingredient under this rule (§ 117.405(a)(2)); (2) a receiving facility may use an alternative verification activity for a supplier that is a shell egg producer that is not subject

to the requirements established in part 118 because it has less than 3,000 laying hens (§ 117.430(e)); (3) when applicable, a receiving facility must verify a supply-chain-applied control applied by an entity other than the receiving facility's supplier (§ 117.405(c); and (4) entities other than the receiving facility may determine, conduct, and document certain specified supplier verification activities, provided that the receiving facility reviews and assesses the other entity's applicable documentation, and documents its review and assessment (§ 117.415). We are establishing the associated documentation requirements in § 117.475(c)(2), (14), (17), and (18), respectively.

In the following sections, we discuss comments on the proposed records for the supplier program. After considering these comments, we have revised the proposed requirements as shown in table 51.

TABLE 51—REVISIONS TO THE PROPOSED REQUIREMENTS FOR RECORDS FOR THE SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Did we receive comments regarding the proposed requirement?	Did we revise the documentation requirement other than editorial and conforming changes associated with the final requirements for the supply-chain program?
117.475(a) .....	N/A .....	The records documenting the supply-chain program are subject to the requirements of subpart F.	N/A .....	Consequential change associated with establishing the requirements for a supplier in subpart G rather than subpart C.
117.475(b) .....	117.136(g) .....	The receiving facility must review the records in accordance with § 117.165(a)(4).	Yes .....	No.
117.475(c)(1) .....	117.136(g)(1) .....	The written supply-chain program .....	No .....	N/A.
117.136(b)(2) .....	117.136(g)(3) .....	Annual written assurance from a receiving facility's customer.	Yes .....	Shifted to be in provisions outside the framework of the supply-chain program in subpart G.
117.475(c)(2) .....	N/A .....	Documentation obtained from an importer.	N/A .....	N/A.
117.475(c)(3) .....	117.136(g)(1) .....	Documentation of the approval of a supplier.	No .....	No.
117.475(c)(4) .....	117.136(g)(1) .....	Written procedures for receiving raw materials and other ingredients.	No .....	No.
117.475(c)(5) .....	117.136(g)(4) .....	Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients.	Yes .....	Yes.
117.475(c)(6) .....	117.136(g)(2) .....	Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients.	No .....	No.
117.475(c)(7) .....	117.136(g)(5) .....	Documentation of the conduct of an onsite audit.	Yes .....	Added a requirement for the documentation to include the name of the supplier subject to the onsite audit.
117.475(c)(8) .....	117.136(g)(6) .....	Documentation of sampling and testing conducted as a supplier verification activity.	Yes .....	Specify that the documentation include the date(s) on which the test(s) were conducted and the date of the report.
117.475(c)(9) .....	117.136(g)(7) .....	Documentation of the review of the supplier's relevant food safety records.	No .....	Specify that the documentation must include the general nature of the records reviewed and conclusions of the review.



TABLE 51—REVISIONS TO THE PROPOSED REQUIREMENTS FOR RECORDS FOR THE SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Did we receive comments regarding the proposed requirement?	Did we revise the documentation requirement other than editorial and conforming changes associated with the final requirements for the supply-chain program?
117.475(c)(10) .....	117.136(g)(8) .....	Documentation of other appropriate supplier verification activities.	Yes .....	Specify that the other appropriate supplier verification activities are based on supplier performance and the risk associated with the raw material or other ingredient.
117.475(c)(11) .....	117.136(g)(9) .....	Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.	No .....	No.
117.475(c)(12) .....	117.136(g)(10) .....	Documentation of an alternative verification activity for a supplier that is a qualified facility.	No .....	Provide for documentation, when applicable, of a written assurance that the supplier is producing the raw material or other ingredient in compliance with relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.
117.475(c)(13) .....	117.136(g)(11) .....	Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient that would not be a covered farm subject to the forthcoming produce safety rule.	Yes .....	No.
117.475(c)(14) .....	N/A .....	Documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 because it has less than 3,000 laying hens.	N/A .....	N/A.
117.475(c)(15) .....	117.136(g)(12) .....	The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal agencies (such as USDA), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit.	No .....	No.
117.475(c)(16) .....	117.136(g)(13) .....	Documentation of actions taken with respect to supplier non-conformance.	No .....	No.
117.475(c)(17) .....	N/A .....	Documentation of verification of a supply-chain- applied control applied by an entity other than the receiving facility's supplier.	N/A .....	N/A.
117.475(c)(18) .....	N/A .....	When applicable, documentation of the receiving facility's review and assessment of documentation of a supplier verification activity provided by a supplier or by an entity other than the receiving facility.	N/A .....	N/A.

#### A. Applicability of the Recordkeeping Requirements of Subpart F

We have added new § 117.475(a) to specify that the records documenting the supply-chain program in subpart G are subject to the requirements of subpart F. Under the proposed human preventive controls rule, the documentation requirements would have been in subpart C, and the applicability of subpart F was specified in § 117.190 in subpart C. The new provision specifying the applicability of subpart F to the records associated with the supply-chain program is a consequential change associated with establishing the requirements for a supply-chain program in subpart G, rather than in subpart C.

#### B. Requirement To Review Records of the Supply-Chain Program (Final § 117.475(b))

We proposed that a receiving facility must review records documenting the supplier program in accordance with the requirements applicable to review of records as a verification activity (*i.e.*, in accordance with § 117.165(a)(4)). (Proposed § 117.136(g))

(Comment 706) Some comments ask us to provide consideration for records associated with the supplier program to be administered and maintained at corporate headquarters rather than at individual facilities, because this is common industry practice.

(Response 706) We are aware that certain programs are administered, and records are maintained, at corporate headquarters rather than at individual facilities. The rule provides that offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review and electronic records are considered to be onsite if they are accessible from an onsite location (see § 117.315(c)). We expect that the facility would be able to access information and records relevant to the supply-chain program within 24 hours (*e.g.*, electronically) when the records are maintained at corporate headquarters. As necessary and appropriate, we intend to work with facilities on a case-by-case basis to determine the best way to review records associated with the supply-chain program when the supply-chain program is administered at the corporate level.

(Comment 707) Some comments ask us to clarify in the regulatory text that the required records are “as appropriate to the supplier program.”

(Response 707) We have revised the regulatory text to specify that the required records are “as applicable to its

supply-chain program” (see § 117.475(c)).

#### C. Documentation Demonstrating Use of the Written Procedures for Receiving Raw Materials and Other Ingredients (Final § 117.475(c)(5))

We proposed to require documentation demonstrating that products are received only from approved suppliers (proposed § 117.136(g)(4)).

(Comment 708) Some comments support the proposed requirement with no changes. Other comments ask us to specify “raw materials and ingredients” rather than “products” in the regulatory text.

(Response 708) We have revised the regulatory text to specify “raw materials and other ingredients” with associated conforming changes.

#### D. Documentation of the Conduct of an Onsite Audit (Final § 117.475(c)(7))

We proposed to require documentation of an onsite audit. This documentation must include: (1) Documentation of audit procedures; (2) the dates the audit was conducted; (3) the conclusions of the audit; (4) corrective actions taken in response to significant deficiencies identified during the audit; and (5) documentation that the audit was conducted by a qualified auditor. For clarity, we have revised the regulatory text to specify documentation of the “conduct” of an audit and added a requirement for the documentation to include the name of the supplier subject to the onsite audit.

(Comment 709) Some comments ask us to maintain the confidentiality of audit reports and exempt such audit reports from disclosure under the FOIA.

(Response 709) These comments are similar to comments we received related to disclosure of other records required by this part (See Comment 647 and Comment 650). We would establish the status of supply-chain program records, such as audit reports, as available for, or protected from, public disclosure on a case-by-case basis. As discussed in Response 647, we primarily intend to copy such records when we conduct an inspection for cause or if the preliminary assessment by our investigator during a routine inspection is that regulatory follow-up may be appropriate (*e.g.*, if the report indicates that a significant food safety problem was noted). See Response 650 for a discussion of situations in which records would, or would not, be protected from disclosure.

(Comment 710) Some comments express concern about maintaining documentation of the conclusions of an

audit and documentation of corrective actions taken in response to significant deficiencies identified during the audit. These comments explain that FDA’s access to such documentation during inspection might discourage suppliers from allowing unannounced audits. These comments ask us to delete these proposed requirements. If the requirement regarding documentation of corrective actions remains in the final rule, these comments ask us to limit such documentation to situations in which the identified deficiencies posed a risk to public health.

(Response 710) We are retaining these documentation requirements as proposed. These comments appear to be suggesting that documentation requirements be established based on whether a business entity would want us to see information during inspection rather than on the utility and value of the documentation. We expect that receiving facilities, in general, maintain documentation of the conclusions of audits that they have conducted or arranged to have conducted. A receiving facility must approve all of its suppliers, and documentation of corrective actions taken in response to significant deficiencies identified during an audit has value to a receiving facility in determining whether to approve a supplier before first receiving any raw materials or other ingredients and then on an ongoing basis.

The rule does not require that onsite audits be unannounced, although we acknowledge that some receiving facilities may see value in unannounced audits. We decline the request to require a receiving facility to maintain documentation of corrective actions only if the identified deficiencies posed a risk to public health. If, for example, a supplier’s facility has filthy conditions or the raw materials and other ingredients it supplies are contaminated with filth, a receiving facility may find it inappropriate to approve that supplier. Even though filth often does not pose a risk to public health, a food may be deemed to be adulterated under section 402(a)(4) of the FD&C Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

#### E. Documentation of Sampling and Testing (Final § 117.475(c)(8))

We proposed to require records of sampling and testing. These records must include: (1) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested; (2) identification of the test(s) conducted,

including the analytical method(s) used; (3) the date(s) on which the test(s) were conducted; (4) the results of the testing; (5) corrective actions taken in response to detection of hazards; and (6) information identifying the laboratory conducting the testing.

(Comment 711) Some comments ask us to not apply the requirement to maintain records related to sampling and testing to the receipt of RACs because sampling and testing of RACs is neither common nor effective for detecting biological or chemical hazards, especially in raw, intact produce.

(Response 711) We decline this request. These comments appear to suggest that documentation requirements be established based on the frequency and utility of sampling and testing a particular commodity rather than on a determination by a receiving facility that sampling and testing is an appropriate supplier verification activity for a particular supplier. We disagree with such a suggestion. A receiving facility that has determined that sampling and testing is an appropriate supplier verification activity needs to maintain records of those results as it would for any other supplier verification activity. To the extent that these comments are concerned that the supply-chain program requires sampling and testing of RACs, we emphasize that this is not the case. See also Response 525 for a discussion of the usefulness of sampling and testing as a verification measure for RACs.

(Comment 712) Some comments ask us to allow documentation of testing to include the date the test results were reported as an alternative to the date(s) on which the test(s) were conducted.

(Response 712) We have revised the provision to require “The date(s) on which the test(s) were conducted and the date of the report.” We agree that the date on which the test results are reported can be important, but it should not be a replacement for the date of the test.

(Comment 713) Some comments ask us to add “if necessary” to the end of the proposed requirement for documentation of corrective actions taken in response to detection of hazards.

(Response 713) We decline this request. The documentation is always necessary if corrective actions are taken. The provision is about maintaining documentation when corrective actions are taken, not about the fact that corrective actions may not always be needed.

#### *F. Documentation of Other Appropriate Supplier Verification Activity (Final § 117.475(c)(10))*

We proposed to require records of other appropriate verification activities based on the risk associated with the ingredient. For clarity and consistency, we have revised the proposed requirement to specify “documentation” of the other appropriate supplier verification activity rather than “records” of the activity. As a conforming change associated with using the term “supplier performance,” rather than “risk of supplier,” when discussing factors associated with suppliers (see Response 673), the final requirement specifies that the other appropriate supplier verification activities are based on the supplier performance and the risk associated with the raw material or other ingredient.

(Comment 714) Some comments ask us to also specify that an “other” appropriate supplier verification activity be based on the risk associated with raw materials and suppliers.

(Response 714) We have revised the regulatory text to specify “Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient.” The revised regulatory text of the documentation tracks the regulatory text of this “other” appropriate supplier verification activity (see § 117.410(b)(4)). As discussed in Response 673, “supplier performance” is more appropriate than “risk associated with the supplier.”

#### *G. Documentation of an Alternative Verification Activity for a Supplier That Is a Farm That Is Not a “Covered Farm” for the Purposes of the Future Produce Safety Rule (Final § 117.475(c)(13))*

We proposed to require documentation of an alternative verification activity for a supplier that is a farm that is not a “covered farm” for the purposes of the future produce safety rule, including: (1) The documentation that the raw material or ingredient provided by the supplier is not subject to the produce safety rule; and (2) the written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. We have revised the documentation to reflect the final requirements of § 117.430(d)—*i.e.*, to require: (1) Written assurance that the supplier is not a covered farm under

part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and (2) the written assurance that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(Comment 715) Some comments ask us to delete this documentation requirement because RACs except fruits and vegetables should be exempt from supplier verification.

(Response 715) See Response 693. This alternative supplier verification activity is intended to minimize the burden on suppliers that are small farms.

(Comment 716) Some comments ask us to include a cross-reference to the applicable requirement.

(Response 716) We have not added this cross-reference. We agree that adding the cross-reference has the potential to be helpful, but it also has the potential to clutter the regulatory text. We considered it would be more useful to specify what the documentation needs to be rather than to specify the cross-reference to the applicable alternative supplier verification activity.

#### **L. Holding Human Food By-Products Intended for Use in Animal Food**

In the 2014 supplemental animal preventive controls notice, we discussed proposed revisions to the human food CGMPs to address comments about the practice of human food manufacturers sending by-products to local farmers or animal food manufacturers for use as animal food (79 FR 58524 at 58558). We explained that we were proposing these revisions as part of the rulemaking for the animal preventive controls rule. (See the discussion of these proposed revisions in the animal preventive controls rule.) Because we proposed these revisions as part of the rulemaking for the animal preventive controls rule, we also are finalizing these provisions as part of that rulemaking. See the final animal preventive controls rule, published elsewhere in this issue of the **Federal Register**, for our response to comments on these proposed revisions to the human food CGMPs. The final provisions, being established in § 117.95 (Holding and distribution of human food by-products for use as animal food), require that:

(1) Human food by-products held for distribution as animal food without

additional manufacturing or processing by the human food processor, as identified in § 507.12, must be held under conditions that will protect against contamination, including the following:

- Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
- Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
- During holding, human food by-products for use as animal food must be accurately identified.

(2) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(3) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

#### LI. Comments by Foreign Governments and Foreign Businesses

We received several comments from foreign governments and foreign businesses covering a wide range of issues. Many of those comments were similar to comments made on certain topics by domestic stakeholders, so we are addressing those comments in other sections throughout this preamble. In this section, we are responding to comments that are primarily focused on international issues, such as the obligations of the United States under the World Trade Organization Agreement (WTO).

(Comment 717) Some comments by foreign government representatives ask us to provide “special and differential treatment” along with technical assistance to help exporters from developing countries meet the requirements of the rule. For special and differential treatment, the comments propose extended periods of time for the implementation of the rule by producers in developing countries, and flexibility

in implementation for small businesses in those countries. For technical assistance, the comments request training and other forms of assistance to help producers understand and implement the regulation.

(Response 717) The concept of special and differential treatment is incorporated in the WTO Agreements. Article 10.2 of the WTO SPS Agreement states: “Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction . . . longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.”

In 2001, at the WTO Ministerial Conference in Doha, WTO Members issued a Ministerial Decision that interpreted the special and differential obligations of the SPS Agreement (Ref. 98). The Ministerial Decision defined “longer time-frame for compliance” to normally mean a period of not less than 6 months.

We recognize that businesses of all sizes may need more time to comply with the new requirements established under this rule. As discussed in section LVI.A, the first compliance date for businesses other than small and very small businesses will be one year after this final rule is published in the **Federal Register**. Recognizing that smaller businesses may need more time to comply with the requirements, FDA is allowing two years for small businesses and three years for very small businesses to comply. We anticipate that these extended implementation periods for small businesses and very small businesses will apply to a number of businesses in developing countries. Because all of these time periods are longer than the 6 month minimum defined in the WTO Ministerial Decision, we believe these implementation periods are sufficient to address the needs of businesses in developing countries, particularly for small and very small businesses in such countries.

In addition to the extended time periods for compliance for small and very small businesses, we have also established modified requirements for very small businesses, which we define as a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee). These modified requirements for very

small businesses are less burdensome and are described in § 117.201 of this regulation.

In addition to the 1 to 3 year time periods for compliance for all firms, and modified requirements for very small businesses, we intend to work with the food industry, education organizations, USDA, the United States Agency for International Development, and foreign governments to develop tools and training programs to facilitate implementation of this rule.

(Comment 718) Some comments assert that the food safety systems of the European Union and other countries afford a similar level of food safety protection and must therefore be recognized by FDA as equivalent under the WTO SPS Agreement. These comments urge FDA to accept the HACCP plans and other steps taken to comply with European food safety laws as being sufficient to comply with this rule.

(Response 718) The concept of “equivalence” for food safety regulatory measures is contained in Article 4 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”) (Ref. 99). That article provides that WTO Member countries “shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member’s appropriate level of sanitary or phytosanitary protection.” This provision of the SPS Agreement envisions a process in which the exporting country provides evidence to the food safety regulator in the importing country in order to “objectively demonstrate” that the food safety system in the exporting country meets the level of food safety protection established by the importing country. To date, FDA has considered equivalence as most appropriately applied to the assessment of a foreign government’s specific programs for specific types of foods, such as shellfish and dairy products. In that context, the equivalence assessment provides a very detailed comparison of each measure that a country applies in controlling risks associated with the particular commodity under review. FDA continues to have latitude to engage in equivalence determinations for market access and as required by our regulations for certain commodities. For example, FDA has active equivalence

deliberations underway on Grade “A” dairy and will continue to engage in equivalence activities as needed.

In contrast to the assessment of equivalence for the regulation of specific foods based upon a detailed review of an individual food safety measure or group of measures applied to a specific food, FDA has established a process of assessing foreign food safety systems to identify systems that offer a comparable level of public health protection as the U.S. food safety system for FDA regulated foods. We refer to that process as “systems recognition,” which we discuss in Response 719.

(Comment 719) Some comments urge FDA to include a provision in this rule that would reflect a determination made by FDA in the “systems recognition” process so that FDA’s compliance framework, including audit and inspection activities, take into account the effectiveness of the regulatory or administrative control of food safety systems. These comments ask us to include a provision in this rule establishing that an affirmative systems recognition determination by FDA for an exporting country would be a sufficient basis to exempt exporting producers from that country from their obligation to comply with the requirements of this rule. Another comment urges FDA to utilize the systems recognition process to recognize the effectiveness of the EU system in order to avoid unnecessary or duplicative requirements and controls on food imports from the European Union.

(Response 719) We agree, in part, with this comment. Since 2010, FDA has been developing a program of “systems

recognition” to explore ways to leverage the work of food safety authorities in countries that have food safety systems that are comparable to that of FDA. Systems recognition assessment provides a tool for identifying countries where FDA can establish closer regulatory partnerships, including leveraging the work conducted by FDA and foreign food safety authorities.

We agree that the systems recognition program can allow FDA to take into account the effectiveness of a foreign food safety regulatory system as we develop a compliance framework for imported foods from a country for which we have made an affirmative determination of comparability via the systems recognition program. While we decline to add an exemption for food imported from a country with affirmative systems recognition determination by FDA, we note that the systems recognition program is based upon the concept that foreign food producers can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country that FDA has found to be comparable or equivalent to that of the United States. Therefore, foreign producers of foods that are subject to a systems recognition agreement can show that their products are meeting FDA’s requirements for imported foods by virtue of the fact that they are meeting their domestic food safety standards. Several provisions of the supply-chain program specifically provide for consideration of relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has

determined to be equivalent to that of the United States (see §§ 117.410(d)(1)(iii)(B); 117.430(c)(2), (d)(2), and (e)(2); and 117.435(b) and (c)(1)(ii).

We also note that we intend to publish a final FSVP rule in the near future. There, we intend to establish modified requirements for food imported from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as “comparable” to that of the United States.

Section 117.405(a)(2) of this rule provides the option for a receiving facility that is an importer to comply with the supplier verification requirements in this rule or with the foreign supplier verification program requirements that we will establish in part 1, subpart L for a raw material or other ingredient. We intend that the final FSVP rule will contain a similar provision (derived from proposed § 1.502), so that only one supplier verification procedure needs to be undertaken in order to comply with both rules when the specified conditions are met.

**LII. Editorial and Conforming Changes**

The revised regulatory text includes several changes that we have made to make the requirements more clear and improve readability. The revised regulatory text also includes several conforming changes that we have made when a change to one provision affects other provisions. We summarize the principal editorial and conforming changes in table 52.

TABLE 52—PRINCIPAL EDITORIAL AND CONFORMING CHANGES

Designation in the revised regulatory text (§)	Revision	Explanation
• 1.227 ..... • 1.328 ..... • 117.3 ..... • 1.227 ..... • 1.328 ..... • 117.3 .....	Alphabetize the examples of harvesting activities in the definition of “harvesting”.  Alphabetize the examples of manufacturing/processing activities in the definition of “manufacturing/processing”.	Make it easier to compare the examples of harvesting activities to the examples of manufacturing/processing activities in the definition of “manufacturing/processing.”  Make it easier to compare the examples of manufacturing/processing activities to the examples of harvesting activities in the definition of “harvesting.”
• 11.1(i) .....	Specify that part 11 does not apply to records required to be established or maintained under part 117, and that records that satisfy the requirements of part 117, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.	Conforming change associated with the recordkeeping requirements in § 117.305, which provide that part 11 does not apply to records required to be established or maintained under part 117.
Throughout part 117 .....	• Substitute the term “adequate” for the term “sufficient”. • Substitute the term “inadequate” for the term “insufficient”.	Conforming change associated with our proposal, in the 2014 supplemental human preventive controls notice, to make this substitution so that the rule consistently uses the term “adequate.”

TABLE 52—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
Throughout part 117 .....	Substitute the term “pathogen” for the term “microorganism of public health significance”.	Conforming change associated with the definition of “pathogen.”
Throughout part 117 .....	Substitute the term “allergen cross-contact” for the term “cross-contact”.	Conforming change associated with the definition of “allergen cross-contact.”
Throughout part 117 .....	Substitute the term “preventive controls qualified individual” for the term “qualified individual”.	Conforming change associated with adding the term “preventive controls qualified individual.”
Throughout part 117 .....	Substitute the term “unexposed packaged food” for the phrase “packaged food that is not exposed to the environment”.	Conforming change associated with the definition of “unexposed packaged food.”
Throughout part 117 .....	Substitute the phrase “chemical (including radiological) hazards” for phrases such as “chemical and radiological hazards”.	Conforming change associated with the definition of “hazard.”
Throughout part 117 .....	Substitute the term “hazard requiring a preventive control” for the term “significant hazard”.	Conforming change associated with the proposed definition of “significant hazard” (which we now refer to as “hazard requiring a preventive control.”)
Throughout part 117 .....	Shorten “raw agricultural commodity as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act” to “raw agricultural commodity”.	Conforming change associated with the new definition of “raw agricultural commodity.”
117.1(a) .....	Redesignate subparagraphs to distinguish between applying the provisions in determining whether food is adulterated and applying the provisions in determining whether there is a violation of the PHS Act.	Improve clarity.
117.3 .....	Substitute “apply” for “are applicable” in the introductory paragraph.	Improve clarity.
117.3 .....	Editorial changes to verb tense in the definition of “ready-to-eat food”.	Improve clarity.
117.3 .....	Specify that the definition of “very small business” includes any subsidiaries and affiliates of the business.	Give prominence to this aspect of the definition of “very small business.” The relevance of subsidiaries and affiliates to the definition of “very small business” is established in the definition of “qualified facility,” but including it again in the definition of “very small business” will help to ensure that it is considered when determining whether the business is within the dollar threshold established in the definition of “very small business.”
117.3, 117.5, 117.7(a), 117.257(d)(1).	Substitute “subparts C and G” for “subpart C”.	Conforming change associated with the redesignation of the requirements for a supply-chain program in new subpart G.
117.5(e) .....	Substitute “packaging” for “packing”.	Correction to use the same term as is used in part 111 for CGMPs for dietary supplements.
117.5(i) .....	Substitute “Subparts C and G of this part do not apply with respect to food <i>that is not</i> an alcoholic beverage” for “Subparts C and G of this part do not apply with respect to food <i>other than</i> an alcoholic beverage” (emphasis added).	Improve clarity.
117.5(k)(2) .....	Specify that the provision applies to those RACs that are produce as will be defined in the final produce safety rule.	Clarification. The provision only applies to those produce RACs that will have applicable requirements in the produce safety rule.
• 117.10(b), (b)(1), and (b)(9) ..... • 117.20(b)(2) and (b)(6) ..... • 117.35(a), (d), (d)(2), (d)(3), (e), and (f).	Editorial changes to clearly distinguish requirements directed to allergen cross-contact from requirements directed to contamination.	Improve clarity.
• 117.40(a)(6) and (b) ..... • 117.80(a)(4) and (a)(6) ..... • 117.80(b)(1), (b)(5), and (b)(7) ..... • 117.80(c)(6), (c)(7), (c)(10), and (c)(12)		

TABLE 52—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
<ul style="list-style-type: none"> <li>• 117.93</li> <li>• 117.10 .....</li> </ul>	<p>Conforming changes associated with the definition of “plant”.</p>	<p>The definition of “plant” focuses on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food. The term “establishment” focuses on a business entity rather than on buildings or other structures.</p>
<ul style="list-style-type: none"> <li>• 117.20(a)</li> <li>• 117.37(d)</li> <li>• 117.305(f)</li> </ul>	<p>Refer to “letter of guarantee” rather than “supplier’s guarantee”.</p>	<p>This long-standing CGMP provision is not limited to documents from a “supplier” as that term is defined in this rule.</p>
<p>117.35(b) .....</p>	<p>Refer to “employees” rather than “its employees”.</p>	<p>Editorial change.</p>
<ul style="list-style-type: none"> <li>• 117.80(b)(1) through (8) .....</li> <li>• 117.80(c)(7) and (c)(9)</li> </ul>	<p>Changes to consistently refer to raw materials and “other ingredients”.</p>	<p>Return to long-standing terminology in the CGMPs previously established in part 110.</p>
<p>117.80(c)(7) .....</p>	<p>Refer to “other food” rather than “food” in the phrase “raw materials and other ingredients, work-in-process, rework, or food”.</p>	<p>Raw materials and other ingredients, work-in-process, and rework are all types of food.</p>
<p>117.126(b)(3), 117.135(c)(4), 117.140(b), 117.160(c)(4), 117.190(a)(5).</p>	<p>Refer to “supply-chain program” rather than “supplier program”.</p>	<p>Conforming change associated with the title of final subpart G (proposed § 117.136).</p>
<ul style="list-style-type: none"> <li>• 117.160(b)(2) .....</li> <li>• 117.170(b)(4)</li> </ul>	<p>Conforming changes associated with the definition of “validation”.</p>	<p>Improve clarity; consistency with the requirements for validation.</p>
<p>117.165(a)(4)(ii) .....</p>	<p>Refer to “supply-chain verification activities,” as well as “supplier verification activities”.</p>	<p>Consequential change as a result of the requirement in § 117.405(c) for verification of an entity that is in the supply-chain but is not a supplier.</p>
<p>117.165(b)(1) .....</p>	<p>Changes to require written procedures for method and frequency of accuracy checks for process monitoring instruments and verification instruments.</p>	<p>Conforming change associated with the requirements to calibrate process monitoring instruments and verification instruments (or check them for accuracy).</p>
<p>117.170(c)(2) .....</p>	<p>Conforming changes associated with the timeframe for validating preventive controls.</p>	<p>Consistency with the requirements for validating preventive controls.</p>
<p>117.170(d) .....</p>	<p>Editorial changes to the requirement to revise the written food safety plan or document why revisions are not needed.</p>	<p>Improve clarity.</p>
<p>117.180(a)(3) .....</p>	<p>Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for validation.</p>	<p>Conforming change associated with flexibility to determine the timeframe for validation of a preventive control.</p>
<p>117.180(a)(4) .....</p>	<p>Change to specify the role of the preventive controls qualified individual in determining that validation is not required.</p>	<p>Conforming change associated with flexibility to determine that validation of a preventive control is not required.</p>
<p>117.180(a)(6) .....</p>	<p>Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for review of records of monitoring and corrective actions.</p>	<p>Conforming change associated with flexibility to determine the timeframe for review of records of monitoring and corrective actions.</p>
<p>117.180(a)(8) .....</p>	<p>Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for completing reanalysis.</p>	<p>Conforming change associated with flexibility to determine the timeframe for completing reanalysis.</p>
<p>117.80(b)(3) .....</p>	<p>Delete “current” from “current FDA regulations”.</p>	<p>“Current” is unnecessary.</p>

TABLE 52—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
117.201(a)(2)(ii) .....	Editorial change to place the clause “including through licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight” at the end of the provision, rather than in a parenthetical at the beginning of the provision.	Improve clarity.
117.206(a)(2) .....	Editorial change to specify “provide assurance that the temperature controls are consistently performed” rather than “provide assurance that they are consistently performed”.	Improve clarity.
• 117.206(a)(4)(ii) .....	Substitute the phrase “records are created” for the phrase “records are made”.	Consistency with other recordkeeping requirements of the rule.
• 117.206(a)(4)(iii) .....		
117.206(a)(4)(iii) .....	Change “within a week” to “within 7 working days”.	Conforming change associated with review of records of monitoring and corrective action records.
Subpart E (title) .....	Substitute the term “qualified facility exemption” for the phrase “exemption applicable to a qualified facility” or the phrase “exemption applicable to a qualified facility under § 117.5(a)”.	Conforming change associated with the definition of “qualified facility exemption.”
• 117.251 .....		
• 117.254 .....		
• 117.257 .....		
• 117.260 .....		
• 117.264 .....		
• 117.280 .....		
• 117.251 .....		
117.251(b)(1) .....	Change “import alert” to “refusal of food offered for import”.	Align with statutory language regarding imports rather than with specific procedures that FDA uses for refusing admission to foods offered for import.
117.254(a) .....	Change “FDA official senior to such Director” to “FDA official senior to either such Director”.	The provision refers to two “Directors” and the clause applies to either Director.
117.257(c)(2) .....	Refer to “conditions or conduct” rather than “conduct or conditions”.	Consistency with regulatory text in § 117.251(a)(2).
• 117.260(a)(2) .....	Change “within 10 calendar days” to “within 15 calendar days”.	Conforming change to reflect a timeframe of 15 calendar days, rather than 10 calendar days, in the order withdrawing a qualified facility exemption.
• 117.264(a)(1) .....		
• 117.267(a)(2) .....		
• 117.270(a) .....		
• 117.287(a) .....		
• 117.287(b)(2) .....		
• 117.287(b)(2) .....		
117.305 .....	Refer to “lot code” rather than “production code”.	Consistency with the definition of “lot.”
117.310 .....	Editorial changes to present the requirement in active voice.	Improve clarity.

**LIII. Comments on FSMA’s Rulemaking Provisions**

*A. Comments on Requirements in Section 418(n)(3) of the FD&C Act Regarding Content*

FSMA specifies that this rule acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods (section 418(n)(3)(C) of the FD&C Act). As previously discussed, we consider that the proposed human preventive controls rule strikes what we

consider to be an appropriate balance between acknowledging differences in risk and minimizing the number of separate standards applied to separate foods (78 FR 3646 at 3785).

(Comment 720) Some comments agree that the proposed human preventive controls rule reflects a risk-based approach and our recognition that a “one -size-fits-all” approach is not appropriate in the application of hazard analysis and risk-based preventive controls across the entire domestic and international food industry. These

comments ask us to retain this flexibility in the final rule by describing the required and expected results of the program, but not going as far as prescribing the process and methodology taken to get there. Other comments emphasize that the final rule must provide sufficient flexibility to allow facilities to adopt practices that are practical and effective for their specific, individual operations.

(Response 720) The final rule directs the owner, operator, or agent in charge of a facility to establish and implement



a food safety plan that includes a written hazard analysis, preventive controls that the facility identifies to control hazards requiring a preventive control, and establish and implement appropriate preventive control management components to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. As requested by the comments, the rule does not prescribe the process and methodology to "get there."

(Comment 721) Some comments ask us to adopt a commodity-specific approach to RACs when activities conducted on RACs are subject to the human preventive controls rule. The requested commodity-specific approach would exempt (or, at a minimum, defer regulation of) "low-risk commodities (such as table grapes)" from the human preventive controls rule. These comments note that we have acknowledged that just five commodity groups (leafy greens, tomatoes, herbs, melons, and sprouts) accounted for 77 percent of all produce-related outbreaks, 54 percent of produce-related illnesses, and 56 percent of produce-related hospitalizations between 1996 and 2010 (78 FR 3504 at 3525). These comments assert that the principal benefits of the FSMA rules will come from regulating these crops and that we cannot claim to have acknowledged differences in risk if we adopt a "one-size-fits-all" strategy. These comments ask us to apply the human preventive controls rule only to RACs that fall within the five highest-risk commodity groups and to any other specific commodities that we have determined pose a comparable risk based on outbreak history and the commodity's characteristics.

Other comments asserting that the rule is "one-size-fits-all" likewise ask us to apply the human preventive controls rule only to the highest risk commodities but do not narrowly direct their request to RACs. Some of these comments state that regulations must be scale- and supply-chain appropriate to be effective and assert that a "one-size-fits-all" approach will put small and mid-sized farms and processors out of business, undermining public health goals, such as increased production of, availability of, and access to healthy foods, as well as economic opportunity, equity, and job-creation goals.

(Response 721) We decline these requests to apply the human preventive controls rule only to foods determined to be of the highest risk and disagree that the rule is "one-size-fits-all." For example, several provisions of the rule expressly qualify that the requirements

apply as appropriate to the facility, the food, the nature of the preventive control and its role in the facility's food safety system, the nature of the hazard, or a combination of these factors (see, e.g., § 117.135(c), (c)(1), and (c)(3); § 117.140(a) and (b); § 117.150(a); § 117.160(a); § 117.165(a) and (b)); and § 117.410(d)(1)). The exemptions we are establishing are provided by section 103 of FSMA. As discussed in Response 222, facilities that are subject to the rule would consider the risk presented by the products as part of their hazard evaluation. A facility that appropriately determines that there are no hazards requiring a preventive control associated with its food products would document that determination in its written hazard analysis but would not need to establish preventive controls and associated preventive control management components for its products. (See also Response 16.)

(Comment 722) Some comments interpret the statutory direction in section 418(n)(3)(C) of the FD&C Act to mean that Congress granted us authority to provide flexibility for businesses of all sizes and types (*i.e.*, not just small businesses), as well as to acknowledge differences in risk. These comments assert that section 418(n)(3)(C) grants us authority to exempt distribution centers from the requirements for hazard analysis and risk-based preventive controls because: (1) Distribution centers are very low-risk facilities and (2) requiring distribution centers to comply with those requirements would not be practicable.

(Response 722) We disagree with these comments. See Response 221 for our response to comments that ask us to establish exemptions based on the risk presented by a food product and Response 226 for our response to comments that request an exemption for facilities such as supermarket distribution centers. The rule establishes an exemption for facilities solely engaged in the storage of unexposed packaged food (see § 117.7(a)), except that there are modified requirements for such establishments engaged in the storage of TCS foods (see § 117.7(b) and 117.206).

(Comment 723) Some comments state that Grade "A" dairy products are already effectively regulated under the PMO, and assert that subjecting these products to the human preventive controls rule would apply two separate standards, doubling rather than minimizing the number of separate standards that apply to separate foods. These comments ask us to instead acknowledge the reduced risk profile of foods produced in accordance with the

PMO and allow dairy products to continue to be regulated under one standard, the PMO. These comments also assert that exempting PMO-regulated facilities from the rule would allow us to better tailor our requirements to those foods not currently manufactured under such regulatory programs, which would also minimize the need to develop separate guidance and standards for this segment of the dairy industry.

(Response 723) See Response 214 for a discussion of our approach to PMO-regulated facilities.

(Comment 724) Some comments assert that the rule addresses differences in risk based on the number of people affected in the event of contaminated product being sold rather than on the types of hazards identified for a particular food and the ability to address those hazards via preventive practices, because the rule bases modified requirements on company revenues, customer type (restaurant and retail establishments), and customer location (275 mile radius). These comments assert that the proposed modified requirements do not properly address food safety risk through prevention and ask us to establish risk-based standards that require preventive practices to address identified hazards for a particular food and process for all companies manufacturing, processing, packing, and holding food.

Other comments assert that the statutory direction to require hazard analysis and risk-based preventive controls for all facilities that are required to register as a food facility under the section 415 registration regulations does not take into consideration the significant differences in risk profiles of fresh produce facilities and food processing and manufacturing facilities. These comments further assert that the section 415 registration regulations are not risk-based but simply served to keep a catalogue of facilities supplying the U.S. food supply and that it is not logical or appropriate that a fresh produce facility that packs RACs should be subject to the same regulatory controls as food manufacturing facilities such as those that produce canned foods or infant formula.

(Response 724) We disagree with these comments. See Response 222, in which we respond to comments asserting that a food safety plan should only be required for high-risk processing facilities. The new requirements for hazard analysis and risk-based preventive controls are not "one-size-fits-all," and facilities that are subject to the rule would consider the risk

presented by the products as part of their hazard evaluation.

*B. Comments on Requirements in Section 418(n)(5) of the FD&C Act Regarding Review of Hazard Analysis and Preventive Controls Programs in Existence on the Date of Enactment of FSMA*

FSMA directs us to review regulatory hazard analysis and preventive control programs in existence on the date of its enactment, including the PMO, to ensure that the regulations we establish are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on that date. (See section 418(n)(5) of the FD&C Act.) Consistent with that statutory direction, we previously compared the key features of our proposed requirements to implement section 418 of the FD&C Act to certain domestic and international food safety standards (Ref. 100) (78 FR 3646 at 3785 to 3788).

In the following paragraphs, we discuss comments specifically directed to the statutory direction in section 418(n)(5) of the FD&C Act. For examples of other comments related to the consistency of the proposed human preventive controls rule with applicable domestic and internationally-recognized standards, see Comment 8, Comment 215, Comment 372, Comment 718, and Comment 719.

(Comment 725) Some comments assert that a proper harmonization is needed with international standards and ask us to harmonize the FSMA requirements for the food safety plan with international and domestic HACCP programs. These comments also ask us to explain any differences between the FSMA food safety plan and the existing HACCP programs and ask us to provide exporters with background information and specific examples of differences, including how firms are directed to set their CCPs and critical limits.

(Response 725) As previously discussed (Ref. 102 and 78 FR 3646 at 3785 to 3788), we believe the human preventive controls rule is consistent with existing food safety programs. We have updated our 2012 memorandum entitled “Comparison of Proposed Subpart C (Hazard Analysis and Risk-Based Preventive Controls) to Various Existing Domestic and International HACCP-Based Standards” (Ref. 102) to reflect the provisions of the final human preventive controls rule (rather than the proposed human preventive controls rule) (Ref. 65). The comparative format of the updated memorandum provides the background information and specific

examples of differences requested by these comments.

However, neither this rule nor our updated memorandum (Ref. 65) provide firms with direction on how to set their CCPs and critical limits. A facility has flexibility to establish and implement appropriate preventive controls, including controls at CCPs and including any critical limits that the facility determines are necessary to provide assurances that hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

(Comment 726) Some comments ask whether we concluded, in light of the statutory direction in section 418(n)(5) of the FD&C Act, that the CGMP requirements in combination with the standards of identity for cheese in part 133 do not provide adequate public health controls within the cheese manufacturing industry. According to these comments, under regulations in part 133 many cheeses have an option to use unpasteurized milk, provided the cheese manufactured from unpasteurized milk is aged for at least 60 days at not less than 35 degrees F. These comments ask whether the 60 day aging process will be recognized as a preventive control.

(Response 726) Section 418(n)(5) of the FD&C Act directs us to review “regulatory hazard analysis and preventive control programs” in existence on the date of its enactment. We have not considered provisions in the standards of identity (whether in part 133 or in other standards of identity) in our analysis directed by section 418(n)(5) of the FD&C Act, because standards of identity are not hazard analysis and preventive controls programs. We establish food standards, such as the standards in part 133 (Cheeses and Related Cheese Products) under section 401 of the FD&C Act (21 U.S.C. 341) to promote honesty and fair dealing in the interest of consumers. In contrast to this role of food standards, hazard analysis and preventive control programs (e.g., HACCP) involve a systematic approach to the identification and assessment of the risk (likelihood of occurrence and severity) of hazards from a particular food or food production process or practice and the control of those hazards (78 FR 3646 at 3659).

We acknowledge that part 133 requires an aging period, such as at least 60 days at not less than 35 degrees F, for cheese manufactured from

unpasteurized milk, and that this aging period was presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was consumed. We recently issued a request for comments and for scientific data and information that would assist us in identifying and evaluating intervention measures that might have an effect on the presence of bacterial pathogens in cheeses manufactured from unpasteurized milk (80 FR 46023, August 3, 2015). It is premature to determine what role, if any, an aging process could play in a food safety plan for the manufacture of cheese from unpasteurized milk.

(Comment 727) Some comments assert that we did not make the required comparison of the proposed human preventive controls rule to the PMO available for review.

(Response 727) The required comparison of the proposed human preventive controls rule to the PMO is available in the docket for this rulemaking (Docket FDA–2011–N–0920) (see Reference 193 to the proposed human preventive controls rule). We stated that it was available during the discussion of section 418(n)(5) of the FD&C Act (36 FR 3646 at 3786). For this final rule, we have both updated this comparison (Ref. 65) and prepared a separate comparison of the final provisions of this rule to the PMO (Ref. 49).

**LIV. Comments on Proposed Removal of 21 CFR Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food**

We proposed to remove current part 110 after the compliance date for all businesses to be in compliance with the requirements of new part 117. We received no comments that disagreed with this proposal. As discussed in section LVI.A, businesses will be required to comply with new part 117 1, 2, or 3 years after September 17, 2015, depending on the size of the business. Thus, part 110 will be removed on September 17, 2018.

**LV. Comments on Proposed Conforming Amendments**

We proposed a series of conforming amendments to current regulations (in §§ 106.100(j) and (n), 114.5, 120.3, 120.5, 120.6(b), 123.3, 123.5(a), 123.11(b), 129.1, 179.25(a), and 211.1(c)) that refer to the requirements of part 110. With the proposed conforming changes, these current regulations would refer to part 117, as well as part 110. We also proposed that when part

110 is removed, all references to part 110 be removed from our regulations.

We received no comments that disagreed with the proposed conforming changes. Therefore, at this time we are amending each of these current regulations so that they refer to part 117, as well as part 110. When part 110 is removed, we will issue conforming amendments to remove all references to part 110 from our regulations.

**LVI. Effective and Compliance Dates**

*A. Effective and Compliance Dates for Part 117*

We proposed that any final rule based on proposed part 117 become effective 60 days after its date of publication in the **Federal Register**, with staggered compliance dates (78 FR 3646 at 3673). Businesses other than small and very small businesses would have 1 year from the date of publication of the final rule to comply with the rule, whereas small businesses would have 2 years and very small businesses would have 3 years to comply with the rule. We proposed that these staggered compliance dates would apply to the modernized CGMPs that would be established in subpart B of part 117, as well as the new requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3674). The staggered compliance dates for compliance with the modernized

CGMPs would apply to all food establishments, including those establishments that are subject to the CGMPs in subpart B, but exempt from the new requirements for hazard analysis and risk-based preventive controls in subparts C and G. For the purpose of determining its compliance date, the definitions of “small business” and “very small business” established in this rule apply, regardless of whether a food establishment is subject to requirements of another rule (such as our HACCP regulation for juice in part 120) that may have a different definition for “small business” and “very small business.”

Most of the comments support staggering the compliance dates. For example, one comment states that the rule would substantially prevent wide-ranging harm associated with contaminated processed foods, but at a reasonable cost to the food industry, with ample exclusions and extended compliance dates for small facilities. However, some of the comments that support staggering the compliance dates suggest extending the compliance dates for some sizes of business (see, e.g., Comment 728, Comment 730, and Comment 731).

In the following sections, we discuss comments that suggest extensions to the proposed compliance dates or ask us to clarify how the compliance dates will apply. After considering these

comments, we are establishing the effective and compliance dates as proposed, except for the following three changes. First, we are extending the compliance date for PMO-regulated facilities to comply with the requirements of subparts C and G to September 17, 2018 (See Response 214). Second, we are establishing an earlier compliance date for the financial records that a facility maintains to support its status as a very small business that is eligible for the qualified facility exemption in § 117.5(a). Specifically, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016. (See Response 155.) Third, we are establishing separate compliance dates for the supply-chain program provisions. As discussed in Response 729, a receiving facility’s compliance date with the supply-chain program provisions of this rulemaking is the later of: (1) March 17, 2017; (2) for a receiving facility that is a small business, September 18, 2017; and (3) when the supplier of a raw material or other ingredient will be subject to the human preventive controls rule or the produce safety rule, 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule. See table 53 and table 54 for a summary of these compliance dates.

**TABLE 53—COMPLIANCE DATES FOR THE REQUIREMENTS OF PART 117 OTHER THAN THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM**

[Subpart G]

Size of business	Compliance date
Qualified facility (including very small business) as defined in § 117.3 ...	September 17, 2018, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016.
Small business as defined in § 117.3 .....	September 18, 2017.
Businesses subject to the Pasteurized Milk Ordinance .....	September 17, 2018.
All other businesses .....	September 19, 2016.

**TABLE 54—COMPLIANCE DATES FOR THE REQUIREMENTS OF THE SUPPLY-CHAIN PROGRAM**

[Subpart G]

Situation	Compliance date
A receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule.	September 18, 2017.
A receiving facility is a small business and its supplier is subject to the human preventive controls rule or the produce safety rule.	The later of: September 18, 2017 or 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule.
A receiving facility is not a small business or a very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule.	March 17, 2017.
A receiving facility is not a small business or a very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule.	6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule.

We also are establishing two additional compliance dates applicable to qualified facilities. First, we are establishing December 17, 2018 as the compliance date for (1) the initial submission of the attestation by a facility that it is a qualified facility (see § 117.201(a)(1)) and (2) the attestation by a qualified facility about its food safety practices (see § 117.201(a)(2)(i)) or that it is in compliance with non-Federal food safety law (see § 117.201(a)(2)(ii)).

Second, we are establishing January 1, 2020, as the compliance date for the notification requirement of § 117.201(e)(1). A qualified facility that submits an attestation that it is in compliance with applicable non-Federal food safety law must notify consumers as to the name and complete business address of the facility where the food was manufactured or processed (see § 117.201(e)). If a food packaging label is required, the required notification must appear prominently and conspicuously on the label of the food (see § 117.201(e)(1)). This notification requirement may require some qualified facilities to update the labels of their packaged food products.

For many labeling requirements, the timeframe for a food establishment to comply with new or revised labeling requirements is governed by a uniform compliance date (see, e.g., 79 FR 73201, December 10, 2014 and 77 FR 70885, November 28, 2012). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices. We generally announce a uniform compliance date during November or December of even-numbered calendar years, and establish the uniform compliance date to be January 1 of an upcoming even-numbered calendar year. For example, in December, 2014, we issued a final rule establishing January 1, 2018, as the uniform compliance date for food labeling regulations that are issued between January 1, 2015, and December 31, 2016 (79 FR 73201). Likewise, in November, 2012, we issued a final rule establishing January 1, 2016, as the uniform compliance date for food labeling regulations that are issued between January 1, 2013, and December 31, 2014 (77 FR 70885, November 28, 2012). These uniform compliance dates

provide a minimum of 1 year between the date when a food labeling regulation is issued and the date when a food establishment must comply with that regulation. Following this pattern, we intend that the next uniform compliance date will be January 1, 2020 for food labeling regulations that are issued between January 1, 2017 and December 31, 2018. A qualified facility that submits an attestation that it is in compliance with non-Federal food safety law would become subject to the notification requirement during this timeframe—*i.e.*, by December 31, 2018.

The compliance date that we are establishing for the notification requirement of § 117.201(e) (*i.e.*, January 1, 2020) is consistent with the approach of a uniform compliance date and will provide a qualified facility that chooses to submit an attestation about compliance with non-Federal food safety law with more than 1 year from the applicable general compliance date to comply with the notification requirement. This compliance date also will provide such a qualified facility with more than 4 years to comply with the notification requirement relative to the date of publication of this rule.

(Comment 728) Some comments assert that one year is not a sufficient amount of time for any size firm to comply with the human preventive controls rule based on experiences with the implementation of our HACCP regulation for seafood. These comments assert that HACCP required a “cultural change” for many seafood processors. The comments acknowledge that the knowledge of HACCP and food safety systems has advanced throughout the food industry in the nearly 20 years since we established our HACCP regulation for seafood but nonetheless assert that firms will need to modify previously developed food safety plans in order to comply with the rule. The comments also assert that training cannot realistically begin until both the final rule and associated guidance are published and that the experiences with implementing our HACCP regulation for seafood should be magnified for the human preventive controls rule because the universe of food processors needing to comply will be much larger, both in the United States and throughout the world. These comments ask us to establish a 2-year compliance period for the largest firms to allow time for the training programs and guidance documents to be developed.

(Response 728) We decline this request. As the comments acknowledge, approximately 20 years have elapsed since we issued the final rule establishing our HACCP regulation for

seafood, and requirements such as conducting a hazard analysis and implementing appropriate preventive controls, with associated preventive control management components, are no longer novel. We agree that the details of the final requirements could not be known until publication of this final rule, and that the guidance we are developing can help businesses develop or modify their food safety plans and training programs. However, the statutory direction in section 418 of the FD&C Act is extensive and, thus, signaled the general nature of the requirements as early as January 4, 2011, when FSMA was signed into law. In addition, we conducted extensive stakeholder outreach during the 10-month comment period for the 2013 proposed human preventive controls rule (79 FR 58524 at 58528). We also provided public notice about proposed changes to the farm-related definitions that affect the determination of whether a business is subject to the rule, the framework for hazard analysis and risk-based preventive controls, and about specific potential requirements for environmental monitoring, product testing, and a supplier program, in the 2014 supplemental human preventive controls notice, and conducted outreach activities to discuss the new or revised proposed provisions in that supplemental notice (see section I.A and Ref. 1 and Ref. 2). In light of the broad awareness of preventive programs such as HACCP, the statutory direction in FSMA, and extensive outreach associated with this rulemaking, we disagree that the largest businesses will need more than one year to fully adapt their programs to the specific requirements of the final rule. Although a business may find it useful to revise certain aspects of its food safety plan, or enhance its training materials, after we issue implementation guidance such as that discussed in Response 2, such revisions would serve to enhance the company's food safety plan rather than be a necessary resource before a food safety plan could be developed and implemented or before employees could be trained in their specific duties associated with implementing the plan.

Moreover, for our HACCP regulation for seafood we established a single compliance date regardless of the size of the business, and announced our intention to monitor the progress of the industry after publication of the final rule. If we determined that the compliance date for that regulation was placing a significant and unreasonable burden on the industry, particularly on small businesses, we were willing to

consider an extension for as much as one additional year or some form of additional technical assistance (**Federal Register** of December 18, 1995, 60 FR 65096 at 65169). Approximately 5 years later, we issued the final rule for our HACCP regulation for juice (January 19, 2001, 66 FR 6138), in which we staggered the compliance dates based on business size and provided only one year for the largest businesses to comply. The staggered compliance dates that we proposed for the human preventive controls rule based on business size are consistent with the approach we took for the HACCP regulation for juice, given increased awareness of hazard analysis and the application of risk-based preventive controls in the years after we issued the final rule for seafood HACCP.

(Comment 729) Some comments point out that there are staggered compliance deadlines for small and very small businesses under both the human preventive controls rule and the produce safety rule. These comments express concern that to the extent a receiving facility subject to the human preventive controls rule is required to comply with the rule sooner than a current or prospective supplier, that receiving facility is in effect creating pressure for that supplier to come into compliance on a timetable inconsistent with that established in the rules. The “adequacy” of the receiving facility’s verification activities becomes potentially even more problematic to demonstrate to FDA inspectors.

(Response 729) We are establishing separate compliance dates for the supply-chain program provisions. While this adds complexity, we are doing this for two main reasons. First, we are aligning, to the extent feasible, the compliance dates of the supply-chain program provisions of this rule with the compliance dates of the forthcoming FSVP rule, which we intend to publish in the near future. This will provide greater consistency across the programs, particularly with respect to the verification of domestic and imported raw materials and ingredients. For the FSVP rule, we proposed a minimum compliance period of 18 months.

Second, to address the concerns expressed in these comments we want to minimize the likelihood that a receiving facility will be required to comply with the supply-chain program provisions of this rule before its supplier is required to comply with applicable new food safety regulations implementing FSMA. Our goal is to avoid a situation in which a receiving facility would be required to develop a supply-chain program for a food from a

particular supplier and then be required to revise this supply-chain program shortly thereafter once the supplier is subject to an applicable new food safety regulation—specifically, the human preventive controls rule or the forthcoming produce safety rule.

Therefore, a receiving facility’s compliance date with the supply-chain program provisions of this rulemaking is the later of: (1) March 17, 2017; (2) for a receiving facility that is a small business, September 18, 2017; and (3) when the supplier of a raw material or other ingredient will be subject to the human preventive controls rule or the produce safety rule, six months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule.

(Comment 730) One comment from a State department of agriculture asserts that the farm-related definitions in the 2013 proposed human preventive controls rule would cover a large sector of agricultural operations that would not be able to comply due to cost and would need a longer compliance schedule.

(Response 730) We believe that the revised definitions that we proposed in the 2014 supplemental human preventive controls notice for “farm,” and for on-farm manufacturing, processing, packing, and holding activities that trigger a requirement for an establishment that is also a farm to register as a food facility, largely address these comments. Many activities that farms conduct on RACs, and that would have triggered a requirement to register under the definitions established in the section 415 registration regulations in 2003 (68 FR 58894), will not trigger a requirement to register under the definitions we are establishing in this final rule.

We are aware of the impact that food safety rulemakings may have on small and very small businesses, and in the 2001 final rule to establish our HACCP regulation for juice we began the practice of reducing the burden on these businesses by staggering the compliance dates and giving small and very small businesses additional time to comply with food safety regulations. Since that time, we have continued this practice of staggering compliance dates in rulemakings such as establishing CGMPs for dietary supplements (June 25, 2007, 72 FR 34752) and preventing *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (July 9, 2009, 74 FR 33030 at 33034). We believe that the staggered compliance dates in this final rule provide adequate time for businesses of all sizes to comply with the rule, and that the additional

compliance time provided for small and very small businesses sufficiently minimizes the burden on those businesses. (See also Response 731.)

(Comment 731) Some comments assert that differences between the proposed compliance dates for different sizes of businesses subject to the human preventive controls rule and the proposed compliance dates for different sizes of businesses subject to the produce safety rule will create confusion within industry and State and local regulators. These comments also express concern that certain farms will be subject to both rules at the same time, and that compliance with each rule will require significant investment of both resources and time, both to understand and to implement the various provisions. These comments ask us to consider a process to permit very small and small farms (as defined under the proposed produce safety rule) that are also mixed-type facilities subject to the human preventive controls rule to apply for a one-time compliance period extension of twelve months by notifying FDA in writing. These comments assert that only a small percentage of businesses will be eligible for such a one-time extension and that the extension will enable a farmer to plan accordingly, first implementing the produce safety rule and then implementing the human preventive controls rule.

(Response 731) We decline this request. See Response 730 regarding the impact of the revised farm-related definitions on businesses that conduct on-farm activities. A small or very small business that only conducts the on-farm low-risk activity/food combinations we have specified as exempt (see § 117.5(g) and (h)) is exempt from all requirements for hazard analysis and risk-based preventive controls. A very small business that conducts on-farm activity/food combinations in addition to those low-risk activity/food combinations would be subject to an exemption as a qualified facility and is subject only to the modified requirements we are establishing in § 117.201.

A small business that would not be exempt because it conducts other activities in addition to those low-risk activity/food combinations that would qualify the business for an exemption will have 2 years to comply with the human preventive controls rule. We acknowledge that complying with both the human preventive controls rule and the produce safety rule involves significant new requirements, but we have provided extended compliance periods and done substantial outreach.

(Comment 732) Some comments ask us to clarify when a very small business would need to comply with the rule if the business starts up after the rule goes into effect. For example, if a very small business starts up six months after the date of the final rule, would that business have 2.5 years to comply, or would it need to comply immediately?

(Response 732) A very small business that is operating as of the date of publication of the final rule, or begins operating any time before the compliance date for very small businesses, must comply with the rule by the compliance date for very small businesses. That date is fixed in time and is not a moving date based on market entry. A very small business that begins operation any time after the compliance date for very small businesses must comply with the rule when it begins operation, and should plan accordingly.

*B. Effective and Compliance Dates for Revisions to Part 1*

This rule includes revisions to the “farm definition,” and to activities related to the “farm definition,” in §§ 1.227 and 1.328. This rule also includes technical amendments to §§ 1.241, 1.276, and 1.361. We did not discuss effective and compliance dates for these revisions to part 1 in either the 2013 proposed human preventive controls rule or the 2014 supplemental human preventive controls notice. See table 55 for the effective dates and compliance dates that we are establishing in this final rule. As with the requirements we are establishing in part 117, the revisions to part 1 become effective 60 days after the date of publication of this rule (*i.e.*, November 16, 2015). The compliance dates for the technical amendments to §§ 1.241, 1.276, and 1.361 are the same as the effective dates. Two of these technical amendments change the citation to the FD&C Act from “the act” to “the Federal Food, Drug, and Cosmetic Act”; the third technical amendment updates a cross-reference to the definition of “manufacturer” in regulations for the prior notice of imported food.

The principal impact of the substantive revisions to the definitions in the section 415 registration regulations and the section 414 recordkeeping regulations is whether the revised definitions affect the classification of a business as an entity that is subject to these regulations. We believe that some businesses that were subject to one or both of these regulations will no longer be subject to either of these regulations because the activities that these businesses conduct

are now within the “farm” definition and, thus, exempt from those regulations. During the 60 day period between the publication of this rule and its effective date, FDA does not intend to prioritize enforcing the section 415 registration regulations and the section 414 recordkeeping regulations for businesses that will no longer be subject to either or both of those regulations once the revisions are effective.

However, we cannot predetermine whether some businesses that previously were not subject to the section 415 registration regulations, the section 414 recordkeeping regulations, or both will not become subject to one or both of those regulations. The approach we are taking to the compliance date for the revisions to these regulations is the same as the approach we took when we first established these regulations. First, for the section 415 registration regulations, the compliance date is the same date as the effective date. Such establishments must register as a food facility by November 16, 2015. (See 68 FR 58894, which establishes an effective date for the section 415 registration regulations but does not establish a different date for compliance with those regulations.) An establishment that is required to register as a food facility by November 16, 2015 will be required to comply with the requirements in part 117 as described in section LVI.A.

For the section 414 recordkeeping regulations, we are requiring that establishments that become subject to these requirements for the first time as a result of the revisions that become effective November 16, 2015 comply with the requirements using the same criteria as we applied when we first established this regulation as shown in table 55. (See 69 FR 71562, December 9, 2004.)

TABLE 55—COMPLIANCE DATES FOR THE SECTION 414 RECORDKEEPING REGULATIONS

Size of business	Compliance date
10 or fewer full-time equivalent employees	September 18, 2017.
Businesses employing fewer than 500, but more than 10 full-time equivalent employees	March 17, 2017.
All other businesses	September 19, 2016.

*C. Effective Dates for Conforming Amendments*

The conforming amendments to regulations in parts 106, 114, 120, 123,

129, 179, and 211 are technical amendments that add a cross-reference to part 117 where the current regulation refers to part 110. The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 117 are not subject to part 11. The conforming amendment to part 16 adds a reference to the scope of part 16 for new procedures in part 117, subpart E that provide a person with an opportunity for a hearing under part 16. These conforming amendments are effective on November 16, 2015, the same date as the effective date of part 117. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance dates will be determined by the dates for compliance with part 117.

*D. Delayed Effective Dates for Provisions That Refer to the Forthcoming Rules for Produce Safety and Third-Party Certification*

The following provisions refer to provisions we intend to establish in the near future in part 112 (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption): §§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13). In addition, paragraph (2) of the definition of “qualified auditor” in § 117.3, and § 117.435(d) refers to provisions we intend to establish in the near future in part 1, subpart M (Accredited Third-Party Food Safety Audits and Food or Facility Certification). In addition, §§ 117.405(a)(2) and 117.475(c)(2) refer to provisions we intend to establish in the near future in part 1, subpart L (Foreign Supplier Verification Programs for Food Importers). We will publish a document in the **Federal Register** announcing the effective dates of paragraph (2) of the definition of “qualified auditor” in § 117.3, and §§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), 117.405(a)(2), 117.435(d), 117.475(c)(2) and 117.475(c)(13).

**LVII. Compliance and Enforcement**

Gaining industry compliance with the provisions of this rule is as important as establishing the provisions. A central element of our strategy to gain industry compliance is to help make available to facilities subject to this rule the education and technical assistance they need to understand and implement the requirements (Ref. 6). Within the Agency we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry

understanding and implementation of FSMA standards (Ref. 6). This will allow us to respond in a timely and consistent way to industry questions on preventive controls technical and compliance issues (Ref. 6).

We also are working in collaboration with the FSPCA to develop training materials and establish training and technical assistance programs (Ref. 5) and (Ref. 7). The FSPCA includes members from FDA, State food protection agencies, the food industry, and academia. It is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health, a nationally-recognized leader in food safety. In addition to developing a standardized preventive controls training curriculum, the FSPCA is developing selected sections of model food safety plans for several food types that will provide needed instructional examples. Although we have provided funding to the FSPCA to develop a standardized preventive controls training curriculum, we are unable to fund training for individual groups who might need particular training materials.

We also are partnering with the NIFA of USDA to administer the FSMA-mandated National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, a grant program to provide technical assistance for FSMA compliance to owners and operators of small and medium-size farms and small food processors (Ref. 8). Such efforts will help ensure widespread voluntary compliance by encouraging greater understanding and adoption of established food safety standards, guidance, and protocols.

With regard to inspections, we will conduct regular inspections of domestic facilities to ensure that facilities subject to this rule are adequately implementing the required preventive controls and supply-chain program, pursuant to our inspection authority under section 704 of the FD&C Act. Our inspections will verify that such facilities are implementing systems that effectively prevent food contamination, and in particular, that they comply with the rule by implementing preventive controls, including supply-chain programs, to provide assurances that any hazard requiring a preventive control or supply-chain applied control has been significantly minimized or prevented.

In order to effectively carry out this new paradigm of food safety prevention, we will need to reorient and retrain our staff. To this end, we are seeking additional funding, including for the training of more than 2,000 FDA

inspectors, compliance officers, and other staff involved in food safety activities (Ref. 12).

We also plan to leverage the resources of State, local, tribal, and territorial governments to conduct domestic verification activities. We are working with officials from these governments through the PFP to develop and implement a national Integrated Food Safety System, which will focus on establishing partnerships for achieving compliance (see section 209(b) of FSMA), and which will allow us to utilize the thousands of State, local, and tribal inspectors available to help with the domestic verification process.

Consistent with FSMA, we will use our current resources, new resources that we obtain, and our partnerships to conduct regular inspections of covered facilities, focusing on those facilities that pose the highest risk to food safety. Section 201 of FSMA mandates that FDA inspect domestic high-risk facilities no less than once every 3 years. We are currently meeting this mandate, and even exceeding it with respect to certain domestic high-risk facilities. Once the FSMA rulemakings come into effect, we intend to build on this track record and to have an FDA or State inspection of domestic high-risk human food facilities on an annual basis to ensure hazards have been significantly minimized or prevented in compliance with this rule.

#### **LVIII. Executive Order 13175**

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of Tribal officials' concerns and how FDA has addressed them (Ref. 101). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at <http://www.fda.gov/pchfrule> or at <http://www.regulations.gov>. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### **LIX. Economic Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health

and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because facilities with less than 20 employees (both qualified and non-qualified facilities) will bear a large portion of the costs, the Agency concludes that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that will exceed this amount.

#### **LX. Analysis of Environmental Impact**

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment (Ref. 102) (Ref. 103). Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **LXI. Paperwork Reduction Act of 1995**

This rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food.

*Description:* The Food and Drug Administration (FDA) is proposing to amend its regulation for Current Good Manufacturing Practice in

Manufacturing, Packing, or Holding Human Food (CGMPs) to modernize it and to add requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. FDA is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in section 418 of the FD&C Act.

*Description of Respondents:* Section 418 of the FD&C Act is applicable to the owner, operator or agent in charge of a food facility required to register under section 415 of the FD&C Act. Generally, a facility is required to register if it manufactures, processes, packs, or holds food for consumption in the United States. There are 83,819 such facilities; 37,134 of these facilities are considered "qualified" facilities and have reduced requirements in regards to this rule-making.

In the following paragraphs, we describe and respond to the comments that we received for the PRA for both our 2013 proposed human preventive controls rule and our 2014 supplemental human preventive controls notice. We numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 733) Comments stated that we overestimated the recordkeeping burden because we assume the burden is evenly distributed across all facilities beginning in the first year. However, facilities that are not small or very small have one year from the effective date of the rule to come into compliance. For small facilities, compliance is delayed for 2 years and very small facilities will have 3 years. The agency's 7 year horizon for discounting burdens would need to be staggered to account for the delayed compliance dates in order to arrive at a consistent annualized burden of the records collection.

(Response 733) We clarify that our estimate for the recordkeeping burden for the first year is for the first full year that all facilities are responsible for the requirements for the rule. We note that the FRIA (Ref. 38) now uses a 10 year horizon for discounting burdens.

(Comment 734) Comments support our estimate that many facilities already keep the records required by section 418 of the FD&C Act and the proposed

human preventive controls rule as good business practice. Comments believe that preventive food safety systems are the norm for the food industry. Comments believe this is demonstrated by what they cite as 57 percent of the industry already operating under HACCP programs. Not accounting for the effects of widespread adoption of HACCP may result in an overestimate. The reason a majority of food facilities have already implemented HACCP or a HACCP-like systems is that preventive systems are the best, most cost-effective means of insuring against recall costs and potential criminal liability for releasing adulterated product into commerce. If the industry standard is prevention, then the baseline for calculating PRA burdens should be adjusted to account for that.

(Response 734) We concur that we do not account for those facilities that are in the process of adopting our requirements independently. We do address the impact of a likely trend toward adopting our requirements in the uncertainty analysis of our FRIA (Ref. 38).

(Comment 735) Comments assert that knowledge transferred from facilities already applying HACCP will be available to small and very small facilities during the delayed implementation period. Delayed implementation periods usually contemplate that smaller businesses will benefit from increased availability of advanced technology and knowledge that can lower the costs of compliance. Related comments suggest that the PRA does not appear to have considered that during the three-year implementation period standardized templates and software for hazard analyses and food safety plans may become available for food facilities. The availability of templates and software would reduce the time needed for small and very small facilities to prepare mandatory documents.

(Response 735) We concur that delayed implementation periods will benefit smaller businesses from the increased availability of advanced technology and knowledge that can lower the costs of compliance. We allowed the staggered compliance period for this very reason. We revised our estimate of the costs to learn about the requirements of rule in the main analysis. In our revised analysis, we estimate that facilities with fewer than 20 employees will devote 5 hours to learning about their requirements, rather than 10 hours. For facilities with 20 to 99 employees, one individual at the level of an operations manager will take about 10 hours to review and assess the

requirements or to learn about the requirements for their facility rather than 15 hours.

(Comment 736) Comments suggest that the PRA review does not account for reduced training costs for small and very small facilities derived from the availability for hire of trained employees. The average turnover rate in manufacturing in 2010 was 15 percent, suggesting some small businesses will be able to hire qualified individuals rather than training current employees.

(Response 736) We agree that some new employees will already be trained but we believe that we accounted for those that are already trained by only including burden hours for employees at facilities that disclosed to our survey that they did not conduct training. In addition, we estimated a turnover rate of 10 percent, which indicates that fewer new employees would require training than proposed by the comments, indicating that we did not overestimate the burden hours.

(Comment 737) Comments assert that we underestimated the recordkeeping burden of the proposed information collection, that our methodology and assumptions are wrong or that it is not possible to adequately assess the accuracy of our recordkeeping burden estimates. Comments further dispute our assessment that creation of a single food safety plan will require 110 hours and that one plan will be required per facility. In the experience of the comments' member organization, it takes considerably longer, with a median of over 200 hours per facility. Additionally, many plants currently have more than one HACCP plan in place. Large plants have multiple products, raw materials, processes, and equipment. Comments report that one large plant has 34 plans in place that took approximately 860 hours to develop and another large plant has 25 plans in place that took approximately 1385 hours to develop.

(Response 737) We concur that establishments might have more than one HACCP plan in place and we acknowledge that large establishments might require considerably more than 110 hours to develop a food safety plan. Our estimate is based on the average time to create a food safety plan for establishments of all sizes, so our estimate includes very small facilities that are likely to require considerably less than 110 hours, too.

(Comment 738) Comments assert that it is not clear if our assessment includes the considerable pre-work time that is required as an input to development of a HACCP plan. Pre-work includes activities such as employee training,



assembling the food safety plan team (which may require outside experts, and specific company experts like microbiologists, procurement, research and development, *etc.*), creating the processing and product profile, and creating a flow diagram. Some estimated that approximately 150–300 hours of pre-work are needed per facility before the actual HACCP plan is prepared.

(Response 738) Our analysis for the PRA includes pre-work time to the extent that pre-work time includes preparing the documents that are required in accordance with the rule. The preparation of records for the validation of process controls might be considered pre-work and would be considered in our estimate. We disagree that all of the pre-work mentioned by the comments should be included in our estimate of the burden hours.

(Comment 739) Comments believe that a robust food safety plan should be developed by a multidisciplinary group of professionals with a broad skill set. These comments believe that it is unclear what wage rate we used in our estimate of the operating and maintenance costs associated with implementing and maintaining a food safety plan or if those estimates consider the range of wages applicable to the broad team involved in plan development.

(Response 739) We concur that a multidisciplinary group of professionals is likely to be involved in the plan development. Our estimate is based on an average wage rate for the type of professional that would be likely to develop the specific document. We included our estimate for the average wage rate that we used for each type of document in our description.

(Comment 740) Comments suggest that our estimate that facilities will keep records of 730 monitoring activities and that each record can be made in about three minutes (36.5 hours total per year per facility), severely underestimates both the number of activities and the time required.

(Response 740) Comments did not provide supporting evidence. In the absence of a better substantiated estimate, we decline to revise our estimate.

(Comment 741) Comments assert that we severely underestimated the number of monitoring records. Comments claim that several of their members reported over 50,000 monitoring events in their facilities annually. They provided as an example that if one production line has two metal detectors and one barcode scanner, there would be three records per shift, with three shifts per day. Assuming 300 days of operation per

year, this one line would have 2700 records per year. Most plants have multiple lines and conduct monitoring beyond metal detectors and bar code scanners. A large plant may have well over 730 monitoring events per day—not per year as FDA estimates.

(Response 741) We concur that a large establishment might have significantly more monitoring events. Our analysis is based on the average of all establishments, including very small establishments that are unlikely to so many events. In the absence of substantiated evidence for the large average number of monitoring events, we decline to revise our estimate.

(Comment 742) Comments let us know that it is unclear what activities are included in our time estimate. Comments claim that the amount of time required to produce a record will vary depending on whether the estimate only includes documenting time to create the record or whether it also includes the underlying task of monitoring and follow-up tasks like filing. Furthermore, the number of monitoring events could be significantly higher than the estimate if all preventive controls are subject to similar monitoring requirements as critical control points. Thus, although some tasks may take only three minutes to monitor, our members suggest that six minutes per monitoring event may be a more accurate estimate of the information collection burden.

(Response 742) We concur with the comments that time will vary by what's included in the task. The PRA requires that we include in our burden estimate the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. We believe our estimate of 3 minutes, as an average over time, accurately reflects the entire requirement for recordkeeping, including the initial time to create, maintain and file the records. Many, if not most, records can be created, maintained and filed in batch to reduce time, especially when done electronically, so we decline to revise our estimate of 3 minutes, in the absence of more evidence.

(Comment 743) Comments claim that our estimated burden for corrective action records assumes that 18,291 facilities subject to preventive controls will have two corrective actions to document, which will take one hour each to record. Our assessment does not explain the basis for estimating that only 18,291 facilities will engage in corrective actions. Because occasional deviations from expected values are an

unavoidable part of any manufacturing environment, it should be expected that all facilities subject to preventive controls regulations will have corrective actions to document annually.

Comments claim that our time estimate also appears to be low. Comments report that their member's facilities typically engage in between 10 and 60 corrective actions per year for critical control point deviations, which is considerably higher than our proposed estimate of two actions per year. Although it may take only one hour to manage the record involved with the corrective action, additional time would be required to investigate the underlying issue and implement the corrective action. We expect it can take between two and four hours to investigate a single corrective action and come up with a solution.

(Response 743) We revised our estimate for the number of establishments that would be subject to the requirements to 16,285 based on the most recent number of facilities registered with FDA and that are subject to subparts C and G. We address elsewhere our reason for not requiring all facilities to be subject to subparts C and G. We recognize that some facilities will conduct more than our estimate of two corrective actions per year. Our estimate is based on actions that must be made to correct a problem that has occurred with the implementation of a preventive control; or that might affect the safety of the food. Many corrective actions might occur to address product quality problems, unrelated to food safety. Further, our estimate for the PRA is necessarily only related to the recordkeeping burden, and should not include the additional time that would be required to investigate the underlying issue and implement the corrective action.

(Comment 744) Comments noted that our estimate for keeping verification records assumes facilities will keep records of 244 verification events and that each record can be made in about three minutes (12.2 hours total per year per facility). Comments claim that our assessment does not explain whether this estimate considers the broad scope of activities included in the definition of "verification" in the proposed rule (proposed § 117.150), although it should. The proposed regulatory definition of verification not only includes verification of monitoring, corrective actions, and implementation and effectiveness (*e.g.*, calibration), but also includes validation and reanalysis. Validation and reanalysis of a food safety plan are extensive activities that take tens, if not hundreds, of hours to conduct. The estimate does not appear

to account for these activities. The comments note that even when considering just the traditional activities considered as verification under HACCP, their members' experience shows that our current verification estimate is too low. They received a wide range of estimates of the number of verification events conducted annually—from about 200 to over 14,000 events per year. Similarly, their members report that it takes them between 8 minutes and 2 hours per verification event. It is unclear whether our estimate includes only the time to handle the record or also the time to conduct the verification. The comments suggest this missing information in our estimate may explain the range of responses in our survey. Comments claim that the time to conduct the verification should be included.

(Response 744) We concur that our estimates should assess the full scope of activities associated with recordkeeping. Our analysis did neglect to include the recordkeeping activities for the validation of process controls, which are an essential part of verification. We added our estimate for the burden of validation and we revised our description about the recordkeeping burden for the food safety plan to state that our estimate does include the burden of reanalysis of the food safety plan. For the purposes of the PRA, our estimate of the burden of recordkeeping is only for the time of recordkeeping, not the full verification activity. We decline to revise our estimate based on the comment because insufficient evidence was presented about just the time for recordkeeping.

(Comment 745) Comments noted that we estimate that 47,484 food manufacturers will need to document the training of their preventive controls qualified individual, which will take 15 minutes per facility. (We note that the proposed rule defined and used the term "qualified individual, but the term in the final rule is "preventive controls qualified individual, and we use the term "preventive controls qualified individual" in describing these comments on this topic.) They are unclear why we estimate that only 47,484 food manufacturers and not all registered facilities subject to preventive controls would be required to have a preventive controls qualified individual and to document that person's training. Comments state that their members found that we are accurate in our assumption, although our estimate for the documentation may take 30 minutes in some situations. Comments also suggest that many facilities may need to document more than one preventive

controls qualified individual. Comments provide as an example, that a thermal process authority outside of the plant may be a qualified individual in terms of confirming the process has a validated kill step, while the same facility will likely have a qualified individual responsible for approving the food safety plan. This situation would increase the time burden beyond estimate.

(Response 745) Our estimate of 47,484 establishments that will need to document the training of their preventive controls qualified individual was based on our estimate of the number of facilities that are subject to subparts C and G of the rule. We updated our estimate to 46,685 based on our most recent count of facilities registered with FDA. Our estimate is based on the requirement that only one preventive controls qualified individual is necessary to perform the requirements of the provisions that require a preventive controls qualified individual. Moreover, some preventive controls qualified individuals may be qualified by experience and there would not be a need for documentation of training.

(Comment 746) Comments note that our estimate for submitting a new domestic food facility profile will take 15 minutes. Comments believe that we grossly underestimate the amount of time retailers will need to respond to the form. Comments believe that the typical distribution center carries 26 of the 27 product categories listed in the Draft Form. Providing detail on the potential hazards and preventive controls implemented for each product will take retailers a total of 20–30 or more hours per facility. Most chain retailers have multiple facilities. A national retailer will easily have a dozen or more distribution centers. The largest food retailers will have several dozen. It is conceivable that hundreds of hazard and preventive control entries will be required to be made for each distribution center to respond to the Draft Form if such facilities are required to input information on hazards they do not control. The typical distribution center carries more than 13,000 different SKUs of FDA-regulated foods. Completing the form itself will require several hours due to all of the entries. Compiling the information for each facility will take 20–30 hours. Under the PRA, comments believe that we are required to consider not only the time it takes to complete the form, but also the time it takes to compile the information. Comments believe that we must revise our estimate of the burden imposed by the information collection request (ICR).

(Response 746) We requested comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan. After considering comments, we decided that we will not establish a requirement for submission of a facility profile. To the extent that this comment is addressing the form used for registering a food facility with FDA, such a comment is outside the scope of this rule-making. Moreover, an establishment that meets the definition of a retail food establishment is not a facility required to register.

(Comment 747) Comments believe that our ICR contains redundant collections. Comments believe that our existing Food Facility Registration Module requests information on facility type and products handled, while our ICR seeks the same information. Commenters believe that we should minimize redundancies to the greatest extent possible and use the information that we already have. As such, we should not be requesting information on facility type, products handled and, if it decides to as we recommend, types of storage, through this ICR. All of these data points are already collected by the existing Food Facility Registration Module.

(Response 747) The ICR associated with this rule-making is not redundant. The ICR associated with food facility registration with FDA is a separate rule-making and a separate burden. This PRA contains the ICR for completing all the requirements for a food facility to develop a hazard analysis and preventive controls; not register their facility. See Response 746.

(Comment 748) Comments suggest that our estimated time and costs to comply with the requirement to label products from certain qualified facilities do not come under the PRA because the address requirement is a disclosure, and not an information collection.

(Response 748) We concur that the requirement to add a qualified facility address to the product label is a third-party disclosure burden, and because it is a disclosure burden, is subject to the PRA. We revised our estimate for the hour burden for each of these disclosures to be 15 minutes as shown in table 69 of the PRA, to reflect that this will not be a coordinated label change for most qualified facilities so most will not be updating their labels anyway.

#### *Information Collection Burden Estimate*

FDA estimates the burden for this information collection as follows:

**Recordkeeping Burden**

We estimate that about 46,685 facilities subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls will need to create a food safety plan (§ 117.175(a)(1)) which is a compilation of many written food safety procedures. We total the hour burdens as presented throughout the FRIA (Ref. 38) to then create an average hour burden for each facility to create or complete a food safety plan. We estimate that creation of the food safety plan will require 110 hours. The total hour burden on an annual basis is 46,685 facilities × 110 hours = 5,135,350 hours. There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate the burden for disclosing to a customer, in documents to accompany foods that require further processing, that the food has not been processed to control a specified hazard (§ 117.136), is 15 minutes per record. We estimate that 16,285 establishments will each make one of these disclosures for a total recordkeeping burden of 4,071 hours.

The burden for keeping monitoring records (§ 117.175(a)(2)) follows the same pattern as that for the food safety plan. We estimate that there are 8,143 facilities subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls that will need to keep additional records of the monitoring that they do of different activities within their food facilities. Based on estimates of monitoring created, when appropriate, throughout the FRIA, we estimate that each of the 8,143 facilities will keep records of 730 monitoring activities and that each record can be made in about 3 minutes (0.05 hours) for a total hour burden of 297,220.

For the burden for corrective action records (§ 117.175(a)(3)) we estimate that twice per year 16,285 facilities subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls will have corrective actions to document. The documentation of those corrective actions is expected to take one hour for each record for a total hour burden of 32,570.

We estimate that there are 8,143 facilities subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls that will need to keep additional records of verification activities. Based on estimates of verification records created, when appropriate, throughout the FRIA, we estimate that 8,143 facilities will keep records of 244 verification activities and that each record can be made in about 3 minutes (0.05 hours) for a total hour burden of 101,675.

The burden for keeping validation records (§ 117.160) follows the same pattern as that for verification records. We estimate that there are 3,677 facilities subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls that will need to keep additional records of the validation of their process control activities within their food facilities. Based on estimates of the establishments that will require validation, when appropriate, throughout the FRIA, we estimate that each of the 3,677 facilities will keep records of six validation activities for a total of 22,062 records. We estimate that each record can be made in about 15 minutes (0.25 hours) for a total hour burden of 5,515.

The burden for keeping supplier records is for the use of approved suppliers and for establishments to document their audits § 117.475(c)(7), the sampling and testing of their ingredients § 117.475(c)(8), and the

review of their supplier's relevant food safety records § 117.475(c)(9), among up to 18 possible supplier related records. Our estimate follows the same pattern as that for other records. We estimate that there are 16,285 facilities subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls that will need to keep as many as 18 additional records for an average of 10 records of their approved suppliers and review records. Based on estimates throughout the FRIA, we estimate that each of the 16,285 establishments will maintain these records and that the total time for this recordkeeping will be about 4 hours for a total hour burden of 651,400.

We estimate that 46,685 establishments subject to subparts C and G Hazard Analysis and Risk-Based Preventive Controls will need to document the training of their preventive controls qualified individuals (§ 117.180(d)). We estimate that this will require 15 minutes (0.25 hours) per facility total for a total hour burden of 11,671.

Under § 117.206(a)(5) facilities are required to keep records documenting (1) the monitoring of temperature controls for refrigerated packaged food, (2) the corrective actions taken when there is a problem with the control of temperature for refrigerated packaged food, and (3) the verification activities relating to the temperature control of refrigerated packaged food. We believe that the keeping of such records is already common industry practice and will not constitute an additional paperwork burden.

Table 56 shows the estimated annual recordkeeping burden associated with this rule. There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 56—ESTIMATED ANNUAL RECORDKEEPING BURDEN**

21 CFR Part 1, Subpart 117	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
117.126 (c) and 117.170(d) food safety plan and reanalysis .....	46,685	1	46,685	110	5,135,350
117.136 assurance records .....	16,285	1	16,285	0.25	4,070
117.145 (c) monitoring records .....	8,143	730	5,944,390	0.05	297,220
117.150 (d) corrective actions and corrections records ....	16,285	2	32,570	1	32,570
117.155(b) verification records .....	8,143	244	1,986,892	0.05	101,675
117.160 validation records .....	3,677	6	22,062	.25	5,515
117.475(c)(7), 117.475(c)(8), and 117.475(c)(9) among up to 18 supplier records .....	16,285	1	16,285	4	651,400
117.180(d) Records that document applicable training for the preventive controls qualified individual. ....	46,685	1	46,685	.25	11,671
<b>Total annual burden hours .....</b>					<b>6,239,471</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information

**Reporting Burden**

Table 57 shows the estimated annual reporting burden associated with this rule.

Qualified facilities must report their status as such a facility every 2 years; status will likely be reported electronically through a web portal maintained by FDA. This requirement will cause the 37,134 qualified facilities

to spend 0.5 hour every 2 years reporting to FDA their status as a qualified facility for a total annual hour burden of about 9,283 hours (37,134 facilities × 0.5 responses annually × 0.5 hours per response).

**TABLE 57—ESTIMATED ANNUAL REPORTING BURDEN**  
[Very small business <\$1 m]<sup>1</sup>

21 CFR Section (or FDA Form No.)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
117.201(e) Qualified facility .....	37,134	0.5	18,567	0.5	9,283
Total burden hours .....					9,283

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**Third Party Disclosure Burden**

Under § 117.201(e) qualified facilities must add the address of the facility where the food is manufactured to their

label. We estimate the hour burden of this disclosure is 15 minutes per disclosure. This requirement will cause the 37,134 qualified facilities to spend

0.25 hours adding their address to their new labels for a total hour burden of about 9,283 hours (37,134 facilities × 0.25 hours per response).

**TABLE 58—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN**  
[Very small business <\$1 m]<sup>1</sup>

20 CFR section (or FDA Form No.)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total hours
117.201(e) Qualified facility .....	37,134	1	37,134	0.25	9,283
Total burden hours .....					9,283

**LXII. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**LXIII. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. These references are also available electronically at <http://www.regulations.gov>. We have verified the Web site addresses, but we are not responsible for any subsequent changes

to Web sites after this document publishes in the **Federal Register**.

1. FDA Memorandum, “FDA Memorandum to Dockets on Records of Outreach,” 2013. See Reference 7 to the 2014 supplemental human preventive controls notice.
2. FDA Memorandum, “Memoranda of Outreach,” 2015.
3. FDA, “Food CGMP Modernization—A Focus on Food Safety,” (<http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm207458.htm>), November 2, 2005. Accessed and printed on March 20, 2015. See Reference 1 to the 2013 proposed human preventive controls rule.
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## List of Subjects

### 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

**21 CFR Part 11**

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

**21 CFR Part 16**

Administrative practice and procedure.

**21 CFR Part 106**

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

**21 CFR Part 110**

Food packaging, Foods.

**21 CFR Part 114**

Food packaging, Foods, Reporting and recordkeeping requirements.

**21 CFR Part 117**

Food packaging, Foods.

**21 CFR Part 120**

Foods, Fruit juices, Imports, Reporting and recordkeeping requirements, Vegetable juices.

**21 CFR Part 123**

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

**21 CFR Part 129**

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

**21 CFR Part 179**

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

**21 CFR Part 211**

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

**PART 1—GENERAL ENFORCEMENT REGULATIONS**

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

**Authority:** 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Revise § 1.227 to read as follows:

**§ 1.227 What definitions apply to this subpart?**

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

*Calendar day* means every day shown on the calendar.

*Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers.

A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

*Farm* means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm

or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(i) and (iii) of this definition.

*Food* has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally



performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

*Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

*Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling,

milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

*Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

*Nonprofit food establishment* means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

*Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

*Packing* means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

*Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens,

and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

*Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

*Trade name* means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

*U.S. agent* means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between the Food and Drug Administration (FDA) and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under § 1.233(e) another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

*You or registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

■ 3. In § 1.241, revise paragraph (a) to read as follows:

**§ 1.241 What are the consequences of failing to register, update, or cancel your registration?**

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act, the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act, the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

■ 4. In § 1.276, revise paragraph (b)(9) to read as follows:

**§ 1.276 What definitions apply to this subpart?**

\* \* \* \* \*

(b) \* \* \*

(9) *Manufacturer* means the last facility, as that word is defined in § 1.227, that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

\* \* \* \* \*

■ 5. In § 1.328, remove the definitions for "Act" and "Packaging"; add definitions in alphabetical order for "Harvesting", "Mixed-type facility", "Packaging (when used as a noun)", "Packaging (when used as a verb)", and

"Packing"; and revise the definitions for "Farm", "Food", "Holding", and "Manufacturing/processing" to read as follows:

**§ 1.328 What definitions apply to this subpart?**

\* \* \* \* \*

*Farm* means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

- (i) Pack or hold raw agricultural commodities;
- (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
- (iii) Manufacture/process food, provided that:

- (A) All food used in such activities is consumed on that farm or another farm under the same management; or
- (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests,

and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(i) and (iii) of this definition.

*Food* has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

\* \* \* \* \*

*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

*Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural

commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

*Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

*Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

\* \* \* \* \*

*Packaging* (when used as a noun) means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act.

*Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

*Packing* means placing food into a container other than packaging the food

and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

\* \* \* \* \*

■ 6. Revise § 1.363 to read as follows:

**§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this part?**

(a) The failure to establish or maintain records as required by section 414(b) of the Federal Food, Drug, and Cosmetic Act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

**PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES**

■ 7. The authority citation for 21 CFR part 11 continues to read as follows:

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 8. In § 11.1, add and reserve paragraphs (g) and (h) and add paragraph (i) to read as follows:

**§ 11.1 Scope.**

\* \* \* \* \*

(i) This part does not apply to records required to be established or maintained by part 117 of this chapter. Records that satisfy the requirements of part 117 of this chapter, but that also are required under other applicable statutory

provisions or regulations, remain subject to this part.

**PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

■ 9. The authority citation for 21 CFR part 16 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 10. In § 16.1(b)(2), add the following entry in numerical order to read as follows:

**§ 16.1 Scope.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

§§ 117.251 through 117.287 (part 117, subpart E of this chapter), relating to withdrawal of a qualified facility exemption.

\* \* \* \* \*

**PART 106—INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS**

■ 11. The authority citation for 21 CFR part 106 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 350a, 371.

■ 12. In § 106.100, revise paragraph (n) to read as follows:

**§ 106.100 Records.**

\* \* \* \* \*

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, 113, and 117 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.

\* \* \* \* \*

**PART 110—[Removed and Reserved]**

■ 13. Remove and reserve part 110, effective September 17, 2018.

**PART 114—ACIDIFIED FOODS**

■ 14. The authority citation for 21 CFR part 114 continues to read as follows:

**Authority:** 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

■ 15. Revise § 114.5 to read as follows:

**§ 114.5 Current good manufacturing practice.**

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in parts 110 and 117 of this chapter, apply in determining whether an article of acidified food is adulterated:

(a) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that it has been manufactured under such conditions that it is unfit for food; or

(b) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

■ 16. Add part 117 to read as follows:

**PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD**

**Subpart A—General Provisions**

Sec.

- 117.1 Applicability and status.
- 117.3 Definitions.
- 117.4 Qualifications of individuals who manufacture, process, pack, or hold food.
- 117.5 Exemptions.
- 117.7 Applicability of subparts C, D, and G of this part to a facility solely engaged in the storage of unexposed packaged food.
- 117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities
- 117.9 Records required for this subpart.

**Subpart B—Current Good Manufacturing Practice**

- 117.10 Personnel.
- 117.20 Plant and grounds.
- 117.35 Sanitary operations.
- 117.37 Sanitary facilities and controls.
- 117.40 Equipment and utensils.
- 117.80 Processes and controls.
- 117.93 Warehousing and distribution.
- 117.110 Defect action levels.

**Subpart C—Hazard Analysis and Risk-Based Preventive Controls**

- 117.126 Food safety plan.
- 117.130 Hazard analysis.
- 117.135 Preventive controls.
- 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.
- 117.137 Provision of assurances required under § 117.136(a)(2), (3), and (4).
- 117.139 Recall plan.
- 117.140 Preventive control management components.
- 117.145 Monitoring.
- 117.150 Corrective actions and corrections.

- 117.155 Verification.
- 117.160 Validation.
- 117.165 Verification of implementation and effectiveness.
- 117.170 Reanalysis.
- 117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.
- 117.190 Implementation records required for this subpart.

**Subpart D—Modified Requirements**

- 117.201 Modified requirements that apply to a qualified facility.
- 117.206 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food.

**Subpart E—Withdrawal of a Qualified Facility Exemption**

- 117.251 Circumstances that may lead FDA to withdraw a qualified facility exemption.
- 117.254 Issuance of an order to withdraw a qualified facility exemption.
- 117.257 Contents of an order to withdraw a qualified facility exemption.
- 117.260 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.
- 117.264 Procedure for submitting an appeal.
- 117.267 Procedure for requesting an informal hearing.
- 117.270 Requirements applicable to an informal hearing.
- 117.274 Presiding officer for an appeal and for an informal hearing.
- 117.277 Timeframe for issuing a decision on an appeal.
- 117.280 Revocation of an order to withdraw a qualified facility exemption.
- 117.284 Final agency action.
- 117.287 Reinstatement of a qualified facility exemption that was withdrawn.

**Subpart F—Requirements Applying to Records That Must Be Established and Maintained**

- 117.301 Records subject to the requirements of this subpart.
- 117.305 General requirements applying to records.
- 117.310 Additional requirements applying to the food safety plan.
- 117.315 Requirements for record retention.
- 117.320 Requirements for official review.
- 117.325 Public disclosure.
- 117.330 Use of existing records.
- 117.335 Special requirements applicable to a written assurance.

**Subpart G—Supply-Chain Program**

- 117.405 Requirement to establish and implement a supply-chain program.
- 117.410 General requirements applicable to a supply-chain program.
- 117.415 Responsibilities of the receiving facility.
- 117.420 Using approved suppliers.
- 117.425 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).
- 117.430 Conducting supplier verification activities for raw materials and other ingredients.

- 117.435 Onsite audit.
- 117.475 Records documenting the supply-chain program.

**Authority:** 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

**Subpart A—General Provisions****§ 117.1 Applicability and status.**

(a) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subpart C, D, E, or F of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

**§ 117.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

*Acid foods* or *acidified foods* means foods that have an equilibrium pH of 4.6 or below.

*Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

*Affiliate* means any facility that controls, is controlled by, or is under common control with another facility.

*Allergen cross-contact* means the unintentional incorporation of a food allergen into a food.

*Audit* means the systematic, independent, and documented examination (through observation,

investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier's food safety processes and procedures.

*Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

*Blanching*, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

*Calendar day* means every day shown on the calendar.

*Correction* means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

*Critical control point* means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

*Defect action level* means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

*Environmental pathogen* means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

*Facility* means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

*Farm* means farm as defined in § 1.227 of this chapter.

*FDA* means the Food and Drug Administration.

*Food* means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

*Food allergen* means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

*Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

*Full-time equivalent employee* is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

*Hazard* means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

*Hazard requiring a preventive control* means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

*Holding* means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

*Known or reasonably foreseeable hazard* means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

*Lot* means the food produced during a period of time and identified by an establishment's specific code.

*Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding,

homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

*Microorganisms* means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

*Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

*Monitor* means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

*Packing* means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

*Pathogen* means a microorganism of public health significance.

*Pest* refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

*Plant* means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

*Preventive controls* means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the

hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

*Preventive controls qualified individual* means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

*Qualified auditor* means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include:

- (1) A government employee, including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

*Qualified end-user*, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

- (1) Is located;
  - (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
  - (ii) Not more than 275 miles from such facility; and
- (2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

*Qualified facility* means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

- (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

- (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

*Qualified facility exemption* means an exemption applicable to a qualified facility under § 117.5(a).

*Qualified individual* means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

*Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

*Raw agricultural commodity* has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

*Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

*Receiving facility* means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

*Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

*Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity ( $a_w$ ). An  $a_w$  will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given  $a_w$  will not support the growth of undesirable microorganisms.

*Sanitize* means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

*Significantly minimize* means to reduce to an acceptable level, including to eliminate.

*Small business* means, for purposes of this part, a business employing fewer than 500 full-time equivalent employees.

*Subsidiary* means any company which is owned or controlled directly or indirectly by another company.

*Supplier* means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

*Supply-chain-applied control* means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

*Unexposed packaged food* means packaged food that is not exposed to the environment.

*Validation* means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

*Verification* means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

*Very small business* means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

*Water activity* ( $a_w$ ) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

*Written procedures for receiving raw materials and other ingredients* means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate

verification activities before acceptance for use).

*You* means, for purposes of this part, the owner, operator, or agent in charge of a facility.

#### § 117.4 Qualifications of individuals who manufacture, process, pack, or hold food.

(a) *Applicability.* (1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties.

(b) *Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.* Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 117.3—*i.e.*, have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and

(2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

(c) *Additional qualifications of supervisory personnel.* Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

(d) *Records.* Records that document training required by paragraph (b)(2) of this section must be established and maintained.

#### § 117.5 Exemptions.

(a) Except as provided by subpart E of this part, subparts C and G of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in § 117.201.

(b) Subparts C and G of this part do not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if you are required to comply with, and are in compliance with, part 123 of this chapter with respect to such activities.

(c) Subparts C and G of this part do not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if you are required to comply with, and are in compliance with, part 120 of this chapter with respect to such activities.

(d)(1) Subparts C and G of this part do not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

(e) Subparts C and G do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

(f) Subparts C and G do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(g)(1) The exemption in paragraph (g)(3) of this section applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the "farm" definition in § 1.227 of this chapter. Activities that are within the "farm" definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) For the purposes of paragraphs (g)(3) and (h)(3) of this section, the following terms describe the foods associated with the activity/food combinations. Several foods that are fruits or vegetables are separately considered for the purposes of these activity/food combinations (*i.e.*, coffee

beans, cocoa beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods.

(i) *Dried/dehydrated fruit and vegetable products* includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(ii) *Other fruit and vegetable products* includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in paragraph (g)(2)(i) of this section. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).

(iii) *Peanut and tree nut products* includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

(iv) *Processed seeds for direct consumption* include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

(v) *Dried/dehydrated herb and spice products* includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(vi) *Other herb and spice products* includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice

products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in paragraph (g)(2)(v) of this section. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.

(vii) *Grains* include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

(viii) *Milled grain products* include processed food products such as flour, bran, and corn meal.

(ix) *Baked goods* include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.

(x) *Other grain products* include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in paragraph (g)(2)(viii) of this section or baked goods as described in paragraph (g)(2)(ix) of this section.

(3) Subparts C and G of this part do not apply to on-farm packing or holding of food by a small or very small business, and § 117.201 does not apply to on-farm packing or holding of food by a very small business, if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations—*i.e.*, packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(i) Baked goods (e.g., bread and cookies);

(ii) Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);

(iii) Cocoa beans (roasted);

(iv) Cocoa products;

(v) Coffee beans (roasted);

(vi) Game meat jerky;

(vii) Gums, latexes, and resins that are processed foods;

(viii) Honey (pasteurized);

(ix) Jams, jellies, and preserves;

(x) Milled grain products (e.g., flour, bran, and corn meal);

(xi) Molasses and treacle;

(xii) Oils (e.g., olive oil and sunflower seed oil);

(xiii) Other fruit and vegetable products (e.g., flours made from

legumes; pitted, dried fruits; sliced, dried apples; snack chips);

(xiv) Other grain products (e.g., dried pasta, oat flakes, and popcorn);

(xv) Other herb and spice products (e.g., chopped or ground dried herbs, herbal extracts);

(xvi) Peanut and tree nut products (e.g., roasted peanuts and tree nut flours);

(xvii) Processed seeds for direct consumption (e.g., roasted pumpkin seeds);

(xviii) Soft drinks and carbonated water;

(xix) Sugar;

(xx) Syrups (e.g., maple syrup and agave syrup);

(xxi) Trail mix and granola;

(xxii) Vinegar; and

(xxiii) Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

(h)(1) The exemption in paragraph (h)(3) of this section applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the “farm” definition in § 1.227 of this chapter. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the “farm” definition in § 1.227 of this chapter. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the “farm” definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the “farm” definition. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) The terms in paragraph (g)(2) of this section describe certain foods associated with the activity/food combinations in paragraph (h)(3) of this section.

(3) Subparts C and G of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for



distribution into commerce, and § 117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk manufacturing/processing activity/food combinations:

- (i) Boiling gums, latexes, and resins;
- (ii) Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (*e.g.*, cutting lemons and limes), baked goods (*e.g.*, slicing bread), dried/dehydrated fruit and vegetable products (*e.g.*, pitting dried plums), dried herbs and other spices (*e.g.*, chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (*e.g.*, shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (*e.g.*, chopping roasted peanuts);
- (iii) Coating dried/dehydrated fruit and vegetable products (*e.g.*, coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (*e.g.*, coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (*e.g.*, adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (*e.g.*, adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (*e.g.*, adding seasonings provided that the seasonings have been treated to significantly minimize pathogens));
- (iv) Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (*e.g.*, drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (*e.g.*, drying chopped fresh herbs, including tea);
- (v) Extracting (including by pressing, by distilling, and by solvent extraction) from dried/dehydrated herb and spice products (*e.g.*, dried mint), fresh herbs (*e.g.*, fresh mint), fruits and vegetables (*e.g.*, olives, avocados), grains (*e.g.*, oilseeds), and other herb and spice products (*e.g.*, chopped fresh mint, chopped dried mint);
- (vi) Freezing acid fruits and vegetables with pH less than 4.2 and

other fruit and vegetable products with pH less than 4.2 (*e.g.*, cut fruits and vegetables);

- (vii) Grinding/cracking/crushing/milling baked goods (*e.g.*, crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (*e.g.*, raisins and dried legumes), dried/dehydrated herb and spice products (*e.g.*, intact dried basil), grains (*e.g.*, oats, rice, rye, wheat), other fruit and vegetable products (*e.g.*, dried, pitted dates), other grain products (*e.g.*, dried cereal), other herb and spice products (*e.g.*, chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (*e.g.*, roasted peanuts);
- (viii) Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens), coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (*e.g.*, corn meal) or that are single-ingredient foods (*e.g.*, wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (*e.g.*, snack chips made from potatoes or plantains), other grain products that do not contain food allergens (*e.g.*, popcorn), other herb and spice products (*e.g.*, chopped or ground dried herbs), peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (*e.g.*, roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (*e.g.*, vitamins, minerals, and dietary ingredients (*e.g.*, bone meal) in powdered, granular, or other solid form);
- (ix) Making baked goods from milled grain products (*e.g.*, breads and cookies);
- (x) Making candy from peanuts and tree nuts (*e.g.*, nut brittles), sugar/syrups (*e.g.*, taffy, toffee), and saps (*e.g.*, maple candy, maple cream);
- (xi) Making cocoa products from roasted cocoa beans;

- (xii) Making dried pasta from grains;
- (xiii) Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
- (xiv) Making molasses and treacle from sugar beets and sugarcane;
- (xv) Making oat flakes from grains;
- (xvi) Making popcorn from grains;
- (xvii) Making snack chips from fruits and vegetables (*e.g.*, making plantain and potato chips);
- (xviii) Making soft drinks and carbonated water from sugar, syrups, and water;
- (xix) Making sugars and syrups from fruits and vegetables (*e.g.*, dates), grains (*e.g.*, rice, sorghum), other grain products (*e.g.*, malted grains such as barley), saps (*e.g.*, agave, birch, maple, palm), sugar beets, and sugarcane;
- (xx) Making trail mix and granola from cocoa products (*e.g.*, chocolate), dried/dehydrated fruit and vegetable products (*e.g.*, raisins), other fruit and vegetable products (*e.g.*, chopped dried fruits), other grain products (*e.g.*, oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;
- (xxi) Making vinegar from fruits and vegetables, other fruit and vegetable products (*e.g.*, fruit wines, apple cider), and other grain products (*e.g.*, malt);
- (xxii) Mixing baked goods (*e.g.*, types of cookies), candy (*e.g.*, varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (*e.g.*, dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (*e.g.*, dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (*e.g.*, flour, bran, and corn meal), other fruit and vegetable products (*e.g.*, dried, sliced apples and dried, sliced peaches), other grain products (*e.g.*, different types of dried pasta), other herb and spice products (*e.g.*, chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (*e.g.*, vitamins, minerals, and dietary ingredients (*e.g.*, bone meal) in powdered, granular, or other solid form);
- (xxiii) Packaging baked goods (*e.g.*, bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products (*e.g.*,

flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

(xxiv) Pasteurizing honey;  
 (xxv) Roasting and toasting baked goods (e.g., toasting bread for croutons);  
 (xxvi) Salting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and  
 (xxvii) Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour).

(i)(1) Subparts C and G of this part do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (i)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) Subparts C and G of this part do not apply to facilities that are solely engaged in the storage of raw

agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k)(1) Except as provided by paragraph (k)(2) of this section, subpart B of this part does not apply to any of the following:

(i) “Farms” (as defined in § 1.227 of this chapter);

(ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this chapter in accordance with § 1.226(f) of this chapter;

(iii) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(iv) Activities of “farm mixed-type facilities” (as defined in § 1.227 of this chapter) that fall within the definition of “farm”; or

(v) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts).

(2) If a “farm” or “farm mixed-type facility” dries/dehydrates raw agricultural commodities that are produce as defined in part 112 of this chapter to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

**§ 117.7 Applicability of subparts C, D, and G of this part to a facility solely engaged in the storage of unexposed packaged food.**

(a) *Applicability of subparts C and G.* Subparts C and G of this part do not apply to a facility solely engaged in the storage of unexposed packaged food.

(b) *Applicability of subpart D.* A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

**§ 117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities.**

Subpart B of this part applies to the off-farm packaging, packing, and holding of raw agricultural commodities. Compliance with this

requirement for raw agricultural commodities that are produce as defined in part 112 of this chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

**§ 117.9 Records required for this subpart.**

(a) Records that document training required by § 117.4(b)(2) must be established and maintained.

(b) The records that must be established and maintained are subject to the requirements of subpart F of this part.

**Subpart B—Current Good Manufacturing Practice**

**§ 117.10 Personnel.**

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

#### § 117.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1)

through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.*, manufacturing, processing, packing, and holding). The plant must:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.  
(ii) Controlling areas over and around the vessels to eliminate harborage for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and

provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

#### § 117.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) *Pest control.* Pests must not be allowed in any area of a food plant.

Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact

surfaces from allergen cross-contact and from contamination.

#### § 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) *Water supply.* The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste

becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

#### § 117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show

the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

#### § 117.80 Processes and controls.

(a) *General.* (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) *Raw materials and other ingredients.* (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause

allergen cross-contact or increase the level of contamination of the food.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) *Manufacturing operations.* (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling  $a_w$  that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and other ingredients that are adulterated:

(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food

against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Batters, breadings, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of  $a_w$  for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

#### § 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

#### § 117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all

times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at <http://www.fda.gov/pchfrule> and at <http://www.fda.gov>.

### Subpart C—Hazard Analysis and Risk-Based Preventive Controls

#### § 117.126 Food safety plan.

(a) *Requirement for a food safety plan.*

(1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(b) *Contents of a food safety plan.* The written food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written supply-chain program as required by subpart G of this part;

(4) The written recall plan as required by § 117.139(a); and

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);

(6) The written corrective action procedures as required by § 117.150(a)(1); and

(7) The written verification procedures as required by § 117.165(b).

(c) *Records.* The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

#### § 117.130 Hazard analysis.

(a) *Requirement for a hazard analysis.*

(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.

(2) The hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of some natural toxins).

#### § 117.135 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be

significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include:

- (i) Controls at critical control points (CCPs), if there are any CCPs; and
- (ii) Controls, other than those at CCPs, that are also appropriate for food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

(1) *Process controls.* Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

- (i) Parameters associated with the control of the hazard; and
- (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) *Food allergen controls.* Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

- (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
- (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) *Sanitation controls.* Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

- (i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
- (ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other

food-contact surfaces and from raw product to processed product.

(4) *Supply-chain controls.* Supply-chain controls include the supply-chain program as required by subpart G of this part.

(5) *Recall plan.* Recall plan as required by § 117.139.

(6) *Other controls.* Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

**§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.**

(a) *Circumstances.* If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart C to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing

the food in accordance with applicable food safety requirements.

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(B) Will only sell to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart); or

(2) Obtain a similar written assurance from the entity's customer, subject to the requirements of § 117.137, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product you distribute and you document the implementation of that system.

(b) *Records.* You must document any circumstance, specified in paragraph (a) of this section, that applies to you, including:

(1) A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that

ensures control, at a subsequent distribution step, of the hazards in the food product you distribute.

**§ 117.137 Provision of assurances required under § 117.136(a)(2), (3), and (4).**

A facility that provides a written assurance under § 117.136(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

**§ 117.139 Recall plan.**

For food with a hazard requiring a preventive control:

(a) You must establish a written recall plan for the food.

(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food—*e.g.*, through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

**§ 117.140 Preventive control management components.**

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 117.145;

(2) Corrective actions and corrections in accordance with § 117.150; and

(3) Verification in accordance with § 117.155.

(b) The supply-chain program established in subpart G of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 117.165(a)(4); and

(3) Reanalysis in accordance with § 117.170.

(c) The recall plan established in § 117.139 is not subject to the requirements of paragraph (a) of this section.

**§ 117.145 Monitoring.**

As appropriate to the nature of the preventive control and its role in the facility's food safety system:

(a) *Written procedures.* You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and.

(b) *Monitoring.* You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c) *Records.* (1) *Requirement to document monitoring.* You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).

(2) *Exception records.* (i) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

**§ 117.150 Corrective actions and corrections.**

(a) *Corrective action procedures.* As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) *Corrective action in the event of an unanticipated food safety problem.* (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and

(ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required.

(c) *Corrections.* You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor



and isolated problem that does not directly impact product safety.

(d) *Records.* All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i).

**§ 117.155 Verification.**

(a) *Verification activities.* Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 117.160.

(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).

(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).

(4) Verification of implementation and effectiveness in accordance with § 117.165; and

(5) Reanalysis in accordance with § 117.170.

(b) *Documentation.* All verification activities conducted in accordance with this section must be documented in records.

**§ 117.160 Validation.**

(a) You must validate that the preventive controls identified and implemented in accordance with § 117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan; or

(B) When necessary to demonstrate the control measures can be implemented as designed:

(1) Within 90 calendar days after production of the applicable food first begins; or

(2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the

control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards; and

(c) You do not need to validate:

(1) The food allergen controls in § 117.135(c)(2);

(2) The sanitation controls in § 117.135(c)(3);

(3) The recall plan in § 117.139;

(4) The supply-chain program in subpart G of this part; and

(5) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

**§ 117.165 Verification of implementation and effectiveness.**

(a) *Verification activities.* You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within 7

working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and

(ii) Records of calibration, testing (e.g., product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) *Written procedures.* As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section.

Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

- (vi) Identify the laboratory conducting the testing; and
- (vii) Include the corrective action procedures required by § 117.150(a)(1).

**§ 117.170 Reanalysis.**

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years;

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the food;

(3) Whenever appropriate after an unanticipated food safety problem in accordance with § 117.150(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

**§ 117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.**

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(a)(2));

(2) Validation of the preventive controls (§ 117.160(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;

(4) Determination that validation is not required (§ 117.160(c)(5));

(5) Review of records (§ 117.165(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;

(7) Reanalysis of the food safety plan (§ 117.170(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

(b) A qualified auditor must conduct an onsite audit (§ 117.435(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

**§ 117.190 Implementation records required for this subpart.**

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 117.136(b), of the basis for not establishing a preventive control in accordance with § 117.136(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(5) Records that document the supply-chain program; and

(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

**Subpart D—Modified Requirements**

**§ 117.201 Modified requirements that apply to a qualified facility.**

(a) *Attestations to be submitted.* A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) *Procedure for submission.* The attestations required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) *Electronic submission.* To submit electronically, go to <http://www.fda.gov/>

*furls* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942a. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from <http://www.fda.gov/pchfrule>;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c) *Frequency of determination of status and submission.* (1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.

(d) *Timeframe for compliance with subparts C and G of this part when the facility status changes to “not a qualified facility.”* When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and G of this part no later than December 31 of

the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) *Notification to consumers.* A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities), as follows:

(1) If a food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the food.

(2) If a food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f) *Records.* (1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

**§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food.**

(a) If a facility that is solely engaged in the storage of unexposed packaged food stores any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected food for safety; and

(iii) Prevent the food from entering commerce, if you cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days;

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

**Subpart E—Withdrawal of a Qualified Facility Exemption**

**§ 117.251 Circumstances that may lead FDA to withdraw a qualified facility exemption.**

(a) FDA may withdraw a qualified facility exemption under § 117.5(a):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public health or

mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, suspension of registration, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

**§ 117.254 Issuance of an order to withdraw a qualified facility exemption.**

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

**§ 117.257 Contents of an order to withdraw a qualified facility exemption.**

An order to withdraw a qualified facility exemption under § 117.5(a) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conditions or conduct associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) Comply with subparts C and G of this part on the date that is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 117.287.

(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.270;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

**§ 117.260 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.**

(a) If you receive an order under § 117.254 to withdraw a qualified facility exemption, you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If you appeal the order, and FDA confirms the order:

(1) You must comply with applicable requirements of this part within 120

calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) You are no longer subject to the modified requirements in § 117.201.

**§ 117.264 Procedure for submitting an appeal.**

(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), you may include a written request for an informal hearing as provided in § 117.267.

**§ 117.267 Procedure for requesting an informal hearing.**

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 117.264 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

**§ 117.270 Requirements applicable to an informal hearing.**

If you request an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1-calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 117.254 and 117.257, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 117.274, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2-calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.270(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) of this chapter does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3) and (a)(5) of this chapter and 117.270(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial

review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

**§ 117.274 Presiding officer for an appeal and for an informal hearing.**

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

**§ 117.277 Timeframe for issuing a decision on an appeal.**

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2-calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within 10-calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

**§ 117.280 Revocation of an order to withdraw a qualified facility exemption.**

An order to withdraw a qualified facility exemption is revoked if:

(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10-calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10-calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10-calendar days after the appeal is filed, or issues a decision revoking the order within that time.

**§ 117.284 Final agency action.**

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

**§ 117.287 Reinstatement of a qualified facility exemption that was withdrawn.**

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 117.251(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 117.5(a), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 117.251(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your exemption under § 117.5(a) in accordance with the requirements of paragraph (b) of this section.

## Subpart F—Requirements Applying to Records That Must Be Established and Maintained

### § 117.301 Records subject to the requirements of this subpart.

(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart.

(b) The requirements of § 117.310 apply only to the written food safety plan.

(c) The requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201.

### § 117.305 General requirements applying to records.

Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:  
(1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);  
(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.  
(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

### § 117.310 Additional requirements applying to the food safety plan.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan:

- (a) Upon initial completion; and
- (b) Upon any modification.

### § 117.315 Requirements for record retention.

(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.155(b)));

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

### § 117.320 Requirements for official review.

All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

### § 117.325 Public disclosure.

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

### § 117.330 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

### § 117.335 Special requirements applicable to a written assurance.

(a) Any written assurance required by this part must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) The applicable assurance under:  
(i) Section 117.136(a)(2);  
(ii) Section 117.136(a)(3);  
(iii) Section 117.136(a)(4);  
(iv) Section 117.430(c)(2);  
(v) Section 117.430(d)(2); or  
(vi) Section 117.430(e)(2);

(b) A written assurance required under § 117.136(a)(2), (3), or (4) must include:  
(1) Acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and

(2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

## Subpart G—Supply-Chain Program

### § 117.405 Requirement to establish and implement a supply-chain program.

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

(3) The requirements in this subpart do not apply to food that is supplied for research or evaluation use, provided that such food:

(i) Is not intended for retail sale and is not sold or distributed to the public;

(ii) Is labeled with the statement “Food for research or evaluation use”;

(iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose,

the food is used only for this purpose, and any unused quantity is properly disposed of; and

(iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce covered by part 112 of this chapter)), because growing, harvesting, and packing activities are under different management, the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

**§ 117.410 General requirements applicable to a supply-chain program.**

(a) The supply-chain program must include:

(1) Using approved suppliers as required by § 117.420;

(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425;

(3) Conducting supplier verification activities as required by §§ 117.430 and 117.435;

(4) Documenting supplier verification activities as required by § 117.475; and

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 117.475, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

(4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 117.3;

(ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or

(iii) A shell egg producer that is not subject to the requirements of part 118

of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or other ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

**§ 117.415 Responsibilities of the receiving facility.**

(a)(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation.

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 117.410(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435.

**§ 117.420 Using approved suppliers.**

(a) *Approval of suppliers.* The receiving facility must approve suppliers in accordance with the requirements of § 117.410(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b) *Written procedures for receiving raw materials and other ingredients.* (1) Written procedures for receiving raw materials and other ingredients must be established and followed;

(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and

(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.

**§ 117.425 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).**

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 117.410(d).

**§ 117.430 Conducting supplier verification activities for raw materials and other ingredients.**

(a) Except as provided by paragraph (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 117.410(b), as determined under § 117.410(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)(1) Except as provided by paragraph (b)(2) of this section, when a

hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans:

(i) The appropriate supplier verification activity is an onsite audit of the supplier; and

(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

(2) The requirements of paragraph (b)(1) of this section do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(c) If a supplier is a qualified facility as defined by § 117.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 117.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject

to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interests that influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity.

**§ 117.435 Onsite audit.**

(a) An onsite audit of a supplier must be performed by a qualified auditor.

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws



and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(c)(1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

**§ 117.475 Records documenting the supply-chain program.**

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 117.165(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(i) The name of the supplier subject to the onsite audit;

(ii) Documentation of audit procedures;

(iii) The dates the audit was conducted;

(iv) The conclusions of the audit;

(v) Corrective actions taken in response to significant deficiencies identified during the audit; and

(vi) Documentation that the audit was conducted by a qualified auditor;

(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:

(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted and the date of the report;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing;

(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:

(i) The name of the supplier whose records were reviewed;

(ii) The date(s) of review;

(iii) The general nature of the records reviewed;

(iv) The conclusions of the review; and

(v) Corrective actions taken in response to significant deficiencies identified during the review;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier,

provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

(i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations

of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

**PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

■ 17. The authority citation for 21 CFR part 120 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

■ 18. In § 120.3, revise the first sentence of the introductory text to read as follows:

**§ 120.3 Definitions.**

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi) of this chapter, and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. \* \* \*

\* \* \* \* \*

■ 19. Revise § 120.5 to read as follows:

**§ 120.5 Current good manufacturing practice.**

Except as provided by § 117.5(c), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

■ 20. In § 120.6, revise the first sentence of paragraph (b) to read as follows:

**§ 120.6 Sanitation standard operating procedures.**

\* \* \* \* \*

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter and in subpart B of part 117 of this chapter that are appropriate both to the plant and to the food being processed. \* \* \*

\* \* \* \* \*

**PART 123—FISH AND FISHERY PRODUCTS**

■ 21. The authority citation for 21 CFR part 123 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 2411, 264.

■ 22. In § 123.3, revise the first sentence of the introductory text to read as follows:

**§ 123.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110

and 117 do not govern such terms where used in this part. \* \* \*

\* \* \* \* \*

■ 23. In § 123.5, revise paragraph (a) to read as follows:

**§ 123.5 Current good manufacturing practice.**

(a) Except as provided by § 117.5(b), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

\* \* \* \* \*

■ 24. In § 123.11, revise the introductory text of paragraph (b) to read as follows:

**§ 123.11 Sanitation control procedures.**

\* \* \* \* \*

(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter and in subpart B of part 117 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

\* \* \* \* \*

**PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER**

■ 25. The authority citation for 21 CFR part 129 continues to read as follows:

**Authority:** 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

■ 26. Revise § 129.1 to read as follows:

**§ 129.1 Current good manufacturing practice.**

The applicable criteria in parts 110 and 117 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

**PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD**

■ 27. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 28. In § 179.25, revise paragraph (a) to read as follows:

**§ 179.25 General provisions for food irradiation.**

\* \* \* \* \*

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of parts 110 and 117 of this chapter and other applicable regulations.

\* \* \* \* \*

**PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS**

■ 29. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 30. In § 211.1, revise the last sentence in paragraph (c) to read as follows:

**§ 211.1 Scope.**

\* \* \* \* \*

(c) \* \* \* Therefore, until further notice, regulations under parts 110 and 117 of this chapter, and where applicable, parts 113 through 129 of this chapter, shall be applied in determining whether these OTC drug products that are also foods are manufactured, processed, packed, or held under current good manufacturing practice.

Dated: August 31, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-21920 Filed 9-10-15; 8:45 am]

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Part III

Department of Health and Human Services

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Food and Drug Administration

21 CFR Parts 11, 16, 117, *et al.*

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 11, 16, 117, 500, 507, and 579**

[Docket No. FDA-2011-N-0922]

RIN 0910-AG10

**Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is adding regulations for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals. These regulations will, for the first time, establish requirements for the current good manufacturing practice (CGMP) for food for animals. In addition, we are adding requirements for certain domestic and foreign animal food facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. We are taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to humans and animals and to implement new statutory provisions in the FDA Food Safety Modernization Act (FSMA). The rule is intended to build an animal food safety system for the future that makes modern science- and risk-based preventive controls the norm across all sectors of the animal food system.

**DATES:** This rule is effective November 16, 2015, except for paragraph (2) of the definition of “qualified auditor” in § 507.3, and §§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2), and 507.175(c)(13). FDA will publish a document in the **Federal Register** announcing the effective dates of paragraph (2) of the definition of “qualified auditor” in § 507.3, §§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2), and 507.175(c)(13). Certain provisions have later compliance dates as discussed in section LIII “Effective and Compliance Dates.”

**FOR FURTHER INFORMATION CONTACT:**

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Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246, email: [jenny.murphy@fda.hhs.gov](mailto:jenny.murphy@fda.hhs.gov).**SUPPLEMENTARY INFORMATION:****Table of Contents**

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- C. Alternative Verification Activity When the Supplier Is a Qualified Facility (Final § 507.130(c))
- D. Alternative Verification Activity When the Supplier Is a Produce Farm That Is Not a “Covered Farm” for the Purposes of the Future Produce Safety Rule (Final § 507.130(d))
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## Executive Summary

### *Purpose and Coverage of the Rule*

This rule is part of FDA's implementation of FSMA, which intends to better protect public (human and animal) health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule establishes new requirements for the production of animal food by registered food facilities in two ways.

First, this rule creates new CGMP regulations that specifically address the manufacturing, processing, packing, and holding of food for animals. These requirements apply to establishments that are required to register with FDA as a food "facility." Second, this rule creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. As with the CGMPs, these requirements apply to establishments that are required to register with FDA as a food facility. This portion of the rule requires registered animal food facilities to maintain a food

safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards, unless an exemption applies. Facilities must also monitor their controls, conduct verification activities to ensure the controls are effective, take appropriate corrective actions, and maintain records documenting these actions.

This final rule is the result of significant stakeholder engagement, beginning before the proposed rule. In response to extensive stakeholder input on the proposed rule, we revised key provisions in a supplemental notice of proposed rulemaking. After the supplemental notice of proposed rulemaking, we conducted even more outreach to the stakeholder community to ensure that the risk-based, preventive requirements in this final rule are practical and protective of public (human and animal) health.

### *Summary of the Major Provisions of the Rule*

The final rule establishes CGMP provisions to ensure the safety and suitability of animal food. Specifically, the rule establishes requirements in the following areas:

- Personnel;
- Plant and grounds;
- Sanitation;
- Water supply and plumbing;
- Equipment and utensils;
- Plant operations;
- Holding and distribution; and
- Holding and distribution of human food by-products for use as animal food.

We have added flexibility and clarity to the CGMPs in response to comments. These CGMPs establish baseline standards for producing safe animal food that take into consideration the unique aspects of the animal food industry and provide flexibility for the wide diversity in types of animal food facilities. In addition, the CGMPs in this final regulation allow human food facilities subject to and in compliance with CGMPs for human food and in compliance with all applicable FDA human food safety requirements to only follow the specific CGMPs for the holding and distribution of human food by-products for use as animal food, as long as they do not further process the by-product. Under this final rule, all other requirements of part 507, including the hazard analysis, preventive controls and supply-chain program provisions, would not apply to these by-products of human food production.

The final rule implements the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a

hazard analysis and risk-based preventive controls. Specifically, the rule establishes requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions and corrections;
- Verification;
- Supply-chain program;
- Recall plan; and
- Associated records.

We have added flexibility and clarity to these provisions in response to comments. Although there are similarities between these requirements of FSMA and the requirements of food safety systems known as Hazard Analysis and Critical Control Point (HACCP) systems, not every provision in FSMA is identical to the provisions of HACCP systems, and we have revised much of our terminology to distinguish FSMA's requirements for hazard analysis and risk-based preventive controls from HACCP requirements. A facility subject to the rule must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring preventive controls. The first step of a hazard analysis is hazard identification, which must consider known or reasonably foreseeable hazards, including biological, chemical, and physical hazards. The hazard analysis must consider hazards that may be present in the animal food because they occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain. We continue to believe that hazards that may be intentionally introduced for economic gain will need preventive controls in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. Economically motivated adulteration that affects product integrity or quality, for example, but not animal food safety, is out of the scope of this rule.

A facility subject to the rule must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by the facility will not be adulterated. The rule establishes preventive control management components (monitoring, corrective actions and corrections, and verification) as appropriate to ensure the



effectiveness of the preventive controls. One way we have clarified the risk-based flexibility of these requirements is by clearly stating in the final rule that a facility must take into account the nature of the preventive control and the facility's food safety system when considering which activities are appropriate for that facility.

We have also added flexibility and made risk-based modifications for specific preventive control management components. For example, the final rule allows flexibility for the specific records required to document monitoring of refrigeration controls during storage of an animal food that requires time/temperature control for safety. These records can be either affirmative records demonstrating temperature is controlled or "exception records" demonstrating loss of temperature control. As another example, the rule includes tailored, less burdensome requirements for corrections. A correction is defined in this rule as an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected animal food from entering commerce). The final rule clarifies that corrections must be taken in a timely manner and must be recorded when appropriate, but they do not, for example, need to be included in a written plan or accompanied by a reanalysis of the written food safety plan.

As a third example, the final rule provides flexibility for which verification activities must occur. In general, a facility is required to conduct verification activities, as appropriate to the nature of the preventive control and its role in the facility's food safety system, including validation, verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, and reanalysis. Validation is not required for all controls. For example, the rule specifies that validation is not required for certain types of preventive controls (*i.e.*, sanitation controls, supply-chain controls, and the recall plan) and provides flexibility for the facility to not validate other preventive controls with a written justification based on factors

such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. Product testing and environmental monitoring are listed as possible verification activities, but, like other preventive control management components in general, they are only required as appropriate to the animal food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system. In many cases, neither product testing nor environmental monitoring will be appropriate. For example, there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold raw agricultural commodities that are rarely consumed unprocessed, such as soybeans.

A facility must reanalyze the food safety plan as a whole at least once every 3 years. The final rule provides the flexibility for a facility to only reanalyze the applicable portion of the food safety plan under certain other circumstances, such as when a facility becomes aware of new information about potential hazards associated with an animal food.

The final rule also adds flexibility to the preventive controls requirements and recognizes the reality of modern distribution chains by not requiring a manufacturing/processing facility to implement a preventive control in certain circumstances when the hazard requiring a preventive control will be controlled by another entity in the distribution chain. For example, if a facility's customer (or another entity in the distribution chain) will control the hazard, then that facility can rely on its customer to provide written assurance that the identified hazard will be controlled by an entity in the distribution chain, with flexibility for how the customer provides that written assurance depending on whether the customer, or an entity subsequent to the customer, will control the hazard. We have identified four specific circumstances in which a manufacturing/processing facility can rely on another entity in the distribution chain to control a hazard, with practical solutions explained further in section XXVII. We also have provided flexibility for a facility to establish, document, and implement an alternative system that

ensures adequate control, at a later distribution step, of the hazards in the food product distributed by a manufacturing/processing facility such that the facility would not need to implement a preventive control.

We revised the proposed provisions for a supplier program to add flexibility, recognizing that the receiving facility and the supplier may be separated by several entities in a supply chain. We are allowing entities such as distributors, brokers, and aggregators to determine, conduct, and document appropriate supplier verification activities as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. However, because the approval of suppliers is ultimately the responsibility of the receiving facility, the rule specifies that only a receiving facility can approve suppliers. To improve clarity and readability we redesignated the proposed provisions into eight distinct sections of regulatory text in a newly established subpart E (Supply-Chain Program).

Each facility subject to the rule must have a recall plan for an animal food with a hazard requiring a preventive control.

Many activities required by the final rule must be conducted (or overseen) by a preventive controls qualified individual, a new term we are coining here. A preventive controls qualified individual is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system.

The rule establishes several exemptions (including modified requirements in some cases) from the requirements for hazard analysis and risk-based preventive controls. All of these exemptions are expressly authorized by FSMA. A facility that manufactures, processes, packs, or holds food and that is required to register with FDA would be required to comply with the requirements for hazard analysis and risk-based preventive controls unless it is covered by an exemption, as shown in the following table.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Who or what is exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
<p>“Qualified Facility” as defined by FSMA:                      Business with average annual sales of &lt;\$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or</p> <ul style="list-style-type: none"> <li>• Very small business, which the rule defines as a business (including any subsidiaries or affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale)</li> <li>• Low-risk, on-farm activities performed by small business (&lt;500 full-time equivalent employees).</li> </ul> <p>-or-</p> <ul style="list-style-type: none"> <li>• Low-risk, on-farm activities performed by a very small business (dollar threshold of \$2,500,000, as described previously).</li> </ul> <p>Activities that are subject to the “low-acid canned food” requirements of part 113 (21 CFR part 113).</p> <p>Activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety) (21 U.S.C. 350h).</p> <p>Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.</p> <p>A facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.</p>	<p>Modified requirements apply—i.e., a qualified facility is required to:</p> <ul style="list-style-type: none"> <li>• Notify FDA about its status and either:                             <ul style="list-style-type: none"> <li>○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or</li> <li>○ Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the animal food was manufactured or processed.</li> </ul> </li> <li>• The notification is in the form of an attestation, and must be submitted every 2 years, during the same timeframe as the facility is required to update its facility registration.</li> </ul> <p>Small and very small on-farm businesses conducting only the specified low-risk activities are exempt from the requirements for hazard analysis and risk-based preventive controls.</p> <p>We define the low-risk, on-farm activities that qualify for the exemption, including the specific animal foods to which they relate (such as re-packing roughage products, or cracking grains).</p> <ul style="list-style-type: none"> <li>• The exemption applies only with respect to microbiological hazards regulated under part 113.</li> <li>• The facility must be in compliance with part 113.</li> </ul> <p>These activities will be established in FDA’s forthcoming rule for produce safety.</p> <p>A facility that stores raw agricultural commodities that are fruits and vegetables is not exempt.</p> <p>Modified requirements apply for the storage of unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.</p>

The rule includes procedures for withdrawing a qualified facility exemption, in the event of an active investigation of a foodborne illness outbreak that is directly linked to the facility, or if FDA determines that it is necessary to protect the public (human and animal) health and prevent or mitigate a foodborne illness outbreak based on relevant conditions or conduct associated with the qualified facility. The final rule provides procedures for a facility to appeal an order to withdraw a qualified facility exemption, for a facility to request an informal hearing, for the conduct of an informal hearing, for an appeal, for revoking an order to withdraw a qualified facility exemption,

and for reinstating an exemption that was withdrawn.

The rule finalizes recordkeeping provisions associated with the new provisions for hazard analysis and risk-based preventive controls. These records allow facilities to show, and FDA to determine, compliance with the new requirements. To meet these requirements, a facility may use existing records as appropriate.

*Costs and Benefits*

This final regulation requires domestic and foreign facilities to adopt a food safety plan, perform a hazard analysis, and to institute preventive controls for the mitigation of those hazards identified as requiring a

preventive control. It also includes requirements for facilities to institute risk-based environmental monitoring, product testing, and a supply-chain program as appropriate to the animal food, the facility and the nature of the preventive controls, as well as a requirement to institute controls to help prevent hazards associated with economically motivated adulteration. The total annualized costs are estimated at \$139.0 to \$170.7 million per year (over 10 years at a 7 percent discount rate), and \$135.6 to \$166.7 million per year (over 10 years at a 3 percent discount rate). The total annualized benefits to pets are estimated at \$10.1–\$138.0 million.

ESTIMATED TOTAL COSTS AND BENEFITS

[Millions]

	One-time	Annual	Total annualized cost at 7% <sup>1</sup>	Total annualized cost at 3% <sup>1</sup>
Total Costs .....	\$135.6 to \$160.1	\$119.7 to \$147.9	\$139.0 to \$170.7	\$135.6 to \$166.7
Total Benefits to Pets .....	<sup>2</sup> N/A	\$10.1 to \$138.0	\$10.1 to \$138.0	\$10.1 to \$138.0

<sup>1</sup> Total annualized cost equal to annualized one-time cost plus annual cost.

<sup>2</sup> N/A = Not applicable

TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	What it means
AAFCO	Association of American Feed Control Officials.
AFSS	Animal Feed Safety System.
BAM	Bacteriological Analytical Method.
Bioterrorism Act	Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188).
CCP	Critical Control Point.
CFR	Code of Federal Regulations.
CGMP	Current Good Manufacturing Practice.
Codex	Codex Alimentarius Commission.
CPG	Compliance Policy Guide.
CVM	Center for Veterinary Medicine.
EPA	U.S. Environmental Protection Agency.
EU	European Union.
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOIA	Freedom of Information Act.
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture.
FSIS Validation Guidelines	FSIS' Compliance Guidelines on HACCP Systems Validation.
FSMA	FDA Food Safety Modernization Act.
FSPCA	Food Safety Preventive Controls Alliance.
FSVP	Foreign Supplier Verification Programs.
GAP	Good Agricultural Practices.
GFSI	Global Food Safety Initiative.
GRAS	Generally Recognized as Safe.
HACCP	Hazard Analysis and Critical Control Point.
HHS	U.S. Department of Health and Human Services.
ISO	International Organization for Standardization.
LACF	Thermally processed low-acid foods packaged in hermetically sealed contain (commonly called "low-acid canned foods").
N/A	Not Applicable.
NACMCF	The National Advisory Committee on Microbiological Criteria for Foods (advisory committee chartered under the USDA).
NIFA	National Institute of Food and Agriculture of the U.S. Department of Agriculture.
OMB	Office of Management and Budget.
PAS	British Standards Institute "Publically Available Specification 222:2011".
PFP	Partnership for Food Protection.
PHS	Public Health Service Act.
PRA	Paperwork Reduction Act.
PSA	Protein Surveillance Assignment.
RA	Risk Assessment.
RAC	Raw Agricultural Commodity.
RFR	Reportable Food Registry.
Section 103(c)(1)(C) draft RA	Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.
Section 103(c)(1)(C) RA	Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (Final).
TCS	Time/Temperature Control for Safe Animal Food.
USDA	U.S. Department of Agriculture.

**I. Background**

*A. FDA Food Safety Modernization Act*

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public (human and animal) health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather

than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal,

and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported animal food. To that end, we proposed the seven foundational rules listed in table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed rule for preventive controls for animal food.	78 FR 64736, October 29, 2013.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA—Continued

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed rule for preventive controls for human food.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule	78 FR 3504, January 16, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule .....	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification rule.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule (human food only).	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food .....	2014 proposed sanitary transportation rule.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice of proposed rulemaking for the rules listed in table 2 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 2—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental notice .....	79 FR 58476, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice ...	79 FR 58574, September 29, 2014.

As FDA finalizes these seven foundational rulemakings, we are putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 1 and 2). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in

food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will protect consumers into the future.

*B. Stages in the Rulemaking for the Animal Food Preventive Controls Rule*

With regard to this rulemaking, we published proposed provisions in the 2013 proposed animal food preventive controls rule and we published new and re-proposed provisions in the 2014 supplemental notice. In the 2014 supplemental notice, we reopened the comment period only with respect to specific proposed provisions. In addition, we emphasized that the re-proposed provisions we included in the regulatory text were based on a preliminary review of the comments.

In this document, we use the broad term “proposed animal food preventive controls rule” to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed animal food preventive controls rule and the new and re-proposed provisions we published in the 2014 supplemental notice. We use the narrow terms “2013 proposed preventive controls rule for animal food” and “2014 supplemental

notice” to refer to specific text published in the **Federal Register** of October 29, 2013 (78 FR 64736) and September 29, 2014 (79 FR 58476), respectively. We use the terms “final preventive controls rule for animal food” and “this rule” to refer to the regulations we are establishing as a result of this rulemaking.

*C. Summary of the Major Provisions of Proposed Rule for Preventive Controls for Food for Animals*

As part of our implementation of new statutory provisions in FSMA, we proposed to add, in newly established part 507, regulations for CGMPs. In addition, we proposed to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. As directed by FSMA (see section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g)), these new provisions would apply to domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) and our regulation for Registration of Food Facilities (21 CFR part 1, subpart H; the section 415 registration regulations). As directed by FSMA (see section 418(l) and (m) of the FD&C Act), we proposed to establish

modified requirements for certain facilities. We requested comment on all aspects of the proposed requirements, including an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain.

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive controls, and related requirements in new 21 CFR 507 as shown in table 3:

TABLE 3—PROPOSED SUBPARTS IN NEW PART 507

Subpart	Title
A .....	General Provisions.
B .....	Current Good Manufacturing Practice.
C .....	Hazard Analysis and Risk-Based Preventive Controls.
D .....	Withdrawal of an Exemption Applicable to a Qualified Facility.
E .....	Reserved.
F .....	Requirements Applying to Records That Must be Established and Maintained.

*D. Draft Risk Assessment*

We issued for public comment a “Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” (the section 103(c)(1)(C) draft risk assessment (RA)) (78 FR 64428, October 29, 2013). The purpose of the section 103(c)(1)(C) draft RA was to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk when conducted in a facility co-located on a farm. We used the tentative conclusions of the section 103(c)(1)(C) draft RA to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities from the requirements for hazard analysis and risk-based preventive controls. We are including the final risk assessment (the section 103(c)(1)(C) RA) in the docket established for this document (Ref. 3).

*E. Public Comments*

We received more than 2400 public submissions on the 2013 proposed preventive controls rule for animal food, and more than 140 public submissions on the 2014 preventive controls supplement notice, each containing one or more comments. We received

submissions from diverse members of the public, including animal food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; pet owners, consumer groups; Congress, Federal, State, local, and foreign Government Agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments address virtually every provision of the proposed animal preventive controls rule. In the remainder of this document, we describe these comments, respond to them, and explain any revisions we made to the proposed preventive controls rule for animal food.

Some comments address issues that are outside the scope of this rule. For example, some comments ask for more inspections of pet food facilities. Other comments express concern about the use of bioengineered animal food ingredients, and ask that animal foods containing such ingredients not be used in pet food. Other comments have concerns with FDA’s general obligations for the outcome of regulations it issues and implements, general concerns with FDA’s regulation and oversight of industry, concerns about banning specific products or imports from specific countries, testing procedures at the borders, and concerns about animal food marketing. We do not discuss such comments in this document.

**II. Legal Authority**

The proposed rule contained an explanation of its legal basis under authorities in FSMA, the FD&C Act, and the Public Health Service Act (the PHS Act). After considering comments received in response to the 2013 proposed rule and the 2014 supplemental notice, we made changes in the final rule. The legal authorities relied on for the final rule are generally the same as in the proposed rule unless otherwise described.

*A. Current Good Manufacturing Practice Regulations*

The CGMP regulations finalized in this document establish current good manufacturing practice requirements for the manufacturing, processing, packing and holding of animal food. FDA’s legal authority to require current good manufacturing practice derives from sections 402(a)(3) and (4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3) and (4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in

part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The CGMP regulations we are establishing are necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

In addition to the FD&C Act, FDA’s legal authority for establishing CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States \* \* \* or from one State \* \* \* into any other State” (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary.) The CGMP regulations are necessary to prevent the spread of communicable disease.

The CGMP regulations finalized in this document include limited labeling requirements. These requirements are partly to help prevent accidental comingling or mix-ups of products at the facility, which could result in contaminated animal food. Thus, FDA’s legal authority for these requirements derives from its authority to require current good manufacturing practice. The labeling requirements also are intended to enable animal producers and owners, and facilities receiving the animal food for further manufacture, to use the animal food appropriately. Accordingly, the requirements are supported by section 403(a)(1) of the FD&C Act, which states that a food is misbranded if its labeling is false or misleading in any particular, and by section 403(i) of the FD&C Act, which states that a food is misbranded unless

its label bears the common or usual name of the food or its ingredients.

*B. Hazard Analysis and Risk-Based Preventive Controls*

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations “to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. . . .” Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms “small business” and “very small business,” taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Further, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit “(t)he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 (of the FD&C Act).”

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to “prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 (of the FD&C Act). . . .” In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b) to (i) contain more specific requirements applicable to facilities. These include hazard analysis (section 418(b)), preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)).

Section 103(c)(2)(C) of FSMA requires that the Secretary adopt a final rule with respect to the requirements under sections 418 and 421 of the FD&C Act

from which the Secretary may issue exemptions or modifications of the requirements for certain types of facilities. Sections 418(j) to (m) of the FD&C Act and sections 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to low-acid canned food (section 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (section 418(k)); qualified facilities (section 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (section 418(m)); and facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses (section 103(c)(1)(D) of FSMA). In sections X, XI, XII, and XXXVI we discuss provisions that implement these exemptions and modified requirements.

In the supplemental notice, we included potential requirements for a supplier program, environmental monitoring, and product testing. We are including provisions for such activities in the final rule. Section 418(o)(3) of the FD&C Act provides supplier verification activities and an environmental monitoring program as examples of preventive controls. Section 418(f)(4) of the FD&C Act provides for the use of environmental and product testing programs as part of required verification that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

In certain circumstances, the final rule does not require a manufacturing/processing facility to implement a preventive control for a hazard requiring a preventive control. Instead, the facility is permitted to rely on a subsequent entity in the distribution chain to significantly minimize or prevent the hazard. In such a circumstance, a facility must disclose in documents accompanying the animal food, that the food is “not processed to control [identified hazard].” This requirement is supported by sections 418 and 701(a) of the FD&C Act (21 U.S.C. 350g and 371(a)). The requirement that facilities apply preventive controls to significantly minimize or prevent hazards is fundamental to the public health benefits of the rule. To accommodate the realities of modern food production, the rule allows a

facility to rely on a subsequent entity in the distribution chain rather than requiring that facility to apply the control. An animal food may pass through multiple entities in the distribution chain before it reaches consumers. Further, ordinarily it is not apparent from visual examination of the animal food whether a hazard requiring a preventive control has been addressed. Consequently, without labeling, a facility might not know that a facility upstream in the supply chain has not applied a preventive control and is relying on a downstream entity to do so. Therefore, the agency concludes that information that animal food has not been processed to control an identified hazard is necessary for a facility to fulfil its obligation under section 418 when a facility is relying on a subsequent entity to control the hazard. The agency also concludes that such labeling is necessary for the efficient enforcement of the FD&C Act because the labelling is critical for FDA to hold facilities responsible for their obligations under this regulatory scheme. Further, when the hazard can cause a communicable disease, FDA concludes that the requirement is necessary to prevent the spread of communicable disease from one state into another state and relies on sections 311, 361, and 368 of the PHS Act.

FDA concludes that the provisions in subpart C and related requirements in subparts A, E and F should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b) (21 CFR 1.225(b))). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 (section 418(o)(2) of the FD&C Act) and does not exclude a facility from the requirements because food from such a facility is not in interstate commerce. Further, the prohibited act provision associated with section 418 (section 301(uu) of the FD&C Act) does not require interstate commerce for a violation.

FDA also is issuing the provisions in subpart C and related requirements in subparts A, E and F, under sections 402(a)(3) and (4), and 701(a) of the FD&C Act to the extent such requirements are necessary to prevent animal food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food. FDA also is finalizing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent

those provisions are necessary to prevent the interstate spread of communicable disease.

### III. General Comments on the Proposed Rule

(Comment 1) Several comments ask us to develop guidance to accompany the rule, particularly with respect to the new requirements for hazard analysis and risk-based preventive controls. For example, comments ask us to provide guidance on topics such as hazard analysis, environmental monitoring, and validation. Some of these comments ask that drafts of the guidance first be made available for public comment. Some of these comments request that the guidance be available as soon as possible and before the rule becomes effective. Some comments request guidance specific to small businesses. Several comments suggest FDA revisit some current compliance policy guidances in light of FSMA and the proposed rules.

Other comments emphasize the importance of education and outreach and ask us to provide support for ongoing education and outreach, including an active role in providing needed instructional examples and lessons learned from current investigations and foodborne outbreaks. Some comments ask us to convene a scientific workgroup that includes experts in food and laboratory science, public health, proficiency testing, quality control, and other areas on at least an annual basis to assess what hazards should be addressed in food safety plan. Other comments ask us to engage universities and extension in education and training efforts.

Some comments ask that funding and information on funding for training be provided. Other comments assert that we must make available adequate resources to support outreach and technical assistance delivered by State regulatory Agencies, as well as Cooperative Extension programs and non-governmental organizations that work directly with farmers and facilities.

(Response 1) We are developing several guidance documents, including general guidance on hazard analysis and preventive controls, as well as guidance for complying with the CGMP requirements of subpart B (Ref. 4). We will develop and issue this guidance in accordance with our good guidance practices regulation, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when

appropriate (§ 10.115(g)) (21 CFR 10.115(g)). The public may submit comments on any guidance document at any time (§ 10.115(g)(5)). In addition, we intend to review current guidance documents and make a determination whether they need to be withdrawn or revised based on this final rule.

We agree with comments that stress the importance of education and outreach. A central element of our strategy to gain industry compliance is to help make available to facilities subject to this rule the education and technical assistance they need to understand and implement the requirements (Ref. 5). Within the Agency we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 5). This will allow us to respond in a timely and consistent way to industry questions on preventive controls technical and compliance issues (Ref. 5).

We also are working in collaboration with the Food Safety Preventive Controls Alliance (FSPCA) to develop training materials and establish training and technical assistance programs (Refs. 5 and 6). The Alliance includes members from FDA, State food protection Agencies, the food (human and animal) industry, and academia. It is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health, a nationally recognized leader in food safety. In addition to developing a standardized preventive controls training curriculum, the FSPCA is developing selected sections of model food safety plans for several food types that will provide needed instructional examples.

Although we have provided funding to the FSPCA to develop a standardized preventive controls training curriculum, we are unable to fund training for individual groups who might need particular training materials.

We also are partnering with the National Institute of Food and Agriculture (NIFA) of the U.S. Department of Agriculture (USDA) to administer the FSMA-mandated National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, a grant program to provide technical assistance for FSMA compliance to owners and operators of small and medium-size farms and small food processors (Ref. 7). Such efforts will help ensure widespread voluntary compliance by encouraging greater understanding and

adoption of established food safety standards, guidance, and protocols.

(Comment 2) Some comments ask us to explain how we will enforce the rule, particularly with respect to coordination with State and local authorities and with other Federal Agencies. For example, some comments ask whether FDA or the States will pay for inspections, whereas other comments ask us to coordinate inspection of imports with USDA's Food Safety and Inspection Service (FSIS) or ask us to combine our inspections with those of USDA where possible. Some comments express concern about the time gap between the effective date of this rule and the time it will take to incorporate applicable provisions into State law.

(Response 2) We are working through the Partnership for Food Protection (PFP) (a group of dedicated professionals from Federal, State, local, tribal, and territorial governments with roles in protecting the food supply and public health) to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA). For an example of our current thinking on establishing partnerships for achieving compliance, see the "best practices" document made available by PFP (Ref. 8). This "best practices" document provides information to FDA field and State programs on a variety of issues, including how to coordinate compliance activities. Our document entitled "Operational Strategy for Implementing FSMA" also recognizes the importance of developing operational partnerships with States and other government counterparts to optimize the effectiveness, efficiency, and consistency of FSMA implementation domestically (Ref. 9).

We are implementing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance (Ref. 10). This new paradigm involves a major reorientation and retraining, for which we are seeking funding, of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of State, local, and tribal inspectors (Ref. 10).

(Comment 3) Some comments ask us to reevaluate the proposed animal food preventive controls rule, compare it with existing programs, and identify a mechanism for integrating compliance verification with existing industry and

governmental programs. These comments note that many handlers/processors use and understand voluntary food safety management systems such as HACCP and HACCP-based certification programs and ask us why we proposed to create a separate inspection framework for FSMA, without integrating that inspection framework with existing programs.

(Response 3) We decline this request. As previously discussed, we are establishing this rule as required by section 103 of FSMA (78 FR 64736 at 64743 through 64745 and 64817 through 64818). However, where compliance with this rule mirrors compliance with existing regulatory requirements, there is no need to duplicate existing records, which may be supplemented as necessary to include all of the required information. (See also Response 2 regarding implementation of a national Integrated Food Safety System.)

(Comment 4) Some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other. One comment specifically asks us to harmonize the human and animal food preventive controls final rules to avoid confusion by firms that produce both human and animal food.

(Response 4) We have aligned the provisions of the various rules to the extent practicable. For example, we use the same definitions of “farm” and the same terms used in the definition of “farm” (*i.e.*, packing, holding, and manufacturing/processing) in this rule, the human food preventive controls rule, and the proposed produce safety rule. However, the statutory direction is not the same for all the rules, and this difference in statutory direction does lead to some differences between the rules. For example, section 418(l) of the FD&C Act (which relates to this rule) provides for modified requirements for facilities that are very small businesses in addition to facilities that satisfy criteria for sales to qualified end-users, but section 419(f) of the FD&C Act (which relates to the proposed produce safety rule) only provides for modified requirements for direct farm marketing.

Likewise, we have worked to align the provisions of this rule with the provisions of the Foreign Supplier Verification Program (FSVP) rule. Again, however, there are statutory differences that lead to some differences between the rules. For example, section 805 of the FD&C Act (21 U.S.C. 348a), applies to an importer, whereas section 418 of the FD&C Act applies to a facility that is required to register under section 415 of the FD&C Act. Except in the circumstance where an importer is also

a manufacturer/processor, an importer must conduct a hazard analysis as part of the foreign supplier verification requirements, whereas a facility that is a manufacturer/processor must conduct a hazard analysis to determine whether the requirements of the animal food preventive controls rule apply to it. As another example, section 805 of the FD&C Act does not provide an exemption for small or very small entities, whereas section 418 of the FD&C Act provides an exemption for “qualified facilities,” which include very small businesses.

To the extent possible, we have attempted to harmonize the animal food preventive controls final rule with the human food preventive controls final rule. The CGMP (subpart B) requirements address the manufacturing, processing, packing, and holding practices at animal food plants, but are similar to those for human food, where appropriate. Furthermore, § 507.1(d) contains provisions for a human food facility that also manufactures, processes, packs, or holds animal food. This is intended to reduce confusion and increase flexibility for facilities that produce both human and animal food.

(Comment 5) Some comments express concern that we will enforce the rule more strictly for domestic facilities than for foreign facilities, *e.g.*, because we lack the funds and manpower to enforce the rule for foreign facilities. Other comments assert that it is unprecedented for importing countries to regulate the production processes in exporting countries and that no scientific evidence supports such regulation. These comments express concern that this regulatory requirement will greatly increase trading costs and might constitute a barrier to trade for exporting countries.

(Response 5) We intend to enforce this rule in a consistent manner to ensure that imported and domestically produced animal foods are in full compliance with the requirements of this rule. We note that the forthcoming FSVP rule will require importers to help ensure that animal food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public (human and animal) health protection as those required under this rule. The implementation of these supplier verification programs by U.S. importers will thus provide assurances that imported animal food is in compliance with this regulation.

We disagree that we are seeking to “regulate the production processes in exporting countries” inappropriately. This rule provides for a flexible set of principles and a framework for hazard analysis and risk-based preventive controls to be applied to a given production process in order to ensure the production of safe animal food destined for the United States. Mandating that a finished animal food is manufactured under general methods applicable to all animal foods (*e.g.*, good manufacturing practices) is a widely accepted regulatory practice and fundamentally different than mandating that animal food be produced in a certain way. We note that other countries have adopted animal food safety regulations that mandate certain principles and conditions to be applied to animal food manufacturing. Because the requirements being implemented by FDA under this regulation are flexible and not prescriptive, we do not agree that this regulation will significantly increase costs or impede trade.

We also disagree that there is no scientific evidence supporting this rule. In the 2013 proposed preventive controls rule for human and animal food, we provided an extensive background discussing the scientific evidence upon which this rule is based (78 FR 3646 at 3659 through 3667, January 16, 2013 and 78 FR 64736 at 64745, October 29, 2013). In addition, the Appendix to the 2013 proposed preventive controls rule provided additional scientific information on activities such as product testing and environmental monitoring to support their role in ensuring safe food and how these align with international standards such as those of Codex Alimentarius (78 FR 64736 at 64834 through 64836).

(Comment 6) Many comments from pet owners are generally supportive of the rule; however, some request additional regulations and oversight for pet food. Many comments state that pet food should meet the same standards as human food. Some comments request that pet food be required to be tested for safety.

(Response 6) The CGMP requirements in subpart B are intended to serve as baseline standards for producing safe animal food across all types of animal food facilities, including pet food facilities. For discussion of the relevance of the CGMP requirements to pet food, see Response 163. Many pet food facilities (as well as facilities producing other animal food) will be subject to the preventive controls requirements of subpart C. These provisions require the pet food manufacturer to identify and evaluate



potential hazards for the pet food to determine whether a preventive control is required (see § 507.33). These could be hazards to the pet consuming the pet food or the person handling the pet food (e.g., Salmonella). The preventive controls provisions also include requirements for product testing for pathogens or other hazards and environmental monitoring for pathogens under certain circumstances (see § 507.49), in order to help ensure the safety of the pet (animal) food. Currently, low-acid canned animal food in a hermetically sealed container (such as canned pet food) is subject to the requirements of § 500.23 (21 CFR 500.23) and part 113 to control microbiological hazards.

(Comment 7) Some comments request communication and coordination with state regulators throughout the FSMA implementation phase. Some comments specifically request training of FDA staff and regulatory partners to inspect animal food facilities because there are differences between animal food and human food facilities. Some comments request that inspectors receive training on the broad range of animal food manufacturing. At least one comment requests we establish a national advisory committee to provide ongoing input throughout FSMA implementation and enforcement. Some comments request that we provide methods for communication with State and other regulatory partners, including possibly a call center or other direct-contact resource for regulators and industry to obtain information on FSMA.

(Response 7) As discussed in Response 1, we are working in collaboration with the FSPCA to develop training materials and programs to be used by industry and regulators. The training will be specific to human or animal food and will include information on developing a food safety plan tailored to each facility's unique hazards. We will consider these and other recommendations for the content of such training as part of that collaborative effort.

As discussed in Responses 1 and 2, we are working through two working groups (FSCPA and PFP) that involve State and local regulators in order to implement this final rule. We will continue to work through these groups, as well as use other methods of communication and coordination (e.g., arranged teleconference meetings with the States (i.e., 50-State calls) to collaborate with State and local regulatory officials to implement this final rule. We will consider these recommendations as we communicate

with State and local regulatory partners during the implementation of this final rule.

(Comment 8) Some comments request that this final rule have a provision similar to the proposed produce safety rule that allows a state or foreign country to request a variance from the rule's requirements due to procedures, processes, and practices that ensure a product is not adulterated.

(Response 8) We are implementing these regulations according to the statutory direction of FSMA. A variance request and review process is specified for produce in section 419(c)(2) of the FD&C Act; however, there are no similar provisions in FSMA directing FDA to create a variance process for facilities subject to the preventive controls regulations and we therefore are declining to do so.

(Comment 9) Some comments ask us to take a "BASE" approach to implementing FSMA. These comments describe this approach as follows: B stands for borders, a critical area where FDA should be focusing its attention and resources; A stands for audits, recognizing that FDA will need to actively audit states and foreign suppliers; S stands for standard, representing the standards FDA will set by which firms will be audited; and E stands for education, ensuring that all stakeholders know their roles and responsibilities required by the rules.

(Response 9) While we do not intend to follow the BASE approach described in the comment, we expect that some of our implementation efforts will be similar to the approach described. For discussion of our implementation planning, see Responses 1 and 2. To the extent this comment is referring to animal food from foreign suppliers presented for import, this is a subject of the forthcoming FSVP rule.

(Comment 10) Some comments requested exceptions or reduced requirements that were not previously proposed. One comment requests a narrower scope of requirements for facilities involved in the production of chemicals used as food additives or in accordance with generally recognized as safe (GRAS) standards.

(Response 10) We decline these requests. The CGMPs in subpart B and preventive controls in subpart C are written to serve as baseline standards for producing safe animal food across all types of animal food facilities, including those producing food additives or other ingredients.

#### IV. Definitions in the Section 415 Registration Regulations (21 CFR Part 1, Subpart H)

##### A. Definitions That Impact a Determination of Whether an Establishment Is a "Farm"

The 2013 proposed rule for human food preventive controls contained a description (78 FR 3646 at 3675 through 3676) of the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations. That description focused on the framework that governs whether an establishment that grows and harvests crops or raises animals satisfies the definition of "farm," because the facility registration requirements of section 415 of the FD&C Act do not apply to "farms." Under that framework, a key factor in whether an establishment falls within the definition of "farm," even with respect to crops it grows and harvests itself, is whether the activities conducted by the establishment fall within definitions of "harvesting," "packing," or "holding" (which are within the "farm" definition). Another key factor is whether activities conducted by the establishment fall within the definition of manufacturing/processing (which have been outside the "farm" definition).

In the 2014 supplemental human preventive controls notice, comments were described regarding proposed revisions to the definitions of "farm," "harvesting," "packing" and "holding," as well as comments regarding the triggers for an activity to be considered manufacturing/processing (79 FR 58524 at 58530 through 58538). Additional revisions were proposed to the definitions of "farm," "harvesting," "packing" and "holding" to address these comments.

Even after the revisions we proposed in the 2014 supplemental human preventive controls notice, some comments assert that the overall "farm" definition still presents an unrealistic and incomplete understanding of how most farms in America are structured with regard to their physical location(s) and business models. See table 4 for revised definitions that are being finalized in the human food preventive controls for the section 415 registration regulations and the section 414 recordkeeping regulations.

In section IV of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, comments on the proposed changes to the section 415

registration regulations and to the section 414 recordkeeping regulations are discussed.

TABLE 4—REVISIONS TO THE PROPOSED DEFINITIONS IN THE SECTION 415 REGISTRATION REGULATIONS AND THE SECTION 414 RECORDKEEPING REGULATIONS

Definition	Revision
Farm .....	<ul style="list-style-type: none"> <li>• A farm is an “operation” rather than an “establishment.”</li> <li>• There are two types of farms: (1) Primary production farm; and (2) secondary activities farm.</li> </ul>
Primary production farm .....	<ul style="list-style-type: none"> <li>• A primary production farm is “under one management” rather than “under one ownership.”</li> <li>• Although a primary production farm continues to be “in one general physical location,” we have clarified that “one general physical location is “not necessarily contiguous.”</li> <li>• A primary production farm is an operation devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. Although some primary production farms both grow and harvest crops, other primary production farms grow crops but do not harvest them, and other primary production farms harvest crops but do not grow them.</li> <li>• Treatment to manipulate the ripening of raw agricultural commodities (RACs), and packaging and labeling the treated RACs, without additional manufacturing/processing, is within the “farm” definition.</li> <li>• We added an example of drying/dehydrating RACs to create a distinct commodity that would fall within the “farm” definition (i.e., drying/dehydrating grapes to produce raisins), as well as an example of additional manufacturing/processing that would cause an operation that dries/dehydrates RACs to create a distinct commodity to fall outside the “farm” definition (i.e., slicing).</li> <li>• We added an example of additional manufacturing/processing that can cause an operation that packages and labels RACs to fall outside the “farm” definition (i.e., irradiation).</li> </ul>
Secondary activities farm .....	<ul style="list-style-type: none"> <li>• A “secondary activities farm” is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.</li> <li>• A secondary activities farm may also conduct those additional activities allowed on a primary production farm.</li> </ul>
Harvesting .....	<ul style="list-style-type: none"> <li>• We added additional examples of harvesting activities.</li> </ul>
Holding .....	<ul style="list-style-type: none"> <li>• We added additional examples of holding activities.</li> </ul>
Manufacturing/Processing .....	<ul style="list-style-type: none"> <li>• We added additional examples of manufacturing/processing activities.</li> </ul>

*B. Proposed Revisions to the Definition of Farm*

In the human food proposed preventive controls rule, we proposed to revise the “farm” definition to (1) Provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACs; (2) include, within the “farm” definition, a description of packing activities that include packaging RACs grown or raised on a farm without additional manufacturing/processing; and (3) provide for drying/dehydrating RACs to create a distinct commodity (such as the on-farm drying of grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing, to remain within the farm definition. See section IV.B of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, for a full discussion of comments and responses on the proposed revisions to the farm definition.

In the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, we have revised the definition of farm to replace the term “under one ownership” with the term “under one

management.” As discussed in section IV.B of the final rule for preventive controls for human food, although the original phrase “under one ownership” was not referring to a single owner, the “farm” definition should reflect modern business models (such as cooperatives, on-farm packinghouses under ownership by multiple growers, food aggregators, and food hubs) and use language that the modern farming community understands. The term “under one management” refers to the control structure of the business, that is, the management of the business entity that is the farm operation. Thus, for example, a primary production farm that hires another company as a contract harvester to perform harvesting services on the primary production farm’s behalf is not “under one management” with the primary production farm just because the primary production farm is directing the contractor’s activities performed on the primary production farm’s behalf. The primary production farm and the contract harvester have separate and independent management structures because they are separate and independent businesses. (See Response 25 in the final rule for preventive controls for human food). As another example, if a poultry processing company contracts with a primary production farm to raise chickens on the

poultry processor’s behalf, the poultry processor and the primary production farm are not “under one management,” even if their contract strictly controls almost all aspects of the raising of the poultry. The poultry processor and the primary production farm have separate and independent management structures because they are separate and independent businesses.

In the final rule for preventive controls for human food, we also revised the farm definition to add a new category: A “secondary activities farm.” (See Response 25 in the final rule for preventive controls for human food). An important limitation on the types of operations that fit within this category is that they must be majority owned (or majority jointly owned) by the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs the secondary activities farm harvests, packs, and/or holds. Thus, both product and majority ownership must link a secondary activities farm to a primary production farm(s).

For example, a primary production farm may own a majority interest in a separate business that holds RACs and processes them into animal food (e.g., a feed mill). If the majority of the RACs held by the feed mill come from the primary production farm that owns the feed mill’s majority interest, the feed

mill is a secondary activities farm and may manufacture/process animal food within the farm definition, but only to the extent that the animal food manufactured is consumed at the feed mill or on another farm whose "one management" is the same management as the feed mill. However, if the feed mill in this example manufactures/processes animal food that is consumed on farms that are not under the same management as the feed mill, that manufacturing/processing is outside the farm definition, the feed mill is subject to registration under section 415 of the FD&C Act, and its manufacturing/processing of animal food for consumption on farms not under the same management is subject to the requirements of this rule.

To further clarify, a feed mill that is not majority owned by a primary production farm(s) cannot be a secondary activities farm. Also, a feed mill that does not receive more than half of the RACs it holds from primary production farm(s) that own a majority interest in the feed mill cannot be a secondary activities farm. For example, a feed mill owned by a poultry processing company will be required to register as a food facility, unless the feed mill otherwise meets the definition of "farm." When a feed mill is owned by a company such as a poultry processor, it is not majority owned by the primary production farm(s) that supply the majority of the RACs it holds, and therefore the feed mill cannot be a secondary activities farm.

#### *C. Proposed Revisions to Definitions of Harvesting, Holding, Manufacturing/Processing, Mixed-Type Facility, and Packing*

See section VIII. for a discussion of comments and responses and revisions to the definitions in part 507 of harvesting, holding, manufacturing/processing, mixed-type facility, and packing. For a discussion of comments and responses to these definitions in the section 415 registration regulations and the section 414 recordkeeping regulations, see section IV.C through IV.G of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

#### *D. Comments on Feed Mills Associated With Fully Vertically Integrated Farming Operations*

In the 2014 supplemental notice for animal food, we requested comment on whether feed mills that are part of fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition

should be required to register under section 415 of the FD&C Act (and thus would be subject to the rule). For comments that supported applying the final preventive controls rule to feed mills that are part of fully vertically integrated farming operations, we requested input on how the farm definition should be modified. If they were required to register, we also requested comment on whether there should be exemptions from registration under section 415 based on size, such as number of animals being fed or the amount of animal food being fed (based on tonnage, monetary value, or some other factor). Lastly, since there would be no total annual sales figure for the animal food produced by these feed mills, we requested comment on how to value the animal food being fed to animals for purposes of determining whether the feed mill would be a qualified facility (proposed § 507.7) and in particular a very small business.

(Comment 11) Some comments generally agree with our recognition that there are different types of farm models for raising animals but request additional clarification on what we mean by a fully vertically integrated farming operation and the depth of integration within an operation.

(Response 11) Feed mills that are part of fully vertically integrated farming operations, or certain cooperative farming operations that meet the definition of a farm (see § 1.227, as revised by the final rule for preventive controls for human food published elsewhere in this **Federal Register**), are not subject to this final rule because they are not required to register under section 415 of the FD&C Act (see § 507.5(a)). Because expanding on the characteristics of a fully integrated farming operation is beyond the scope of this rule, we decline to further clarify the fully vertically integrated farming operation farming model discussed in the 2014 supplemental notice.

(Comment 12) Some comments do not support modifying the farm definition to subject feed mills that are part of fully vertically integrated farming operations to the requirements of this final rule. These comments state that these feed mills are currently making safe animal food and that some are following industry best practices that would meet or exceed the requirements of our proposed CGMPs. Some comments also state that these feed mills are producing a narrower range of animal food when compared to independent feed mills because these integrated feed mills typically provide animal food to a single species and therefore utilize fewer ingredients, resulting in less chance of

harmful error. Some comments note that for large farming operations, feeding of the animals is overseen by dedicated individuals, such as a nutritionist, which ensures an extra layer of oversight for the safety of animal food.

Some comments express concern that feed mills associated with contract farming operations (contract feed mills) will be treated differently because, as proposed in the 2013 proposed rule, they would need to comply with the rule unlike the feed mills that are part of fully vertically integrated farming operations. These comments recommend modifications to the farm definition to incorporate the contract feed mills into the farm definition, resulting in the contract feed mills no longer being required to register under section 415 and therefore no longer being subject to the requirements of this rule. Some comments (including ones that support and ones that oppose modifying the farm definition) generally agree there is no evidence that the safety of animal food varies depending on whether a feed mill is associated with vertically integrated or contract farming. These comments also state that the farm definition as proposed has the potential to create disparity in regulatory requirements that feed mills must follow based solely on the type of farming model with which they are associated (*i.e.*, some will be subject to CGMP and preventive controls requirements, while some will be subject to neither).

Some comments support modifying the farm definition to subject feed mills that are part of fully vertically integrated farming operations to the requirements of this final rule, and some of those comments also support providing an exclusion if it is limited to small on-farm animal food mixers. Other comments contend that some of the feed mills that are part of fully vertically integrated farming operations produce large volumes of animal food that feed a substantial portion of the U.S. food-producing animal population and that these feed mills should be subject to the final rule to ensure continual production of safe animal food. Some comments state concern that the feed mills that are part of fully vertically integrated farming operations could introduce food safety hazards into the human food supply because they are not being adequately controlled due to the feed mills' exemption from this rule.

Comments that support modifying the farm definition to subject feed mills that are part of fully vertically integrated farming operations to the requirements of this final rule recommend that any exemption from this final rule

applicable to farms be limited based on the volume of the animal feed produced or animal equivalency units.

(Response 12) The farm definition in 21 CFR part 1 has been modified based on other comments received to both the 2014 supplemental notice for human food preventive controls and to the 2014 supplemental notice for animal food preventive controls (see section IV.B of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**). However, feed mills that are part of fully vertically integrated farming operations still meet the definition of farm. As a result, they are not required to register as a food facility under section 415 and are not subject to the requirements of this rule including CGMPs (subpart B) and Hazard Analysis and Risk-Based Preventive Controls (subpart C), and supply-chain program (subpart E). We remain concerned that this leaves a gap in the protection of public (human and animal) health because these feed mill operations manufacture significant amounts of animal food. While some of these feed mills may be voluntarily implementing some type of animal food safety measures, not all feed mills that are part of vertically integrated farming operations do. In addition, the voluntary measures adopted by some feed mills may not meet the standards of the food safety requirements in this rule. Moreover, we do not and cannot enforce compliance with purely voluntary practices. Finally, we recognize that other feed mills not part of a “farm” as defined in part 1 will have to comply with the requirements of this rule (unless they qualify for an exemption). As we have previously stated, we do not have evidence that the safety of animal food varies depending on whether a feed mill is part of vertically integrated or contract farming. Therefore, we intend to publish a proposed rule that would require some feed mill operations that currently are part of a farm to comply with the CGMPs (subpart B) of this rule.

The animal food CGMP requirements help ensure that animal food is protected from contamination during manufacturing, processing, packing, and holding (see sections XIV to XXII for further discussion of the animal food CGMP). By implementing these CGMPs, we believe that feed mills not currently covered by this rule would be able to provide a baseline level of animal food safety, thus further protecting the public (human and animal) health. We will continue to review the comments received from the 2014 supplemental proposed rule and other available data in considering a proposed rule for feed

mills that are part of fully vertically integrated farming operations that are not required to register under section 415, but produce a large volume of animal food. One reason we are not finalizing new food safety requirements for feed mills that are part of fully integrated farming operations in this rulemaking is that we need more information to help guide the scope of the requirements. As part of the future rulemaking process we will seek input on the best way to subject vertically integrated feed mills that produce large volumes of animal food to food safety requirements while avoiding overburdening on-farm feed mixers that produce a small amount of food for a small number of animals. The proposed rulemaking would not change the applicability of subpart C, “Hazard Analysis and Risk-Based Preventive Controls,” for feed mills that are part of a farm. Because farms meeting the definition of § 1.227 are not required to register under section 415 of the FD&C Act, § 507.5(a) exempts them from compliance with subpart C, as required by FSMA.

#### **V. Comments on the Organizing Principles for How the Status of a Food as a Raw Agricultural Commodity or as a Processed Food Affects the Requirements Applicable to a Farm Under Sections 415 and 418 of the FD&C Act**

In the 2014 supplemental notice (79 FR 58476 at 58482), we referred to the 2014 supplemental human preventive controls notice that discussed comments on the organizing principles that formed the basis for proposed revisions to section 415 registration regulations and the section 414 recordkeeping regulations (79 FR 58524 at 58538). We also explained how its proposed revisions to the “farm” definition would require FDA to reconsider those organizing principles (79 FR 58524 at 58538).

For discussion of comments, see section V of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

#### **VI. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities**

##### *A. Section 103(c)(1)(C) of FSMA*

We previously described provisions of FSMA that direct us to conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the “farm” definition and, thus, subject to the requirements for hazard analysis

and risk-based preventive controls (see section 103(c)(1)(C) of FSMA and 78 FR 64736 at 64751 and 64752 through 64754). Consistent with this statutory direction, we developed the section 103(c)(1)(C) draft RA and made it available for public comment (Ref. 11 and 78 FR 64428). We are including the final risk assessment (the section 103(c)(1)(C) RA) in the docket established for this document (Ref. 3).

We previously described provisions of FSMA that direct us to consider the results of the science-based risk analysis and exempt facilities that are small or very small businesses from the requirements for hazard analysis and risk-based preventive controls (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of on-farm activities that we determine to be low risk involving specific animal foods that we determine to be low risk (see section 103(c)(1)(D) of FSMA and 78 FR 64736 at 64751, 64753 through 64754, and 64763 through 64764). In section X.F, we discuss the provisions we are establishing in § 507.5(e) and (f), based on the results of the section 103(c)(1)(C) RA, to exempt farm mixed-type facilities that are small or very small businesses from requirements for hazard analysis and risk-based preventive controls if the only activities that the business conducts that are subject to those requirements are low-risk activity/animal food combinations.

We also previously described provisions of FSMA that direct us to: (1) Identify high risk-facilities and allocate resources to inspect facilities according to the known safety risks of the facilities (as determined by several factors) and immediately increase the frequency of inspection of all facilities (see the discussion of section 421 of the FD&C Act at 78 FR 64736 at 64754) and (2) consider a possible exemption from or modification of requirements of section 421 of the FD&C Act as we deem appropriate (see the discussion of section 103(c)(1)(D) of FSMA at 78 FR 64736 at 64744). We tentatively concluded that we should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in low-risk activity/animal food combinations and is a small or very small business and requested comment on this tentative conclusion.

##### *B. Comments on Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition*

(Comment 13) Some comments address the qualitative nature of the section 103(c)(1)(C) draft RA and assert

that it is based on professional judgment rather than data. These comments ask us to update the section 103(c)(1)(C) draft RA when more data become available. Some comments assert that we should not rely on data from the Food Processing Sector Study (Ref. 12), but instead collect data from large-scale surveys of actual farm mixed-type facilities and their activities. Other comments ask us to collect, analyze, and interpret data about the levels of hazards from animal food samples taken from small and very small mixed-type facilities and use consumption to estimate the likelihood of exposure to hazards in animal food from such facilities. Some comments ask us to consult with subject matter experts to ensure that the final risk assessment reflects sufficient geographic diversity.

(Response 13) We have acknowledged the limitations of the section 103(c)(1)(C) draft RA (Ref. 11 and 78 FR 64428; see section I.F in that document). Rather than limit public input to subject matter experts, we requested comment from all interested persons, and received a number of comments about activity/animal food combinations conducted on farms and farm mixed-type facilities, including comments from diverse geographic areas comprising both areas where farms and farm mixed-type facilities tend to be small and where they tend to be large. We disagree that we need to conduct large scale surveys, or enter into agreements with agencies/organizations, to collect additional information in light of the previous opportunity for broad public input regarding the activity/animal food combinations conducted on farms and farm mixed-type facilities.

(Comment 14) Some comments assert that we should revise the section 103(c)(1)(C) draft RA and then make it available for additional public comment before finalizing the rule.

(Response 14) We subjected the section 103(c)(1)(C) draft RA to peer review in accordance with the requirements of the Final Information Quality Bulletin for Peer Review (issued by the Office of Management and Budget to implement the Information Quality Act (Pub. L. 106–554)) before we made it available for broader public comment during a time period that exceeded 10 months. The additional iterative process recommended by these comments is not necessary and would go beyond the processes we routinely apply for public input on a risk assessment.

### *C. Comments Regarding an Exemption for Small and Very Small Farm Mixed-Type Facilities Under Section 421 of the FD&C Act*

#### 1. Request for Comment on Data Submission Requirements

We requested comment on whether we should establish data submission requirements that would allow us to identify types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act. We provided examples of such data elements, including identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees, and animal food category/activity type. We also requested comment on any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

Comments did not support these data submission requirements. We are not establishing any data submission requirements that would allow us to identify types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act.

#### 2. Request for Comment on an Exemption From the Requirements of Section 421 of the FD&C Act

We received no comments that disagreed with our tentative conclusion that we should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in low-risk activity/animal food combinations and is a small or very small business. We are not establishing any exemption from, or modification to, the frequency requirements under section 421 for facilities that only engage in low-risk activity/animal food combinations and are a small or very small business.

### **VII. Subpart A: Comments on Proposed § 507.1—Applicability and Status**

We proposed in § 507.1 to establish the significance of this part in determinations of whether animal food is adulterated. We also proposed a provision relevant to FSMA's statutory provisions for a prohibited act under section 301(uu) of the FD&C Act. We proposed that animal food covered by specific CGMPs would also be subject to those requirements. For facilities required to comply with CGMPs and preventive controls for both the proposed preventive controls rule for animal food and the proposed

preventive controls rule for human food, we proposed that the facility must comply with either rule for the animal food, as long as the food safety plan addresses hazards unique to animal food. Some comments support the proposed provisions without change. Some comments that support the proposed provisions ask us to clarify how we will interpret the provisions.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements, disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements along with editorial and conforming changes as shown in table 31.

#### *A. Comments on Proposed § 507.1(a)—Applicability*

We proposed that the criteria and definitions in part 507 apply in determining whether a food is adulterated: (1) Within the meaning of section 402(a)(3) of the FD&C Act in that the food has been manufactured under such conditions that it is unfit for food; or (2) Within the meaning of section 402(a)(4) of the FD&C Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. We also proposed that the criteria and definitions in part 507 also apply in determining whether an animal food is in violation of section 361 of the PHS Act.

(Comment 15) Some comments note that FSMA granted FDA mandatory recall authority for adulterated food. These comments express concern that theoretically we could use a violation of the requirements for hazard analysis and risk-based preventive controls to determine that food is adulterated, thereby providing the basis for a mandatory recall of that food. These comments raise three issues relevant to how we will apply § 507.1(a), with consequences for a potential mandatory recall of food.

First, these comments note that the regulatory text stating that the “criteria and definitions” apply in making a determination of adulteration appears to encompass the entirety of the rule. As a result, farms or facilities that violate any of the requirements in the proposed rules, including components not directly related to the safety of the food (such as recordkeeping requirements), could face a risk that we would deem their food adulterated.

Second, these comments assert that the regulatory text suggests that we

would not automatically consider a food adulterated as a result of a violation of the proposed rule, because it states that the criteria and definitions “apply in determining” whether a food will be considered adulterated, rather than that the food “is” adulterated.

Third, these comments state that it is not clear how the exemption applicable to qualified facilities is included in the “criteria and definitions” used in making a determination of adulteration. These comments ask us to clarify that we will not just automatically assume that qualified facilities are selling adulterated food because they are by definition exempt from the requirements for hazard analysis and risk-based preventive controls.

(Response 15) The comments are correct that the criteria and definitions “apply in determining” whether an animal food will be considered adulterated, rather than that the animal food “is” adulterated. In determining whether an animal food that is manufactured, processed, packed, or held in violation of part 507 (including a violation of the recordkeeping requirement) is adulterated, we would consider the totality of the available data and information about the violation and the animal food before reaching a conclusion that the animal food is adulterated.

Although this rule does not address the mandatory recall provisions of FSMA, the statutory provisions establish two basic criteria. (See section 423(a) of the FD&C Act (21 U.S.C. 3501).) First, we must determine that there is a “reasonable probability” that the animal food is adulterated under section 402 of the FD&C Act. A violation of part 507 would be relevant to determining whether an animal food is adulterated under section 402 of the FD&C Act. Second, we must determine that there is a reasonable possibility that the use of, or exposure to, that animal food will cause serious adverse health consequences or death to humans or animals. Not all animal food that is adulterated has a reasonable probability of causing serious adverse health consequences or death to humans or animals. For examples of animal food contamination with a reasonable probability of causing serious adverse health consequences or death to humans or animals, see the annual reports of the Reportable Food Registry (RFR) (Refs. 13, 14, 15, and 16).

A facility that is exempt from any requirement of part 507, including the requirements for hazard analysis and risk-based preventive controls, would not be in violation of part 507 if it did

not comply with provisions that it is not subject to.

#### *B. Comments on Proposed § 507.1(b)—Prohibited Act*

We proposed that the operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States is a prohibited act under section 301(uu) of the FD&C Act if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C, D, or F of part 507 and § 507.7 (proposed § 507.1(b)).

(Comment 16) Some comments from State regulatory Agencies note that this new provision is not covered under the applicable state statute and that making any changes to the state statute can be a lengthy process that takes up to 3 years to complete.

(Response 16) See Response 2 for a discussion of our approach to working with our food safety partners in the States.

#### *C. Comments on Proposed § 507.1(c)—Specific CGMP Requirements*

We proposed § 507.1(c) would establish that animal food covered by specific current good manufacturing practice regulations also be subject to the requirement of those regulations. We received no comments that disagreed with our proposal, and are finalizing the proposed provision without change.

#### *D. Comments on Proposed § 507.1(d)—Human Food Facilities That Manufacture Animal Food*

We proposed in § 507.1(d) that a facility that would be required to comply with subpart B of part 507 and would be required to comply with subpart B of proposed part 117 for human food, may choose to comply with part 117 for the animal food. We also proposed that a facility that would be required to comply with subpart C of part 507 and would be required to comply with subpart C of proposed part 117 for human food, may choose to comply with part 117 for the animal food as long as the food safety plan also addressed hazards that are reasonably likely to occur in the animal food. We also proposed that when applying the requirements of part 117 to animal food, the term “food” in part 117 would include animal food.

Based on comments received in the 2014 supplemental notice, we proposed in § 507.12 that human food by-products held by the human food processor for distribution for use as animal food without additional manufacturing/processing by the human food processor

would only need to comply with proposed § 507.28 in part 507 and proposed § 117.95 in part 117 (79 58476 at 58487 to 58489). (See section XIII for a discussion of comments received on proposed § 507.12.) We are finalizing the proposed provisions in 507.1(d) with the exceptions in § 507.12.

For further discussion of comments on applicability and status, see section VIII in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

#### **VIII. Subpart A: Comments on Proposed § 507.3—Definitions**

We proposed definitions in the preventive controls rule for animal food to be consistent with the proposed preventive controls rule for human food with some minor differences and clarifications applicable to animal food (e.g., adding “animal” before “food”). Some comments support one or more of these proposed definitions without change. For example, some comments state that they support the proposed definitions for “microorganism” and “subsidiary” with no suggested revisions. Some comments support our proposal in the 2014 supplemental notice to use the phrase “chemical (including radiological)” in the definition of “hazard,” noting that doing so is consistent with FSMA, current industry practice, and Codex and global HACCP standards. Some comments that support a proposed definition suggest alternative or additional regulatory text, such as adding examples to make the definition clearer. Some comments that support a proposed definition ask us to clarify how we will interpret the definition. Comments generally ask that we maintain consistency of terms among the FSMA rules to avoid confusion and ensure regulatory compliance.

We did not receive comment on the following terms and therefore, are finalizing them as proposed: “calendar day,” “FDA,” “pest,” “water activity,” and “you.”

We removed some proposed definitions because the final rule does not use them. The proposed definitions that are removed in this final rule are “batter,” “blanching,” “packaging,” “quality control operation,” “safe moisture level,” “should,” and “significant hazard.”

In the following sections, we discuss comments that ask us to clarify proposed definitions or that disagree with, or suggest one or more changes to, a proposed definition. After considering these comments, we have revised the proposed requirements with editorial

and conforming changes as shown in table 31.

We also discuss definitions for additional terms (*i.e.*, “audit,” “correction,” “full-time equivalent employee,” “hazard requiring a preventive control,” “qualified facility exemption,” “raw agricultural commodity,” “supply-chain-applied control,” “unexposed packaged animal food,” and “written procedures for receiving raw materials and other ingredients”) that we are establishing in the final rule to simplify the regulatory text throughout the regulations and improve clarity. We also discuss a new name (*i.e.*, “preventive controls qualified individual”) for the definition of a term that we had proposed to name “qualified individual,” and are establishing a new definition for the term “qualified individual.” Finally, we also discuss definitions that comments ask us to add, but that we did not add, to the final rule.

#### *A. Definitions We Proposed To Establish in Part 507*

##### 1. Adequate

We proposed to define the term “adequate” to mean that which is needed to accomplish the intended purpose in keeping with good public health practice.

(Comment 17) Some comments express concern that there is no standard or definition for “good public health practice” and, for animal food establishments, the term “good public health practice” creates more uncertainty than it removes. The comments request that we remove from the definition the term “good public health practice.” Other comments ask us to develop guidance on thresholds and processes that qualify as “adequate.” Other comments assert that the word “adequate” must be used in combination with the word “reasonable” to properly describe the intended measures and precautions.

(Response 17) We disagree that there is no standard for “good public health practice.” However, we have revised the definition to add after public “(human and animal)” to clarify it includes both. Our intent in using the term “adequate” is to provide flexibility for an animal food establishment to comply with the requirement in a way that is most suitable for its establishment. We decline the request to develop guidance to explicitly address “thresholds” or to describe processes that qualify as adequate. The CGMPs and preventive controls requirements established in this rule are broadly applicable procedures and practices rather than

very specific procedures and practices where additional interpretation from FDA might be appropriate.

##### 2. Affiliate and Subsidiary

We proposed to define the term “affiliate” to mean any facility that controls, is controlled by, or is under common control with another facility. We proposed to define the term “subsidiary” to mean any company which is owned or controlled directly or indirectly by another company. These proposed definitions would incorporate the definition in section 418(l)(4)(A) and (D) of the FD&C Act and would make the meanings of these terms clear when used in the proposed definition of “qualified facility.”

(Comment 18) Some comments ask us to clarify that a facility that has no material connection with another food processing operation would not be considered as an “affiliate” of that operation.

(Response 18) It is not clear what the comments mean by “no material connection with another food processing operation.” To the extent that a facility does not control, is not controlled by, or is not under common control with another facility, we agree that the facility would not be considered an affiliate of that food processing operation.

(Comment 19) Some comments assert that the definitions of “affiliate” and “subsidiary” fail to account for the legal differences between a piece of property (*i.e.*, a facility) and a business entity or person. These comments ask us to consider amending the proposed definition of “qualified facility” to clarify what sales to include in determining whether a facility so qualifies.

(Response 19) See Response 57.

##### 3. Animal Food

We proposed to define the term “animal food” to mean food for animals other than man that includes pet food, animal feed, and raw materials and ingredients.

(Comment 20) Several comments voice concerns about including within the definition of animal food the term “raw materials.” The main concern is whether firms producing raw materials for animal food must register and create animal food safety plans. The comments fear firms would dispose of the raw material products due to the high cost of developing and maintaining safety plans, and disposal of those raw material products would have a significant economic impact due to a considerable increase in the cost of animal food in the United States.

(Response 20) We decline to change the definition. We do not expect that the inclusion of the term “raw materials” in the definition for animal food will change current practices, noting that a facility producing raw materials for animal food is already required to register. The definition of “animal food” is intended to clarify that the rule refers to “food for animals” and not “food derived from animals.”

##### 4. Critical Control Point

We proposed to define the term “critical control point” (CCP) to mean a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

(Comment 21) Some comments oppose the use of “critical control point” in the rule because the term is confusing and not understood by the relevant industry in the context of FSMA and the required preventive controls. The comments suggest critical control point is a HACCP term and not appropriate for use in this rule where the scope is defined differently by the statute.

(Response 21) We decline to modify or remove the definition as these comments request because we believe the term is helpful to industry. The proposed definition matches the statutory definition in section 418(o)(1) of the FD&C Act and is consistent with definitions in the Federal HACCP regulations for seafood, juice, and meat and poultry (parts 123 and 120 (21 CFR part 123 and 120) and 9 CFR part 417 respectively). By specifying that a point, step, or procedure in an animal food safety process would reduce a hazard to an “acceptable level,” the definition provides flexibility for a facility to determine an appropriate level in a particular circumstance.

(Comment 22) Some comments request that we define the term “control point.” The comments suggest defining this term as a point, step, or procedure in the production of an animal food at which a control may be applied.

(Response 22) We decline this request. We define “critical control point” as a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level. Also, “control point” is not a term used in the regulatory text of the rule and therefore does not need to be defined.

##### 5. Environmental Pathogen

We proposed to define the term “environmental pathogen” to mean a

pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. We also proposed to specify that environmental pathogen does not include the spores of pathogenic sporeformers. By “pathogenic sporeformers,” we mean “pathogenic sporeforming bacteria,” and we are substituting the term “pathogenic sporeforming bacteria” for “pathogenic sporeformers” in the definition of “environmental pathogen” to make that clearer.

(Comment 23) Some comments ask us to include *Salmonella* spp. and *Listeria monocytogenes* in the regulatory text as examples of environmental pathogens. Other comments believe the definition is too broad because it would include any pathogen that is capable of surviving or persisting in the environment, and the definition should be limited to the pathogenic bacteria that are more appropriate for protecting animal food safety.

(Response 23) We agree that *Salmonella* spp. and *L. monocytogenes* are useful examples of environmental pathogens and have added these two examples to the proposed definition, which had not included examples. Adding these two examples to the definition does not mean that these two pathogens are the only environmental pathogens that a facility must consider in its hazard analysis. New environmental pathogens can emerge at any time, and other pathogens can also be environmental pathogens. *Salmonella* spp in pet food have been involved in foodborne illness outbreaks in humans (78 FR 64736 at 64747). In addition, there have been recalls of pet food found to contain *L. monocytogenes*, though no human or animal illnesses were associated with these recalls to date (Refs. 17 and 18).

(Comment 24) Some comments ask us to clarify the meaning of the term “persisting” as used in the definition, such as whether it means that a sanitation process will not remove the microorganism.

(Response 24) We use the term “persisting” to mean that a pathogen can get established if cleaning is not adequate. Once a pathogen gets established, appropriate sanitation measures can remove the pathogen. However, sanitation procedures necessary to eliminate an environmental pathogen that has become established

generally are more aggressive than routine sanitation procedures.

#### 6. Facility

We proposed to define the term “facility” to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act in accordance with the requirements of part 1, subpart H. Comments directed to the meaning of the term “facility” address its meaning as established in the section 415 registration regulations, rather than this definition established in part 507.

For a discussion of comments on definitions in part 1, see section IV of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

#### 7. Farm

We proposed to define the term “farm” by reference to the definition of that term in § 1.227(b) rather than by repeating the full text of the “farm” definition in part 507. For a discussion of comments to the farm definition and of the “farm” definition that we are establishing in § 1.227, see section IV of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

#### 8. Food

We proposed to define the term “food” to mean food as defined in section 201(f) of the FD&C Act and to include raw materials and ingredients. Under section 201(f), the term “food” means: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(Comment 25) Some comments ask us to include examples in the definition. These comments also ask us to clarify whether the definition applies to food for human consumption, animal consumption, or both.

(Response 25) We decline the request to include examples in the definition. There are many examples of food and adding a limited list of examples could be confusing rather than helpful. Although the definition of food includes food for both human consumption and animal consumption, the provisions of the rule are clearly directed to food for animal consumption.

(Comment 26) Some comments ask us to consider fundamental and important differences between food additives and GRAS substances and finished food. These comments explain that food additives and GRAS substances may be synthesized using various chemical and biochemical processes, or may be extracted, hydrolyzed or otherwise

modified from their natural sources, and result in food safety hazards that are quite different from finished food preparations. These comments also explain that food additives and GRAS substances are often produced using processes that minimize microbial contamination hazards and are almost always used in food products that undergo further downstream processing. These comments assert that food additives and GRAS substances generally present a significantly lower public health hazard compared to finished food and should be regulated accordingly.

(Response 26) Substances such as food additives and GRAS substances are food and are subject to the requirements of this rule. Both the CGMP requirements in subpart B and the requirements for hazard analysis and risk-based preventive controls in subparts C and E provide flexibility to address all types of food. (As discussed in section XL, the final rule establishes the requirements for a supply-chain program in subpart E, rather than within subpart C as proposed. As a result, this document refers to subparts C and E when broadly referring to the requirements for preventive controls.) A manufacturer of a food additive or GRAS substance has flexibility to comply with the requirements of the rule based on the nature of the production processes and the outcome of the hazard analysis for that animal food substance.

#### 9. Food-Contact Surfaces

We proposed to define “food-contact surfaces” to mean those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” include food-contact surfaces of utensils and equipment.

(Comment 27) Several comments state that the terms “drainage” and “utensils” are not widely used or understood within animal feed and pet food industry and that the definition for “food-contact surfaces” should be revised by deleting “drainage, or other,” and by replacing “utensils” with “tools.”

(Response 27) We decline these requests. See our discussion of the term “utensils” in Response 169. We believe the term “drainage” is commonly understood.

#### 10. Harvesting

We proposed to define the term “harvesting” to apply to farms and farm



mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed on RACs on a farm, and that harvesting does not include activities that transform a RAC into a processed food. The proposed definition included examples of activities that would be harvesting.

In this final rule, we added or modified several examples of harvesting (see Response 28). As noted in table 31, we have reorganized the listed examples of harvesting to present them in alphabetical order.

We are defining the term “harvesting” to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as animal food. The definition includes examples of activities that are harvesting, as described in this section. Harvesting is also limited to activities performed on RACs, or on processed foods created by drying/dehydrating a RAC without additional manufacturing/processing, on a farm.

(Comment 28) Some comments ask us to provide more examples of harvesting activities, in the regulatory text and in guidance. Examples of the requested activities include braiding; bunching; cutting the edible portion of the crop from the plant; hydro-cooling; maintaining hydration of product; refrigerating; removing foliage; removing free water from (*e.g.* spinning); removing or trimming roots; trimming the tops of bunches of allium crops such as leeks, chives, or garlic and root crops such as carrots, beets, turnips, parsnips, etc. to prepare them for sale; and trimming the lower stems of harvested herb crops such as parsley, basil, or cilantro, or the lower stems of leafy greens. Other comments ask us to specify that harvesting also encompasses seed conditioning (*i.e.*, cleaning the seed, including removal of leaves, stems, and husks to prepare for marketing), ripening (artificial or natural) of fruit, and waxing or coating of RACs.

(Response 28) We have added or modified several examples of harvesting in the regulatory text (*i.e.*, cutting (or otherwise separating) the edible portion of the RAC from the crop plant, removing or trimming part of the RAC (*e.g.*, foliage, husks, roots or stems) and field coring and hulling). In table 1 in the Appendix to the 2014 supplemental

notice (79 FR 58476 at 58520 through 58521), we provided a more extensive list of examples of harvesting activities, including examples that are not in the regulatory text. We have classified some of these activities in more than one way (see 79 FR 58476 at 58520 through 58521). For example, trimming of outer leaves from RACs can be a harvesting activity, as well as a manufacturing/processing activity. Artificial ripening of fruit is manufacturing/processing (not harvesting), but is now within the “farm” definition.

(Comment 29) Some comments ask us to periodically review the list of harvesting activities to ensure that it reflects current practices.

(Response 29) If particular activities present questions in the future about whether the activity is a harvesting activity within the “farm” definition, or a manufacturing/processing activity that is outside the “farm” definition, we will consider issuing guidance or updating any existing guidance to clarify our recommended classification of the activity.

(Comment 30) Some comments note that the proposed definition for “harvesting” seems to be much more inclusive than FDA’s original proposed regulation, but is significantly more restrictive than the current regulation in part 1 because it excludes future technological developments. The comment further notes as technology and harvesting techniques advance, the risk of tying the definition to traditional activities will have a negative effect on agriculture’s ability to adapt. Furthermore, harvesting is merely the first step in transforming a RAC into processed food.

(Response 30) The comment did not make a specific request or provide any suggestions as to how future technological developments should be handled; therefore, we are finalizing the definition with the changes previously described.

#### 11. Hazard

We proposed to define the term “hazard” to mean any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in humans or animals in the absence of its control.

(Comment 31) Some comments express concern that the rule would refer to four levels of “hazard,” *i.e.*, “hazard,” “known or reasonably foreseeable hazard,” “significant hazard,” and “serious adverse health consequences or death to humans or animals” hazard. These comments ask us to provide sufficient clarity to be able to distinguish between these types of

hazards and to provide examples in guidance as to how these terms will be applied in determining compliance with the rule. Other comments express concern that the definitions do not establish a meaningful distinction between “hazard” and “significant hazards” and do not sufficiently distinguish between the hazards identified in the first and second steps of the hazard analysis (first narrowing hazards to “known or reasonably foreseeable hazards” and then narrowing the “known or reasonably foreseeable hazards” to “significant hazards”).

(Response 31) The rule uses three of these terms (*i.e.*, “hazard,” “known or reasonably foreseeable hazard,” and the proposed term “significant hazard”) to establish a tiered approach to the requirements for hazard analysis and risk-based preventive controls. The term “hazard” is the broadest of these three terms—any biological, chemical (including radiological), or physical agent has the potential to cause illness or injury. To conduct its hazard analysis, a facility starts by first narrowing down the universe of all potential hazards to those that are “known or reasonably foreseeable” for each type of food for animals manufactured, processed, packed, or held at its facility. The outcome of the facility’s hazard analysis is a determination of “significant hazards,” *i.e.*, the subset of those known or reasonably foreseeable hazards that require a preventive control.

To make this clearer, we have: (1) Revised the proposed definitions of “hazard” and (2) changed the term “significant hazard” to “hazard requiring a preventive control” (formerly “significant hazard”). See Responses 32 and 62.

The rule does not define the term “serious adverse health consequences or death to humans or animals” hazard. However, the requirements for a supply-chain program refer to a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (see § 507.130(b)). For additional information on how we interpret “serious adverse health consequences or death to humans or animals,” see our guidance regarding the RFR (Refs. 19 and 20), which addresses statutory requirements regarding “reportable foods.” As explained in that guidance, a “reportable food” is an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or

death to humans or animals. The guidance includes examples of circumstances under which food might be reportable.

(Comment 32) Some comments assert that the distinction between the definitions of “hazard” and “significant hazard” is not discernable because the proposed definition of “hazard” currently takes into account whether or not a “hazard” is or is not controlled. These comments ask us to delete the phrase “in the absence of its control” from the definition of “hazard” to clarify that hazards are simply the agents that are reasonably likely to cause illness or injury. Likewise, other comments assert that any hazard that is “reasonably likely to cause illness or injury in the absence of its control” will, if known or reasonably foreseeable, likely be controlled by any knowledgeable person.

(Response 32) We have deleted the phrase “in the absence of its control” from the definition of “hazard.” We agree that deleting this phrase from the definition of “hazard” will more clearly distinguish between the terms “hazard” and “hazard requiring a preventive control” that we are establishing in this rule.

We also replaced the phrase “that is reasonably likely to cause illness or injury” with “that has the potential to cause illness or injury” to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard.” This increases the alignment of the definition of “hazard” in this rule with the Codex definition of “hazard.”

(Comment 33) Some comments ask us to include “in the intended species” in the definition of “hazard.”

(Response 33) We decline this request. During the hazard analysis the facility must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards requiring a preventive control (§ 507.33(a)). During the hazard evaluation, the facility must consider the effect of the intended or reasonably foreseeable use on the safety of the finished animal food for the intended animal (§ 507.33(d)(8)).

## 12. Holding

We proposed to define “holding” to mean storage of food, including activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for

the distribution of that food (such as blending of the same RAC and breaking down pallets)), but not including activities that transform a RAC into a processed food. We proposed that holding facilities could include warehouses, cold-storage facilities, storage silos, grain elevators, and liquid-storage tanks.

(Comment 34) Some comments ask us to provide more examples of holding activities, in the regulatory text and in guidance. Examples of the requested activities include fumigating RACs; application of chemicals (including fungicides, sanitizers, and anti-oxidants); and “coating” grain RACs with diatomaceous earth to control insects. According to these comments, these activities are incidental to storage and do not transform RACs into processed food. Other comments wanted examples of holding of human-food by-products destined for animal food (for example wet pasta that dries naturally while being held).

(Response 34) We have added or modified several examples of holding in the regulatory text (*i.e.*, fumigating animal food during storage, and drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). In table 1 in the Appendix to the 2014 supplemental notice (79 FR 58476 at 58520 through 58521), we provided a more extensive list of examples of holding activities, including examples that are not in the regulatory text. We have previously classified some of these activities in more than one way (see 79 FR 58476 at 58520 through 58521) depending on when the activity occurs. For example, sorting, culling, and grading RACs can be either a holding activity or a packing activity. Drying/dehydrating RACs is holding when the drying/dehydrating does not create a distinct commodity, but is manufacturing/processing when the drying/dehydrating creates a distinct commodity (see section IV). Holding of certain human food by-products for use as animal food is discussed in sections XIII and XXII.

(Comment 35) Some comments ask us to clarify that mixing or blending intact RACs is considered “holding” regardless of whether the RACs are the same or different.

(Response 35) We use the term “blending” when referring to RACs such as grain and when the RACs are the same. For example, we consider the activity of “blending” different lots of the same grain to meet a customer’s quality specifications to be a practical necessity for product distribution and, thus, to be within the definition of

“holding” (see 79 FR 58476 at 58483). However, we use the term “mixing” when the RACs are different. For example, we consider the activity of “mixing” corn and oats in the production of animal food to be manufacturing/processing, because mixing two different foods is “making food from one or more ingredients” (which is our definition of “manufacturing/processing”) and the animal food produced by mixing corn and oats is a processed food.

We classify “mixing” intact RACs that does not create a processed animal food as incidental to, and therefore part of, “packing” or “holding” as applicable. For example, mixing heads or bunches of lettuce does not create a processed food, because the mixing has not created a distinct commodity, but only a set of mixed RACs. On the other hand, mixing that creates a processed animal food is not “packing” or “holding.” The definitions of both “packing” and “holding” are limited so that they do not include activities that transform a RAC into processed animal food. Some kinds of mixing of RACs does create a distinct commodity (for example, mixing corn and oats to make animal food). In such cases, the mixing is manufacturing/processing and is not within the farm definition.

(Comment 36) Some comments ask us to clarify whether the expanded definition of holding that we proposed in the 2014 supplemental human preventive controls notice would mean that a warehouse that both stores and fumigates a RAC to prevent pest infestation would be exempt from the requirements for hazard analysis and risk-based preventive controls for a facility solely engaged in the storage of RACs (other than fruits and vegetables) for further distribution or processing (§ 507.5).

(Response 36) Fumigating RACs to prevent pest infestation would be within the definition of “holding” and therefore would not prevent a facility that stores RACs (other than fruits and vegetables) from being eligible for the exemption in § 507.5(g), provided that the facility does not conduct other activities not classified as “holding.” However, a threshold question for any facility solely engaged in the storage of RACs is whether the stored RACs are fruits or vegetables.

(Comment 37) Some comments ask us to clarify whether there is a timeframe associated with holding and to better distinguish between “holding” and “storage.”

(Response 37) There is no timeframe (maximum or minimum) associated with holding. The definition of holding

states "Holding means storage of food" and, thus, there is no distinction between "holding" and "storing."

(Comment 38) Some comments ask us to clarify how the definition of holding relates to practices, such as fumigation, on almond hull stockpiles held on a farm, a farm mixed-type facility or off-farm.

(Response 38) Practices that are incidental to storage of food, such as fumigation of almond hull stockpiles, are holding, regardless of whether they are conducted on-farm, on a farm mixed-type facility, or off-farm.

(Comment 39) Some comments ask us to clarify that value added activities (such as repacking and blast freezing) conducted in facilities such as warehouses would be considered holding when product is not exposed to the environment.

(Response 39) We consider the activities described in these comments to be activities performed as a practical necessity for the distribution of the food and, thus, to be within the definition of holding.

(Comment 40) Several comments do not support the proposed definition of "holding" stating that the definition would exempt grain receiving and storage facilities that are the primary suppliers of the main ingredient in many animal foods including distiller's products. Some comments ask us to clarify what is a practical necessity.

(Response 40) Section 418(m) of the FD&C Act provides us with the authority to exempt certain facilities from the requirements of section 418, or to modify those requirements. We proposed to use this authority to exempt facilities that solely engage in the storage (holding) of RACs (other than fruits and vegetables) intended for further distribution or processing. We tentatively concluded that there would not be significant public (human and animal) health benefit to be gained by having these facilities subject to the requirements of subpart C. Outbreaks of illness associated with feeding RACs to animals have not been traced back to storage facilities solely engaged in the storage of RACs, therefore we think it is appropriate to exempt them from the requirements of subparts C and E of the final rule. Such facilities remain subject to the requirements of section 402 of the FD&C Act that the animal food being held is not adulterated.

The revised definition of "holding" encompasses activities performed as a practical necessity for the distribution of RACs, such as blending of the same RAC and breaking down pallets. Sampling for grading or quality control purposes, repacking, and drying grains

and oilseeds would also be considered performed as a practical necessity for the distribution of animal food within the definition of "holding."

### 13. Known or Reasonably Foreseeable Hazard

We proposed to define the term "known or reasonably foreseeable hazard" to mean a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

(Comment 41) Some comments support the definition as proposed, noting that it implies that the implementation of a preventive control be based both on the severity and likelihood of the hazard, can help to distinguish between the requirements of this rule and HACCP requirements, and provides for the proper consideration of both the food and the facility when determining whether a hazard is "known or reasonably foreseeable." Other comments ask us to modify the definition to specify that the term means a hazard "that is known to be, or has the potential to be, associated with the facility or the food" to better align with the term as FDA proposed to define it in the proposed FSVP rule. (See 79 FR 58574 at 58595.)

(Response 41) We have revised the definition as requested by the comments to better align with the proposed FSVP rule.

(Comment 42) Some comments ask us to revise the definition so that it addresses a hazard that is known to be, or has the potential to be, associated with a food, the facility in which it is manufactured/processed, or the location or type of farm on which it is grown or raised. These comments assert that the type of farm may affect those hazards that are known or reasonably foreseeable.

(Response 42) We decline this request, which appears related to another difference between the definition proposed in this rule and the definition of this term in the proposed FSVP rule. The proposed FSVP rule would define "known or reasonably foreseeable hazard" as a hazard that is known to be, or has the potential to be, associated with a food or the facility "in which it is manufactured/processed." (See 79 FR 58574 at 58595.) In this rule, we do not need to specify that the applicable facility is the one "in which the food is manufactured/processed" because this rule applies to the owner, operator, or agent in charge of the facility in which the food is manufactured, processed, packed, or held, and that applicability does not need to be repeated in each provision.

To the extent that this comment is expressing concern about raw materials or other ingredients that a facility would receive from a farm, those concerns would be considered in the facility's hazard analysis, which would include a hazard evaluation that considers factors such as those related to the source of raw materials and other ingredients (see § 507.33(d)(3)).

### 14. Lot

We proposed to define "lot" to mean the food produced during a period of time indicated by a specific code.

(Comment 43) Some comments state that many animal food processors operate on a batch-production basis rather than a continuous-production basis and request that we take this into account with respect to the definition of "lot." Other comments suggest replacing "lot" with "lot identifier" where "lot identifier" means a unique identifier for each lot, batch or production run that enables the manufacturer to trace accurately the complete manufacturing and distribution history of the product. Other comments ask us to modify the proposed definition so that it is not limited by a period of time and suggest using an approach that would allow for a lot to be defined by either time or by a specific identifier. Other comments express the view that the individual operators should be able to define their lot designations and make these definitions available to FDA upon request.

(Response 43) Although the term "lot" is associated with a period of time, an establishment has flexibility to determine the code, with or without any indication of time in the code. For example, a code could be based on a date, time of day, production characteristic (such as origin, variety, and type of packing), combination of date/time/production characteristic, or any other method that works best for the establishment. To clarify that the rule does not require that time be "indicated" by the code, and emphasize the establishment's flexibility to determine the code, we have revised "period of time indicated by a specific code" to "period of time and identified by an establishment's specific code."

### 15. Manufacturing/Processing

We proposed to define "manufacturing/processing" to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. We proposed that examples of manufacturing/processing activities would be cutting, peeling, trimming,

washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. In this rule, we add more examples to include, “artificial ripening,” “boiling,” “canning,” “drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins),” “evaporating,” “extruding,” and “pelleting.” We also alphabetize the list of examples.

(Comment 44) Some comments express concern that some activities included in the definition of “manufacturing/processing” overlap with activities (such as trimming, washing, and cooling) included in the definition of “harvesting.”

(Response 44) We acknowledge that there is some overlap in the activities that the regulatory text lists as examples of both “manufacturing/processing” and “harvesting,” because some activities can occur during more than one operation (see table 1 in the Appendix to the 2014 supplemental notice (79 FR 58476 at 58520 through 58521)). For example, “cutting” lettuce from the crop plant occurs on-farm in the field where the lettuce is harvested, and “cutting” the core of the lettuce from the rest of the harvested lettuce occurs in a fresh-cut processing facility. An important consequence of the multiple revisions we have made to the “farm” definition in this rulemaking is that there are fewer situations in which classification of a particular activity is the only trigger for an operation to be subject to the section 415 registration requirements. For example, the revised “farm” definition no longer classifies the packing and holding of others’ RACs to be a manufacturing/processing activity that triggers the registration requirement. As another example, the revised “farm” definition specifies three manufacturing/processing activities that are within the “farm” definition. We conclude that the overlap in the examples of activities listed in the definitions of “harvesting” and “manufacturing/processing” does not create problems with determining the status of an operation as a “farm” or a “facility” and we are retaining examples in both definitions because doing so reflects current practices on farms and in manufacturing/processing facilities.

#### 16. Microorganisms

We proposed to define the term “microorganisms” to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including species having animal or human health significance. We also proposed that the term “undesirable microorganisms” includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. We have revised the definition to replace “includes species having animal or human health significance” with “and includes species that are pathogens,” and replacing “undesirable microorganisms” includes those microorganisms that are of animal or human health significance” with “undesirable microorganisms” includes those microorganisms that are pathogens.”

(Comment 45) Some comments express concern that the term “undesirable microorganisms” includes microorganisms that subject food to decomposition. These comments assert that the definition would expand regulation beyond food safety and ask us to clarify that decomposition means a degradation of product that is only relevant when it affects the safety of the product, rather than simple spoilage.

(Response 45) We have not modified the regulatory text of this longstanding definition of the term “undesirable microorganisms” regarding microorganisms that subject food to decomposition. The regulations established by this rule are designed to prevent the growth of undesirable microorganisms. The scope of the definition of “undesirable microorganisms” is not limited to microorganisms of public health significance because these regulations are also concerned with sanitation, decomposition, and filth (51 FR 22458 at 22460, June 19, 1986).

#### 17. Mixed-Type Facility

We proposed to define “mixed-type facility” to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. We proposed that an example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be

registered. As a conforming change associated with the revisions to the “farm” definition, we have revised the example of a “farm mixed-type facility” to specify that it is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. (See section IV of the final rule for preventive controls for human food published elsewhere in this addition of the **Federal Register**.)

(Comment 46) Some comments ask us to revise the definition to exclude those establishments that only conduct low-risk activities specified in the exemptions for on-farm, low-risk activity/animal food combinations (§ 507.5(e) and (f)).

(Response 46) We decline this request. Whether a particular establishment that falls within the definition of “mixed-type facility” is subject to the requirements for hazard analysis and risk based preventive controls is governed by the exemptions established in this rule.

#### 18. Monitor

We proposed to define the term “monitor” to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(Comment 47) Some comments assert that our proposed definition of monitor is directed to the narrow circumstance of monitoring that would be applied to a CCP under the National Advisory Committee on Microbiological Criteria for Foods (advisory committee chartered under the USDA) (NACMCF) HACCP guidelines and the Codex HACCP Annex. These comments also assert that, using such definitions, monitoring would not apply to control measures for which parameters cannot be established and that are not amenable to documentation. These comments suggest that we use a definition of monitoring consistent with that provided in ISO 22000:2005 (conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended) to clarify that monitoring may be conducted where appropriate for preventive controls that are not CCPs. (ISO is an abbreviation for “International Organization for Standardization.” ISO develops and publishes International Standards.) According to these comments, an advantage of this definition is that it also would clarify the difference between monitoring activities (observations conducted during the

operation of a control measure to ensure that it is under control) and verification activities (to evaluate performance of a control measure).

(Response 47) We have revised the definition of monitor to mean to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. We agree that the revised definition, which reflects an international standard, more effectively communicates that monitoring also applies to controls that are not at CCPs and may apply to control measures for which parameters cannot be established. However, we disagree that this definition signals that it is not possible to obtain documentation when monitoring preventive controls that are not at CCPs, such as for controls that are not process controls and do not involve parameters and maximum or minimum values, or combinations of values, to which a parameter must be controlled to significantly minimize or prevent a hazard requiring a preventive control. For example, it is possible to monitor that a specific sanitation control activity has taken place, such as the cleaning of a piece of equipment to prevent cross-contact.

The requirement for documenting monitoring in records is established by the requirements for monitoring, not by the definition of monitor. As discussed in section XXX.C, we have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary.

#### 19. Packaging (When Used as a Verb)

We proposed to define “packaging (when used as a verb)” as placing food into a container that directly contacts the food and that the consumer receives.

Based on comments received to the proposed rule for preventive controls for human food, we have decided not to establish the definition “packaging (when used as a verb)” in part 507. For a discussion of those comments received to the human food preventive controls rule, see section IX.C.20 in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

#### 20. Packing

We proposed to define “packing” as placing food into a container other than packaging the food, including activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but not including activities that transform a raw agricultural commodity, as defined in

section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg). We have revised the definition to clarify that packing includes “re-packing.”

For comments on the definition of “packing,” see section IV.G of the final rule for preventive controls for human food, published elsewhere in this addition of the **Federal Register**.

We are finalizing the definition as proposed, with the addition of another example of an activity performed for the safe or effective packing of the food, *i.e.*, weighing or conveying incidental to packing or repacking, and the addition of “animal” in front of food.

#### 21. Pathogen

We proposed to define the term “pathogen” to mean a microorganism of public (human or animal) health significance.

(Comment 48) Some comments ask us to revise the definition to mean a “microorganism of such severity and exposure that it would be deemed of public health significance” because the significance of pathogens to public health depends on the organism’s severity and the nature of exposure.

(Response 48) We decline this request. Our purpose in defining the term pathogen was to simplify the regulations, including our longstanding CGMP regulations for human food, by substituting a single term (*i.e.*, “pathogen”) for a more complex term (*i.e.*, “microorganism of public health (human and animal) significance”) throughout the regulations. These comments fail to explain how we have interpreted the current term “microorganism of public health significance” in a way that does not take into account factors such as the severity of illness and the route of exposure.

#### 22. Plant

We proposed to define the term “plant” to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

(Comment 49) Some comments state that it would not be helpful to use “plant” interchangeably with “establishment” when referring to a business that is not required to register. These comments ask us to consistently use one of these terms and to define a term that would mean “a business that is not required to register” to help distinguish such businesses from “facilities.”

(Response 49) We agree that it is appropriate to consistently use one term when referring to a business entity.

However, we disagree that it is necessary to establish a definition for a business entity that is not required to register. A business that meets the definition of “facility” is required to register; a business that is not required to register is simply a business that does not meet the definition of “facility.”

To address these comments, we have revised provisions of the rule in three ways. First, we have revised the definition of “plant” to focus it on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food, rather than on the “building or establishment.” Second, we have revised applicable provisions of part 507 to use “establishment” rather than “plant” when focusing on a business entity rather than on buildings or other structures. Third, we have revised provisions that use the terms “plant,” “establishment,” or both to conform to the definition of “plant” and the described usage of “establishment.” For example, § 507.14 establishes requirements for “the management of the establishment” rather than “plant management,” because “establishment” is the term focusing on the business entity. As another example, § 507.17(a)(1) establishes requirements for properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the “plant” rather than within the immediate vicinity of the “plant buildings or structures,” because the defined term “plant” focuses on the buildings and structures, and it is not necessary to repeat “buildings and structures” when the term “plant” is used.

#### 23. Preventive Controls

We proposed to define the term “preventive controls” to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

(Comment 50) Some comments ask us to clarify the meaning of “current scientific understanding” because scientific understanding can vary depending on the risk profile of a commodity.

(Response 50) By “current scientific understanding,” we mean to emphasize

that scientific information changes over time and a facility needs to keep current regarding safe handling and production practices such that the facility has the information necessary to apply appropriate handling and production practices.

#### 24. Preventive Controls Qualified Individual

We proposed to define the term “qualified individual” to mean a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system. We have changed the proposed term “qualified individual” to “preventive controls qualified individual” because we are establishing a new definition for “qualified individual,” with a meaning distinct from “preventive controls qualified individual.” To minimize the potential for confusion, for when the term “qualified individual” refers to the proposed meaning of the term and when the term “qualified individual” refers to the meaning of that term as finalized in this rule, in the remainder of this document we use the new term “preventive controls qualified individual” whenever we mean “a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system,” even though the proposed rule used the term “qualified individual.” Likewise, we use the new term “preventive controls qualified individual” for the proposed term “qualified individual” when describing the comments to the proposed rule, even though those comments use the term “qualified individual.”

In the following paragraphs, we discuss comments on this proposed definition. (See also our discussion in section XXXVII.B of the requirements applicable to the preventive controls qualified individual (§ 507.53(c)).)

(Comment 51) Some comments assert that the proposed definition of preventive controls qualified individual is ambiguous.

(Response 51) The comments provide no basis for asserting that this definition is ambiguous. The proposed definition includes a performance standard (qualified to develop and apply a food

safety system), two criteria for how a person can become qualified (specialized training or job experience), and a description of the type of applicable training (development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum). The proposed definition provides flexibility for how an individual can become qualified, but this flexibility does not make the definition ambiguous.

(Comment 52) Some comments ask us to expand the definition so that it includes a team of preventive controls qualified individuals, not just a single person.

(Response 52) We decline this request. The definition applies to each preventive controls qualified individual that a facility relies on to satisfy the requirements of the rule without limiting the number of such preventive controls qualified individuals. The requirements of the rule make clear that a facility may rely on more than one preventive controls qualified individual (see, e.g., § 507.53(a)).

(Comment 53) Several comments state that there is a lack of specificity about what constitutes appropriate training and experience to qualify as a “preventive controls qualified individual.” Another comment asks us to clarify how the qualification of the “preventive controls qualified individual” will be assessed. One comment asks how the resume and experience of preventive controls qualified individuals in other countries will be evaluated by FDA to determine that they meet the required qualifications.

(Response 53) As discussed further in Response 395, we do not expect to directly assess the qualifications (whether obtained by training or by job experience) of persons who function as preventive controls qualified individuals. Instead, we intend to focus our inspections of both domestic and foreign facilities on the adequacy of the food safety plan prepared by the preventive controls qualified individual (or under their oversight). As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate training or experience to carry out the required functions. If the food safety plan suggests the preventive controls qualified individual does not have adequate training or experience, we will perform a more in-depth review of the preventive controls qualified individual’s training or experience,

including any associated documentation.

See also our discussion in section XXXVII.B about the requirements applicable to the preventive controls qualified individual (§ 507.53(c)).

#### 25. Qualified Auditor

We proposed to define the term “qualified auditor” to mean a person who is a preventive controls qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 507.53(c)(2). As discussed in Response 399, we have revised the definition to specify that “qualified auditor” means a person who is a “qualified individual” as that term is defined in this final rule, rather than a “preventive controls qualified individual,” because some auditors may be auditing businesses (such as produce farms) that are not subject to the requirements for hazard analysis and risk-based preventive controls, and it would not be necessary for such an auditor to be a “preventive controls qualified individual.” We also have clarified that the technical expertise is obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function to align the description of applicable education, training, and experience with the description of applicable education, training, and experience in the definition of “qualified individual” (see § 507.3).

(Comment 54) Some comments ask us to revise the definition of qualified auditor to include persons who have technical expertise obtained by a combination of training, experience, or education appropriate to perform audits. Some comments ask us to recognize that training and/or experience can make a person a qualified auditor; the comments state that people with experience performing audits likely have applicable training but might not have completed a specific regimen of courses. Some comments maintain that we should recognize the role of the education of a potential qualified auditor, as well as training and experience to meet the criteria.

(Response 54) We agree that a qualified auditor might obtain the necessary auditing expertise in part through education, as well as through training and experience, and we have revised the definition of qualified auditor accordingly. The revised definition states that a qualified auditor has technical expertise obtained through education, training, or experience (or the combination thereof).

(Comment 55) Some comments that support the proposed definition ask us to revise the definition to specify certain individuals who would be considered qualified auditors, such as FDA inspectors, properly trained Federal auditors, and State and private auditors operating under a contract with the Federal Government.

(Response 55) We have revised the regulatory text to specify that examples of potential qualified auditors include: (1) A government employee, including a foreign government employee and (2) an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M (*i.e.*, regulations in our forthcoming third-party certification rule implementing section 808 of the FD&C Act (21 U.S.C. 348d)). Although we agree that it is useful to include examples of individuals who would have the appropriate qualifications, the example of an audit agent of a certification body that has been accredited in accordance with our regulations in our forthcoming third-party certification rule adds context about the standard for such individuals. Because paragraph (2) of the new provision refers to provisions in a future third-party certification rule, we will publish a document in the **Federal Register** announcing the effective date of paragraph (2) when we finalize the third-party certification rule.

#### 26. Qualified End-User

We proposed to define the term “qualified end-user” to mean, with respect to an animal food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227(b)) that: (1) Is located (a) in the same State as the qualified facility that sold the food to such restaurant or establishment; or (b) is not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. We have revised the definition of “qualified end-user” to add “or the same Indian reservation” to clarify for purposes of this rule that “in the same State” under section 418(l)(4)(B)(ii)(I) of the FD&C Act includes both within a State and within the reservation of a Federally-Recognized Tribe.

(Comment 56) One comment requests the term “restaurant” be removed from the proposed definition of “qualified end-user” and replaced with the appropriate definitional terms for “restaurant” provided in § 1.227: Pet shelters, kennels, and veterinary facilities in which animal food is

provided to animals. The comment also suggests we modify the definition of “qualified end-user” to be reflective of the customer who is the purchaser of the animal food.

(Response 56) We decline these requests. The definition of “qualified end-user” is consistent with the definition in section 418(l)(4)(B) of the FD&C Act. As discussed in Response 81, we decline to define consumer.

#### 27. Qualified Facility

We proposed to define “qualified facility” by incorporating the description of “qualified facility” in section 418(l)(1) of the FD&C Act with editorial changes to improve clarity. That definition includes two types of facilities: (1) A facility that is a very small business as defined in this rule and (2) a facility to which certain statutory criteria apply regarding the average monetary value of animal food sold by the facility and the entities to which the animal food was sold.

For the second type of facility, to represent accurately the language of section 418(l) of the FD&C Act, we have changed “animal food” to “food.”

Some comments discuss issues related to the definition of very small business. See section VIII.A.36 for the discussion of the definition of very small business.

(Comment 57) Some comments assert that the definitions of “affiliate” and “subsidiary” in the definition of “qualified facility” fail to account for the legal differences between a piece of property (*i.e.*, a facility) and a business entity or person. These comments ask us to consider revising the proposed definition of “qualified facility” to clarify what sales to include in determining whether a facility so qualifies.

(Response 57) We have not revised the proposed definition of “qualified facility” as requested by these comments. The sales to be included when a facility determines whether it meets the definition of a qualified facility are the sales of animal food by a business entity meeting the “very small business” definition or food by a business entity meeting the other qualified facility definition, each of which includes the parent company and all its subsidiaries and affiliates. The total sales are applicable to each entity, whether it is the parent, the subsidiary or the affiliate. We intend to address issues such as these in guidance as directed by section 418(l)(2)(B)(ii) of the FD&C Act.

(Comment 58) Some comments ask us to clarify who will determine whether a particular facility is a qualified facility.

(Response 58) Any facility that determines that it satisfies the criteria for a “qualified facility” must notify FDA of that determination (see § 507.7) and, thus, the first determination will be made by the facility itself. During inspection, the investigator could ask to see the records that support the facility’s determination to verify the facility’s determination.

In this rule, we remove the term “quality control operation” because the term is very broad within the animal food industry and may not be specific to animal food safety.

#### 28. Receiving Facility

We proposed to define the term “receiving facility” to mean a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

(Comment 59) Some comments ask us to modify the definition to specify that the receiving facility could receive the raw material or ingredient directly from a supplier or by means of an intermediary entity. These comments assert that without this added regulatory text the proposed definition implies that the material or ingredient must be received directly from the supplier.

(Response 59) We decline this request. As discussed in section XLII.B and C, the two parties that are critical to the supplier verification program are the receiving facility and the supplier, even if there are entities in the supply chain between the two. The definition of receiving facility does not preclude the participation of intermediary entities in the supply chain, and the rule does provide for such participation (see § 507.115). However, the definition of receiving facility does highlight the fact that a receiving facility must have a link to a supplier.

#### 29. Rework

We proposed to define “rework” to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. In this rule, we add “animal” before food for clarity.

(Comment 60) Several comments request that we replace “insanitary” with “unclean” as the former term is not utilized in the animal food industry. Other comments state that the proposed definition for “rework” is too narrow and does not represent its use in animal food production.

(Response 60) We decline this request. The word “insanitary” is used in the FD&C Act and human food

regulations, including the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (currently 21 CFR part 110 and updated and included in the final rule for preventive controls for human food (21 CFR part 117) published elsewhere in this **Federal Register**). Because of the use of the term in the FD&C Act and various FDA regulations, we think industry is familiar with the word “insanitary” and it is an appropriate word to use in this final rule.

We disagree that the definition of the term “rework” is too narrow. The definition allows the flexibility for an establishment to consider clean, unadulterated animal food that was never adulterated or was successfully reconditioned to be rework.

### 30. Sanitize

We proposed to define “sanitize” to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal or human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

(Comment 61) Several comments request that we replace the term “sanitize” with “clean,” as the former term is not utilized in the animal food industry. Other comments ask us to modify the definition because the destruction of all microorganisms of animal or human health concern is not always practical, and because the terminology “adversely affecting the product or its safety for animal or humans” is ambiguous. Others ask us to revise the definition to state that “adequate” or “adequately” means to reduce the presence of organisms of concern sufficient to help prevent illness through cleaning and sanitizing using EPA registered/FDA regulated food use antimicrobials and other means such as heat, ozone, etc. Some comments ask us to clarify that the “cleaning” should be appropriate to the specific food system and method used for sanitizing, and that cleaning should only be required when the sanitizing process alone would not be effective without a prior cleaning step.

Some comments express concern about whether the proposed definition of “sanitize” would preclude the continued, routine use of dry cleaning methods with no sanitizing step. These comments note that adding routine aqueous-based cleaning and sanitizing procedures could create a public health risk in certain operations such as low

moisture food production. These comments also note that dry cleaning procedures can result in equipment that, while sanitary, is neither visibly clean nor suitable for aqueous chemical sanitizers.

(Response 61) When the destruction of microorganisms is required, we use the terms “sanitize” or “sanitizing,” to differentiate from “cleaning” or “sanitation,” which is consistent with how these terms are used throughout our current regulations for human food. Therefore, we believe that “sanitize” is a word that is commonly understood by industry and is used in this final rule in a way that is consistent with how it is used in our other regulations relating to food.

We consider that systems such as steam systems clean the surfaces, as well as sanitize them and, thus, satisfy the definition of “sanitize.” The definition of “sanitize” does not preclude the continued use of dry cleaning methods with no sanitizing step because the definition describes the meaning of the term “sanitize” without establishing any requirement for when equipment must be sanitized.

We have revised the definition so that it means adequately treating “surfaces” rather than “food-contact surfaces.” As a technical matter, adequately treating any surface—regardless of whether it is a food-contact surface—by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans, is “sanitizing” the surface. Clarifying this technical meaning of the term “sanitize” imposes no requirements to sanitize surfaces other than animal food-contact surfaces; the requirements for sanitizing surfaces are established by provisions such as § 507.19(b)(2), not by the definition of the term “sanitize.”

### 31. Significant Hazard (Hazard Requiring a Preventive Control)

We proposed to define the term “significant hazard” to mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food. The rule would use the term “significant hazard” rather than “hazard reasonably likely to occur” to reduce the potential for a misinterpretation that all necessary preventive controls must be established

at CCPs (79 FR 58476 at 58477 through 58478).

(Comment 62) Comments support using a term other than “hazard reasonably likely to occur” and agree that using a term other than “hazard reasonably likely to occur” throughout the rule will reduce the potential for a misinterpretation that all necessary preventive controls must be established at CCPs.

Some comments support the regulatory text of the proposed definition of the term “significant hazard.” These comments state that the proposed regulatory text more closely aligns with the principles in FSMA (“reasonably foreseeable” and “significantly minimize or prevent”) and provides operators the flexibility to implement a range of preventive controls that are commensurate with the risk and probability posed by a specific hazard. Some comments agree that the proposed regulatory text can clarify the difference between HACCP rules and the animal preventive controls rule. Some comments state that the proposed regulatory text plainly reflects the concept that significant hazards are those hazards to be addressed through the very broad category of preventive controls, and the rule is explicit that preventive controls may be controls other than CCPs. Some comments state that the definition reflects the risk-based nature (*i.e.*, both the severity of a potential hazard and the probability that the hazard will occur) of the requirements and provides additional flexibility so that facilities can take into account the nature of the preventive control in determining when and how to establish and implement appropriate preventive control management components. Some comments support including the phrase “based on the outcome of a hazard analysis” in the definition because it ensures that identification of significant hazards will be risk based. Some comments ask us to be clear about FDA’s expectations concerning a hazard analysis conducted by those involved in animal food production. Some comments ask us to preserve in the final definition two key aspects that grant the animal food industry the flexibility that it needs: (1) The logical conclusion that not all hazards will have the same impact or will even constitute “significant hazards” at all, depending on the facility’s products and position in the supply chain and (2) the fact that a “person knowledgeable about the safe manufacturing, processing, packing, or holding of food” must be knowledgeable about the specific food produced at that



facility and in that specific sector of the food industry.

Some of the comments that support the regulatory text of the proposed definition nonetheless express concern about the term “significant hazard.” Some of these comments express concern that a facility may not recognize hazards that need to be controlled because they do not rise to the commonly understood meaning of “significant.” Other comments express concern that the adjective “significant” is subject to many interpretations and suggest that the term “hazard requiring control” would be more straightforward, accurate, and suitable.

Other comments express concern that the term “significant hazard” could cause confusion because it has implications in HACCP systems. For example, “significant hazard” is often used in the context of CCPs and preventive controls are not necessarily established at CCPs. Some of these comments suggest that we eliminate the term and instead use the full regulatory text of the proposed definition in place of “significant hazard” throughout the regulations. Other comments suggest using a term such as “food safety hazard” or “actionable hazard” instead of “significant hazard to avoid a term that has HACCP implications. Other comments state that the term “significant hazard” has implications for facilities that follow the Codex HACCP Annex and express concern that foreign facilities would be especially likely to be confused by the term “significant hazard.”

Some comments ask us to ensure that the term “significant hazard” is used consistently and express the view that some regulatory text refers to a “hazard” or “known and reasonably foreseeable hazard” where “significant hazard” should instead be used. As discussed in Comment 31, some comments express concern that the rule would refer to multiple levels of hazard and ask us to provide sufficient clarity to be able to distinguish between these types of hazards.

(Response 62) We have changed the term “significant hazard” to “hazard requiring a preventive control.” The new term uses the explicit language of FSMA (*i.e.*, “preventive control”), is consistent with the specific suggestion of one comment (*i.e.*, hazard requiring a control”), and is not commonly associated with HACCP systems. We decline the request to use the term “food safety hazard” because that term already is established in Federal HACCP regulations for seafood and meat/poultry, and the comments are particularly concerned about using a

term that has implications for HACCP systems. We also decline the request to use the term “actionable hazard,” because the term “actionable” is associated with violations at a food processing plant.

We reviewed the full regulatory text of proposed subpart C and replaced “significant hazard” with “hazard requiring a preventive control” in most cases. See table 31.

We also reviewed the full regulatory text of proposed subpart C to evaluate whether there were any circumstances where the regulatory text should more appropriately refer to “hazard requiring a preventive control” rather than “hazard” or “known or reasonably foreseeable hazard.” The term “known or reasonably foreseeable hazard” appears only once, in the requirement for a facility to conduct a hazard analysis (§ 507.33(a)). We are retaining “known or reasonably foreseeable hazard” in that requirement because it is necessary to implement the tiered approach to the requirements for hazard analysis and risk-based preventive controls (see Response 31). To reinforce this tiered approach, and emphasize that the facility only conducts a hazard analysis for known or reasonably foreseeable hazards, we revised “hazard” to “known or reasonably foreseeable hazard” in two additional provisions in the requirements for hazard identification (see the introductory regulatory text for § 507.33(b)(1) and (2)).

In our review of the full regulatory text of proposed subpart C, we did not identify any circumstances where we believe it is appropriate and necessary to specify “hazard requiring a preventive control” in place of “hazard.” It is not necessary for the regulatory text of requirements for preventive controls, the supply-chain program, the recall plan, corrective actions, and verification to specify “hazard requiring a preventive control” every time that the requirements use the term “hazard” because the context of the requirement establishes the applicability to “hazards requiring a preventive control.” Although we acknowledge that using “hazard requiring a preventive control” in place of “hazard” throughout applicable provisions of proposed subpart C would emphasize the tiered approach to the requirements for hazard analysis and risk-based preventive controls, doing so would make the regulatory text unnecessarily bulky and awkward and would be inconsistent with comments that ask us to make the regulatory text understandable (see Comment 13 in section III of the final rule for preventive

controls for human food, published elsewhere in this issue of the **Federal Register**).

(Comment 63) Some comments ask us to allow facilities to continue to implement existing controls outside the framework of this rule (*i.e.*, outside the framework that requires preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the food safety system) when a hazard addressed by the existing controls does not rise to the level of “significant hazard.”

Other comments express concern that the term “significant hazard” may create a disincentive for facilities to voluntarily implement preventive controls for hazards that only pose a remote risk or are very rarely encountered, because implementing preventive controls for hazards of very low probability and severity may be misinterpreted as requiring preventive controls applicable to a “significant hazard” even if the hazard does not meet the definition of “significant hazard” established in the rule. Some comments ask us to revise the definition to provide facilities with the flexibility and discretion to establish appropriate preventive controls for hazards that do not rise to the criteria of a “significant hazard,” as well as ensuring that preventive controls that address remote or very unlikely hazards not be subject to the preventive control management requirements for a “significant hazard.”

(Response 63) We have revised the definition to specify that the term “hazard requiring a preventive control” applies when a knowledgeable person would, based on the outcome of a hazard analysis, “establish one or more preventive controls” rather than “establish controls.” By narrowing “controls” to “one or more preventive controls,” we mean to signify that the proposed term “significant hazard” (which we now refer to as “hazard requiring a preventive control”) only applies to those controls that the facility establishes to comply with the requirements of subparts C and E for hazard analysis and risk-based preventive controls. A facility that establishes other controls (such as those that the comments describe as “prerequisite programs,” or controls directed to hazards of very low probability and severity) for hazards that are not, based on the outcome of the facility’s hazard analysis, “hazards requiring a preventive control” would not need to establish preventive control management components for such controls. However, some controls

previously established in “prerequisite programs” would be considered “preventive controls.” We provide some flexibility for facilities with respect to how they manage preventive controls, and the preventive control management components may be different for hazards that have been managed as “prerequisite programs” compared to those managed with CCPs. A facility that is concerned about the potential for an investigator to disagree during inspection that certain controls are not directed to “hazards requiring a preventive control” could, for example, include information relevant to its classification of those other controls in its hazard analysis, whether by merely listing the “other controls” or by providing a brief explanation why such controls are not “preventive controls” as that term is defined in this rule.

(Comment 64) Some comments assert that the proposed definition of “significant hazard” is tautological because it essentially establishes a “significant hazard” to be a known or reasonably foreseeable hazard (*i.e.*, the type of hazards identified in the first step of the analysis) for which preventive controls should be implemented. These comments assert that the proposed definition of “significant hazard” would collapse the second step of hazard analysis into the first, which in turn would lead to the unintended consequence of facilities identifying the same hazards in the second step as in the first. Some comments ask us to revise the definition to include evaluation of severity and probability, because these concepts are integral for making a proper determination of whether a hazard is significant. Other comments ask us to revise the definition to better reflect the risk-based approach that preventive controls be implemented to control hazards that have a higher probability of resulting in public health consequence in the absence of control.

(Response 64) We have revised the definition of “significant hazard” (which we now refer to as “hazard requiring a preventive control”) to specify that the hazard analysis includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. By specifying that the determination of a “significant hazard” is based on the outcome of a hazard analysis, the proposed definition did, as requested by the comments, include the risk-based nature of the determination. However, explicitly adding that the hazard analysis is based on probability and severity (*i.e.*, risk)

makes the risk-based nature of the determination clearer.

We disagree that the proposed definition was tautological and would collapse the second step of hazard analysis into the first. A facility begins its hazard analysis by narrowing down the universe of all potential hazards to those that are “known or reasonably foreseeable” for each type of animal food manufactured, processed, packed, or held at its facility. The outcome of the facility’s hazard analysis is a determination of a subset of those known or reasonably foreseeable hazards, *i.e.*, those hazards requiring a preventive control. To the extent that these comments are asserting that the tautology was created by the phrase “in the absence of its control” in the proposed definition of “hazard,” we have deleted that phrase from the final definition of “hazard.”

We decline the request to repeat in the definition of “hazard requiring a preventive control” the requirement for the types of information that a facility would consider in conducting its hazard analysis. The requirements for hazard analysis clearly specify that a facility must conduct its hazard analysis based on experience, illness data, scientific reports, and other information (see § 507.33(a)).

(Comment 65) Some comments that broadly address the overall framework for the new requirements for hazard analysis and risk-based preventive controls ask us to consistently refer to “the nature of the preventive control” (rather than simply to “the preventive control”) when communicating the flexibility that a facility has in identifying preventive controls and associated preventive control management components. Other comments that broadly address the overall framework for the new requirements for hazard analysis and risk-based preventive controls ask us to emphasize that the requirements for preventive control management components convey not only that the application of a particular element is appropriate (*i.e.*, capable of being applied), but also necessary for food safety. Some comments recommend that we do so by specifying that preventive control management components take into account the role of the preventive control in the food safety system.

(Response 65) We agree with these comments and have revised the definition of “hazard requiring a preventive control” to specify that preventive control management components are established as appropriate to “the nature of the

preventive control and its role in the facility’s food safety system.”

(Comment 66) Some comments assert that the problem is how to separate the hazards addressed by “HACCP” from those addressed by CGMPs. These comments suggest that control measures that are implemented for hazards from ingredients and food-contact packaging material, and from production and process, be called CCPs and that control measures that are implemented for hazards from personnel, equipment, and the plant be called preventive controls.

(Response 66) The facility must control hazards through the application of CGMPs and preventive controls as appropriate to the hazard. Although some preventive controls will be established at CCPs, and “CCP” is a term commonly used in HACCP systems, this rule establishes requirements for hazard analysis and risk-based preventive controls, not “HACCP,” and this rule provides that preventive controls include controls at CCPs, if there are any CCPs, as well as controls, other than those at CCPs, that are also appropriate for animal food safety (see § 507.34(a)(2)).

Under the rule, some hazards may be addressed by CGMPs and others by preventive controls. For example, a facility could control a physical hazard such as metal by using screens and magnets under CGMPs and then use a metal detector as a preventive control.

(Comment 67) Some comments express concern that the term “significant hazard” may lead to misunderstanding by medium and smaller processors and ask how businesses with limited food safety experience will understand the difference between a food safety hazard that is “reasonably likely to occur” (and, thus, must be controlled by a full HACCP Plan) and a “significant hazard” that can be controlled by a preventive control plan.

(Response 67) It will not be necessary for an animal food processor to understand the difference between a hazard that is “reasonably likely to occur” in the concept of HACCP requirements and a “hazard requiring a preventive control” in the context of this rule. FDA does not have any HACCP regulations that apply to animal food.

(Comment 68) Some comments ask us to concur that “temporal hazards” in some food products (specifically, aflatoxin, pesticides, and radiological contamination) do not represent “significant hazards” that require monitoring and verification activities on an ongoing basis. These comments also ask us to acknowledge that in many

cases the testing done by FDA and others is sufficient for protecting public health and that it is not necessary to require ongoing monitoring by individual facilities in order to comply with the rule.

(Response 68) We decline these requests because such a determination should be facility specific. However, we have revised the considerations for the hazard evaluation to clarify that in making the determination as to what hazards require preventive controls, the facility can consider factors such as the temporal nature of the hazard (see § 507.33 and section XXV). In determining the appropriate preventive control management components, the facility can take into account the nature of the preventive control and its role in the facility's food safety system (see § 507.39(a)).

### 32. Significantly Minimize

We proposed to define the term "significantly minimize" to mean to reduce to an acceptable level, including to eliminate. We did not receive comment and are finalizing it as proposed.

### 33. Small Business

We proposed to define the term "small business" to mean, for the purposes of part 507, a business employing fewer than 500 persons. We conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 12) and used the results of the study in defining the term "small business." (78 FR 64736 at 64758 through 64759.) We made the results of the Food Processing Sector Study available in Docket No. FDA-2011-N-0922 and requested public comment on that study.

(Comment 69) Some comments express concern that the Food Processing Sector Study is not comprehensive. Some comments assert that FDA did not sufficiently collaborate with USDA, and that FDA significantly underestimated the number of mixed-use facilities, particularly by neglecting to count farms that perform the processing steps on RACs to become a processed food. Other comments assert that the Food Processing Sector Study is woefully inadequate and must be undertaken again to comply with the law.

(Response 692) We previously acknowledged the limitations of the Food Processing Sector Study (78 FR 64736 at 64758 through 64759). We have revised and extended the results of our earlier study by expanding our data sources and by including representatives from USDA's Economic

Research Service, USDA's Agricultural Marketing Service and the American Farm Bureau to help oversee the revised study. The revised Food Processing Sector Study is available in the docket of this rule (Ref. 21).

Our original analysis was based on the merger of Dun & Bradstreet data and FDA's Food Facility Registration data to help us estimate the number of manufacturing facilities that are also classified as farms. We have updated that data source and added data sources. To better account for farms that perform processing activities, we included Census of Agriculture (Ag Census) data both to provide a count of total U.S. farms and to estimate the number of farms conducting food processing activities, to the extent that the data identifies processing activities. We also included the Agricultural Resource Management Survey (ARMS) data because it included questions about some processing activities for select commodities.

Both the Ag Census and ARMS are silent about many processing activities. Therefore, we also obtained estimates from commodity specialists at trade associations, USDA, and universities with in-depth knowledge of the processing activities for specific agricultural commodities.

(Comment 70) Some comments ask us to explain how to calculate the number of full-time equivalent employees, *e.g.*, with respect to temporary workers, seasonal workers, and part-time workers. Other comments say it is unclear whether fewer than 500 full-time equivalent employees means those involved in the entire business or those involved only in the animal food-related portions of the business, noting that the term "business" is unclear (*i.e.*, whether business means a corporation and all its subsidiaries or only the portion of the business related to animal food be it animal feed, pet food and/or ingredients).

(Response 70) As previously discussed, we proposed to establish the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR part 121 for most food manufacturers, and the limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility (78 FR 64736 at 64759). We will base the calculation on "full-time equivalent employees" and use the same approach to calculating full-time equivalent employees for the purpose of this rule as we used to calculate full-time equivalent employees in the section 414 recordkeeping regulations (see § 1.328).

This approach is similar to the approach the Agency used to calculate the small business exemption for nutrition labeling of food (§ 101.9(j)(18)(iv)(D)). Under this approach, the number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity claiming the exemption and of all of its subsidiaries and affiliates by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks).

The calculation for the number of employees affects exemptions (*i.e.*, the exemptions for on-farm, low-risk activity/animal food combinations in § 507.5(e) and (f), which apply only to small and very small businesses), not just compliance dates. Therefore, we are establishing the definition of "full-time equivalent employee" in the definitions for this rule (§ 507.3) and modifying the definition of "small business" to use the term "500 full-time equivalent employees" rather than "500 persons."

(Comment 71) Some comments assert that there should be no exemption from compliance with this rule based on total annual sales or number of employees, noting that all companies regardless of size should have food safety programs in place.

(Response 71) The definition of "small business" is relevant to the exemptions for on-farm, low-risk activity/animal food combinations for manufacturing/processing, packing, and holding animal food by mixed-type facilities. This exemption is a risk-based exemption, because it only applies to activity/animal food combinations that are low-risk and, thus, should not affect animal food safety.

### 34. Supplier

We proposed to define the term "supplier" to mean the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

As discussed in section IV.B of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, we have revised the "farm" definition to explicitly include business models in which one operation grows crops but does not harvest them, and another operation, not under the same management, harvests crops but does not grow them. This revision represents a change from the existing and proposed

“farm” definitions, which describe a “farm” as an entity “devoted to the growing *and* harvesting of crops” (emphasis added). We proposed the “supplier” definition in the context of a single business entity “devoted to the growing *and* harvesting of crops” (emphasis added). We used the term “harvesting,” rather than “growing,” to reflect the last stage of production on a farm, except for packing.

Because the proposed “supplier” definition contemplated that the same business entity that grows crops also harvests them, we have revised the “supplier” definition so that the grower remains the supplier when the harvester is under separate management. Specifically, “supplier” is now defined to include an establishment that “grows” food rather than an establishment that “harvests” food. Doing so focuses the requirements for the supply-chain program (see subpart E) on the entity that produces the food, rather than on the entity that removes the food from the growing area, when the grower and the harvester are not under the same management. Doing so also simplifies the determination of who the supplier is in complex business models, such as when a “handler” arranges for harvest by another business entity.

(Comment 72) Some comments assert that the definition of supplier is not workable because the status of warehouses and brokers is unclear in the definition. Other comments ask us to modify the definition to specify, in addition to the proposed definition, that the supplier could be an intermediary entity that takes responsibility on behalf of the receiving facility to ensure that the food meets the requirements of this part.

(Response 72) As discussed in section XL, we agree that the role of intermediaries in the supply chain is critical and we have added options for entities other than the receiving facility to perform certain supplier verification activities, provided that the receiving facility reviews and assesses the documentation produced by the other entity and documents that review and assessment. However, this does not mean that these entities take on the role of the supplier. As discussed in Response 59 and in section XL, we believe it is important to supplier verification to retain the identities of two parties involved—the receiving facility and the supplier. Therefore, we are retaining our definition of supplier, with the minor change previously discussed.

(Comment 73) Some comments regarding RACs ask us to modify the

definition of supplier in the case of comingled RACs, such that the supplier would be the person immediately back from the receiving facility in the supply chain provided that this entity (presumably a warehouse or aggregator) voluntarily complies with the requirements of subpart C of this part. One comment asks us to clarify in our definition that the supplier must be the establishment that controls the hazard in question.

(Response 73) We decline this request. As discussed in section XL, we recognize that doing supplier verification with comingled products will be a challenge. However, we believe it is important that there be a link between the receiving facility (which is manufacturing/processing the animal food) and the supplier (who controlled the hazard(s) in the animal food). We are allowing an entity such as an aggregator or distributor to perform some verification activities, so the outcome requested by these comments will be achieved while maintaining the identities of the two primary parties in the supplier verification relationship (see Response 492).

(Comment 74) One comment asks us to clarify that the proposed definition of supplier does not include sources of processing aids or chemicals required for post-harvest treatments and packing processes (including waxes, fungicides, detergents and sanitizers).

(Response 74) As defined, the supplier is the establishment growing the food, not those establishments providing inputs (such as waxes, fungicides, detergents and sanitizers) to that entity.

### 35. Validation and Verification

We proposed to define the term “validation” to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. We proposed to define the term “verification” to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

(Comment 75) Some comments ask us to revise the definitions of “validation” and “verification” to be consistent with the Codex definitions. Codex defines “validation” to mean obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. Codex defines “verification” to mean the application of methods,

procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (Ref. 22).

Some comments ask us to more clearly distinguish between “validation” and “verification.” Some comments assert that validation is not an element of verification as stated in our proposed definition and suggest that we clearly separate requirements for validation from requirements for verification, *e.g.*, by moving the proposed requirements for verification to a distinct section in the regulatory text.

(Response 75) We have explained how our proposed definitions for “validation” and “verification” align with a variety of widely recognized definitions, including definitions established by Codex, the NACMCF HACCP guidelines, and Federal HACCP (78 FR 64736 at 64758). We disagree that validation is not an element of verification, but acknowledge it is not necessary to say so within the definition of “validation.” Although we have moved the details of the requirements for validation from its proposed location within the requirements for verification (*i.e.*, proposed § 507.45(a)) to a separate section (§ 507.47), we did so as an editorial change to improve clarity and readability rather than as a substantive change to signal that validation is not an element of verification (see table 8, 79 FR 58476 at 58504).

We agree that validation can apply to a specific control measure as specified in the Codex definition. We also agree that validation can apply to a combination of control measures as specified in the Codex definition. The food safety plan is one example of a combination of control measures.

Although we likewise agree that verification can apply to a specific control measure as specified in the Codex definition, we disagree that to be consistent with the Codex definition we should adopt a definition that excludes the application of verification to the food safety plan. It is well established that some verification measures, such as testing for a pathogen, verify that multiple control measures operated as intended.

To more clearly distinguish between “validation” and “verification,” the definition of “validation” we are establishing in this rule specifies that validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, *when properly implemented*, is capable of effectively controlling the identified

hazards (emphasis added). We also made conforming changes associated with the revised definition of “validation” in the requirements for validation (see § 507.47(b)(2)). The definition of “verification” we are establishing in this rule specifies that verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures *is or has been operating as intended* and to establish the validity of the food safety plan as a whole (emphasis added). Consistent with the request of the comments, the definition of “verification” uses the Codex description of verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring.

### 36. Very Small Business

We proposed to define the term “very small business” to mean, for the purposes of proposed part 507, a business that has less than \$2,500,000 in total annual sales of food for animals, adjusted for inflation. As discussed in the proposed rule, we conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 12) and used the results of the study in defining the term “very small business” (78 FR 64736 at 64758 through 64760). We made the results of the Food Processing Sector Study available in Docket No. FDA–2011–N–0922. Some comments support defining “very small business” as a business that has less than \$2,500,000 in total annual sales of animal food, adjusted for inflation. Other comments disagree or offer alternative recommendations.

(Comment 76) Some comments ask us to clarify how to classify the size of a business that does not take ownership or directly sell food (*e.g.*, warehouses and contract manufacturers) to determine status as a qualified facility. Some comments recommend modifications to the proposed very small business definition based on a discussion of certain farming models in the 2014 supplemental notice for animal food (79 FR 58476 at 58482). These comments express concern that the proposed definition of very small business would not account for animal food that is not “sold,” but is manufactured and then distributed to another entity without a sale, such as in the contract farming model discussed in the 2014 supplemental notice.

Other comments recommend modifications to the definition to use the value or volume of animal food manufactured and distributed in

establishing whether a facility is a very small business. The comments state that this would account for the animal food manufactured by feed mills servicing contract farms. Some of these comments state that the value of food produced by feed mills operating under this contract model often exceeds the \$2,500,000 threshold of the proposed very small business definition. They state that because this proposed definition only includes sales, it would allow large facilities to be considered very small businesses (as they would have no or a very small amount of actual sales).

Other comments request that we modify the proposed definition to specify that animal food produced for contract farms is not included in “sales” in the definition for very small business; thereby allowing these feed mills to be very small businesses, which would result in qualified facility status.

Some comments ask us to specify that the monetary threshold for the definition be based on average sales during a 3-year period on a rolling basis because otherwise firms may be subject to significant changes in status from year to year. These comments also ask us to clarify that the sales are to be evaluated retrospectively, not prospectively.

(Response 76) We have revised the definition of very small business to specify that it is based on an average during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale). The applicable calendar year is the year after the 3 calendar years used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the 3 calendar years used to determine whether a facility is a very small business are 2021 to 2023. The exception is when 3 calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

As a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis by no later than July 1 of each calendar

year (see § 507.7(c)(1)). Although this requirement was implicit in the proposed requirement that a facility must resubmit a notification to FDA if its status changes as a qualified facility (proposed § 507.7(c)(2), which we are finalizing as § 507.7(c)(3)), we are making this requirement explicit to clarify the responsibility of the facility to affirmatively determine its status when the calendar years that apply to the 3-year average change. The July 1 deadline for a facility to determine its status provides facilities with 6 months to make the determination after the end of the previous 3 calendar years.

We also are establishing an earlier compliance date for the financial records that a facility maintains to support its status as a very small business. Specifically, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. Even with this earlier compliance date for these records, we realize that although the calculation for “very small business” in the regulatory text is based on 3 calendar years, a facility will only be required to have 2 calendar years of records as of the general compliance date for very small businesses. Specifically, by December 16, 2019 a facility that begins retaining applicable financial records on January 1, 2017, would only have such records for 2 previous calendar years. Therefore, it would be reasonable for a facility to make the calculation based on the 2 previous calendar years. If a facility has records for 3 previous calendar years, the facility could make the calculation based on the longer time period. During inspection in 2019, when a facility has records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years, we will accept records for the preceding 2 calendar years as adequate to support status as a qualified facility based on calculating an average for those two years. We note that in some situations, a shorter time period is sufficient to determine that a facility is not a very small business. For example, a facility with sales exceeding \$7,500,000 for the preceding calendar year cannot qualify as a very small business because no amount of sales from other years will reduce average sales below the threshold of \$2,500,000.

The available financial records for a facility that begins operations between January 1, 2018 and September 17, 2019 would not cover even 2 complete calendar years by September 17, 2019. During the first 3 calendar years of such a facility’s operation, it would be reasonable for a facility to make the calculation based on records it has (*i.e.*, for 1 or 2 preceding calendar years), and

we will accept records for the preceding 1 or 2 years as adequate to support status as a qualified facility in these circumstances.

When a facility does not begin operations until after January 1, 2019, it would be reasonable for the facility to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the facility's number of full-time equivalent employees. After the facility has records for 1 or 2 preceding calendar years, it would be reasonable for the facility to make the calculation based on records it has (*i.e.*, for 1 or 2 preceding calendar years) and we will accept records for the preceding 1 or 2 years as adequate to support status as a qualified facility in these circumstances.

We agree with the comments that state the animal food distributed, but not "sold," by feed mills operating under contract farming agreements (and required to register as a food facility under section 415 of the FD&C Act) should be included in determining whether a facility is a very small business. In addition to annual sales of animal food, the market value of the animal food supplied to a farm(s) without sale must be included when determining if a business is a very small business for purposes of this rule.

The qualified facility exemption of § 507.7 applicable to very small businesses is intended to enable these businesses to comply with modified requirements because they have fewer resources to direct to full compliance with subpart C and E of the rule and they provide a small volume of animal food for consumption. Many of the businesses that have feed mills that provide animal food under contract farming agreements are extensive and sophisticated businesses, such as some large-scale meat and poultry operations. Such businesses are not the intended beneficiaries of the qualified facility exemption because they should have adequate resources, such as personnel, equipment, and expertise, to implement the requirements of subparts C and E at their feed mills. In addition, many of these feed mills manufacture and distribute a large volume of animal food yearly. These were some of the factors we considered when we revised the proposed definition of a very small business to include the market value of the animal food that is manufactured, processed, packed, or held without sales or supplied to a farm without sales.

(Comment 77) Some comments support the proposed dollar threshold of \$2,500,000, noting that it would provide

sufficient flexibility to companies that receive the exemption to allow them to continue to operate. Some comments say there should be no exemption from compliance with this rule based on total annual sales or number of employees and that all companies regardless of size should have food safety programs in place. Several comments request different dollar amounts for determining the threshold.

Some comments propose that the threshold should be \$1,000,000, a figure that would provide greater coverage than the \$2,500,000 proposed threshold and also would simplify compliance with all FSMA rules for animal food facilities. Other comments suggest the definition for a very small business should mean, for purposes of part 507, a business that has less than \$1,000,000 in total annual sales of animal food, adjusted for inflation, and distributes less than 5,000 tons of animal food annually. Several comments urge us to consider applying a \$500,000 threshold to the value of animal feed produced by a facility, not just the value of animal food that is sold. The comments state that the vertically integrated structure of some livestock and poultry operations means that some animal feed produced at large operations may never be sold because the company supplies feed to contract operations raising animals owned by the company.

Other comments suggest ensuring sufficient flexibility for a diverse array of animal food businesses and that we should establish an outright exemption from the rule for businesses with, at the very most, \$100,000 or less in annual average monetary value of animal food sold over the previous 3-year period, adjusted for inflation. Another comment suggests a threshold of \$250,000. Other comments recommend defining a very small business as one with less than \$10,000 in annual sales believing that a rule encompassing virtually all ingredient and feed manufacturing and distribution facilities will encourage large firms to continue to do business with very small firms. One comment suggested excluding the value of donated by-product in the calculation of total annual sales of animal food.

(Response 77) We are establishing a \$2,500,000 threshold for the definition of "very small business." Under section 418(l)(1)(A) and (B) of the FD&C Act, a very small business is a qualified facility; under the exemption authorized in section 418(l)(2) of the FD&C Act, a qualified facility is subject to modified requirements rather than the requirements for hazard analysis and risk-based preventive controls. We have acknowledged that a \$2,500,000

threshold exempts a greater portion of the animal food supply than thresholds of either \$500,000 or \$1,000,000 (79 FR 58476 at 58502), but reaffirm that under the \$2,500,000 threshold the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness; businesses that fall within this definition of "very small business," collectively, produce less than 0.6 percent of the animal food supply (Ref. 3). In addition, most of these facilities will be subject to the CGMP requirements in subpart B; the only exemptions from those CGMP requirements are the exemptions in § 507.5(a) (which applies to farms and activities of "farm mixed-type facilities" that fall within the definition of "farm"), and in § 507.5(h) (which applies to: (1) The holding or transportation of one or more RACs; (2) hulling, shelling, and drying nuts and hulls (without manufacturing/processing); and (3) the ginning of cotton (without manufacturing/processing)). Facilities subject to and in compliance with human food CGMPs and applicable FDA human food safety requirements that process human food and "donate" or sell the human food by-products without further processing for use as animal food are only subject to certain provisions in subpart B for those by-products. This applies whether they are a qualified facility or not. They are not subject to the requirements of subparts C and E for the human food by-products used for animal food.

(Comment 78) Some comments ask us to only include the total annual sales of food in the United States, adjusted for inflation, for foreign facilities that export food to the United States.

(Response 78) We decline this request. The purpose of the definition of "very small business" is principally to enable such businesses to comply with modified requirements, because they have fewer resources to direct to full compliance with the rule. A foreign business that sells more than the threshold dollar amount of animal food has more resources than the businesses being excluded, even if less than that threshold dollar amount reflects sales to the United States. Likewise, a domestic business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if that domestic business exports some of its food and, as a result, less than that threshold dollar amount reflects sales within the United States.

(Comment 79) Some comments ask us to base the threshold on the total “volume of product” or “amount of product” handled or sold. These comments assert that an approach using product volume or amount would be more risk based because it would correlate more closely to consumer exposures than dollar amounts, which can be skewed by product values.

(Response 79) We acknowledge that dollar amounts can be skewed by product values but nonetheless disagree that we should base the threshold on the total “volume of product” or “amount of product” handled or sold. We see no practical way to identify a threshold based on volume or amount of product that could be applied across all product sectors, and the comments provide no suggestions for how their recommendation could be carried out.

(Comment 80) Some comments express concern that establishing a threshold based on U.S. dollars would place domestic firms at a disadvantage relative to foreign firms whose sales are often denominated in currencies valued lower than the dollar and often reflect much lower costs for factors such as land, labor, and environmental compliance. These comments ask us to base the threshold on an alternate measure, such as number of employees, or to calculate the sales of foreign very small businesses using an appropriate measure of purchasing power parity, if there is a straightforward way to do so.

(Response 80) We decline these requests. As previously discussed, we use dollar estimates to evaluate the percent of all food produced in the United States that would not be covered by the rule (79 FR 58476 at 58502). We acknowledge that the definition of “small business” is based on number of employees, and that two exemptions (*i.e.*, the exemptions in § 507.5(e) and (f) for on-farm, low-risk activity animal food combinations) apply to small businesses. However, the exemptions for on-farm, low-risk activity animal food combinations are limited to a narrow sector of the animal food industry, whereas the exemption applicable to a very small business will apply to all sectors of the animal food industry.

We do not know of a straightforward way to calculate the sales of foreign very small businesses using an appropriate measure of purchasing power parity and, thus, are basing the threshold only on U.S. dollars.

### *B. Comments Asking FDA To Establish Additional Definitions or Otherwise Clarify Terms Not Defined in the Rule*

Some comments ask us to define certain terms such as “associated,” “contaminate,” “directly linked,” “integrated operator,” “material to the safety of food,” “written,” and “necessary.” We believe that it is not necessary to define these and certain other new terms proposed by the comments. We discuss in this section of this document comments that ask us to establish other new terms or clarify terms in the rule not defined.

#### 1. Consumer/Final Consumer/Customer

(Comment 81) A few comments request that we define consumer as the animal consuming the food. Some comments ask us to define “customer” as the purchaser of the animal food. Other comments ask us to define “final consumer” to mean a person that feeds animals under the control or ownership of that person. The comments suggest “final consumer” could be used in the animal food rule to help clarify the meaning of qualified end user.

(Response 81) We decline these requests. We stated that for purposes of the proposed rule, the term consumer refers to the person purchasing the animal food to feed to an animal(s), as well as the animal(s) consuming the food (78 FR 64736 at 64756 through 64757). To limit the definition of consumer to the animal consuming the food would be inconsistent with how that term is used throughout FSMA and would create confusion. Therefore, “consumer” also includes the person purchasing the animal food.

#### 2. Corrections

(Comment 82) Some comments assert that clearly distinguishing between the terms “corrective actions” and “corrections” will be imperative for industry to comply with the rule and for regulators to enforce the rule. Some comments ask us to use the ISO definitions of “corrective actions” and “corrections.” (According to ISO 22000:2005 definition 3.13, a “correction” is action to eliminate a detected non conformity; according to ISO 22000:2005 definition 3.14, corrective action is action to eliminate the cause of a detected non conformity or other undesirable situation.) Other comments ask us to eliminate the term “correction” and instead revise the rule to clarify the type of situation in which “corrective actions” are neither necessary nor appropriate. As an example, these comments suggest that the proposed provisions for corrections

could refer to “prompt actions taken in response to minor and isolated deviations that do not directly impact product safety.”

Other comments agree with the concept of simple “corrections” but assert that the term “corrections” is unnecessary and could be confusing because different facilities may use the term differently. These comments explain that sometimes “correction” is used to refer to the action taken to fix a deviation, and may or may not be part of an overall corrective action taken to identify the root cause of the deviation and to prevent a similar occurrence. These comments suggest that the provisions explain that prompt actions taken to address minor and isolated deviations are not subject to the same requirements as corrective actions to address potentially systemic concerns, without defining the term “corrections.”

(Response 82) We are defining the term “correction” to mean an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce). We agree that clearly distinguishing between the terms “corrective actions” and “corrections” will be important for both industry and regulators. We acknowledge that one way to distinguish between “corrective actions” and actions that we would consider “corrections” could be to avoid the term “corrections” and instead say what we mean each time the rule uses the term “corrections.” However, after reviewing the full regulatory text of proposed subpart C, we concluded that it was not practical to do so, because the term “corrections” was used more often in a title or a cross-reference than in a provision where the full text of what we mean by the term “corrections” is necessary to communicate a requirement. Our definition of “corrections” focuses on the first step in a “corrective action procedure” (*i.e.*, identify and correct the problem) and also specifies those aspects of a corrective action procedure that do not apply to a correction (*i.e.*, actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce). (A note to the ISO 22000:2005 definition of corrective action indicates that it includes cause analysis and is taken to prevent recurrence.) We believe that this definition will be adequate to

distinguish “corrective actions” from “corrections.”

As an example, if a facility applies sanitation controls for an environmental pathogen such as *Salmonella* spp. and animal food residue is observed on “clean” equipment prior to production, corrections would involve re-cleaning and sanitizing the equipment before it is used. Because the observation of animal food residue was made prior to production of animal food, no animal food is affected, and no actions are needed with respect to animal food. Although there are actions that can be taken to prevent reoccurrence, such as retraining sanitation personnel, these types of situations may reoccur from time to time.

### 3. Crop

(Comment 83) Some comments request we define a new term “crop” to mean the edible or inedible cultivated or harvested plants.

(Response 83) We decline this request. The term “crop” has a common meaning, and it is not necessary to establish a meaning for this term in this rule.

### 4. Establishment

(Comment 84) Several comments request we establish a definition for establishment as it is used in the supplier definition. Also, the comments suggest that we replace in the definition of farm the term “establishment” with “operation.”

(Response 84) Comments concerning the meaning of the term “establishment” as it relates to the “supplier” definition are addressed in section XL pertaining to subpart E, the supply-chain program. Comments directed to the meaning of the term “establishment” as it relates to the farm definition are addressed in section IV.A and B of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

### 5. Parameter and Value as Used in the Requirements for Process Controls

(Comment 85) Some comments ask us to define the terms “parameter” and “value” used in the requirements for preventive controls (§ 507.34). These comments ask us to define “parameter” as a measurable attribute and “value” as a specific measurement.

(Response 85) We decline this request. Both of these terms are used in the context of process controls and both have common meanings when associated with process controls. Therefore, it is not necessary for the rule to define them.

### 6. Prerequisite Program

(Comment 86) Some comments ask that we adapt the definition of prerequisite program from the ISO’s food safety standard, ISO 22000:2005, noting that the ISO definition is: Basic practices and procedures in animal food production that are necessary for the manufacture, handling and provision of safe end products and safe food for animal consumption.

(Response 86) We do not use the term “prerequisite program” in the regulations established by this rulemaking and do not find it necessary to define it. We understand that some facilities may refer to practices and procedures such as CGMPs, training, or certain controls for hazards as a “prerequisite program.”

### 7. Qualified Facility Exemption

(Comment 873) Some comments note that some of the terminology associated with the exemption for qualified facilities in the preventive controls rule is different from terminology associated with an exemption in the proposed produce safety rule. These comments point out that the exemption in the proposed produce safety rule refers to “qualified exemptions” (§ 112.5), whereas the exemption in the proposed animal preventive controls rule refers to “exemptions” and “qualified facilities” (§ 507.5(d)).

(Response 873) We have added a definition for the term “qualified facility exemption,” to mean an exemption applicable to a qualified facility under § 507.5(d) (see the regulatory text in § 507.3). We also have made conforming changes throughout the rule to use the term “qualified facility exemption” when it applies. (See table 31).

### 8. Qualified Investigator

(Comment 88) Once comment proposes a new term “qualified investigator” where the term “qualified investigator” means an FDA or state commissioned investigator that has successfully completed a formal training course on inspections; CGMPs; hazard analysis and preventive controls for animal food facilities, both animal feed and pet food, and has demonstrated an understanding of the differences between pet food and animal feed manufacturing facilities.

(Response 88) We decline this request. Our inspectors will be trained on the requirements of this part.

### 9. Reanalysis

(Comment 89) Some comments request we define the term reanalysis to mean a reassessment of the validity of

a preventive control or food safety plan to control a hazard.

(Response 89) We decline this request. Section 418(i) of the FD&C Act sets the requirement for conducting a reanalysis, which is in the regulatory text in § 507.50, including how often and under what circumstances a reanalysis of the food safety plan must be performed, and how to handle the results. Therefore, we have determined that a definition of “reanalysis” is not necessary. For a discussion of the reanalysis requirement, see section XXXV.

### 10. Risk Assessment

(Comment 90) Some comments request that we add a new term “risk assessment” and define this term as a scientifically based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.

(Response 90) We do not use the term “risk assessment” in the regulations established by this rulemaking and do not find it necessary to define it. As directed by section 103(c) of FSMA, we issued for public comment a draft risk assessment, as described in section I.D and are including the final risk assessment in the docket established for this rule.

The definition proposed by the comment is similar to the requirements for the hazard analysis of § 507.33. The term “hazard analysis” comes from section 418 of the FD&C Act. For discussion of hazard analysis, see section XXV.

### 11. Undesirable Microorganisms

(Comment 91) Some comments request we define a new term “undesirable microorganisms” as those microorganisms that are of animal or human health significance, thereby rendering the animal food unfit for consumption or distribution.

(Response 91) We decline this request. See Response 45.

### 12. Unexposed Packaged Animal Food

As discussed in section XXXVI, some comments ask us to clarify that modified requirements for packaged animal food that is not exposed to the environment only apply to such animal food that requires time/temperature controls for safety (TCS animal food). To do so, we are defining the term “unexposed packaged animal food” to mean packaged animal food that is not exposed to the environment and using this term throughout the rule. Doing so simplifies the regulatory text and makes it clearer.



*C. Additional Definitions To Clarify Terms Not Defined in the Proposed Rule*

1. Audit

As already noted, some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other, and we have worked to align the provisions of this rule with the provisions of the FSVP rule to the extent practicable. (See Comment 4 and Response 4.) To align these provisions, we are establishing in this final rule a definition of “audit” analogous to the definition of “audit” we proposed for the FSVP rule. For the purposes of this rule, “audit” means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier’s food safety processes and procedures.

2. Full-Time Equivalent Employee

As discussed in Response 70, we have established a definition for “full-time equivalent employee” as a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its subsidiaries and affiliates by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

3. Qualified Individual

As discussed in section IX.A, we are clarifying in new § 507.4(b)(1) that each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual’s assigned duties. To better align with the FSVP rule, we use the term “qualified individual” in new § 507.4 and are defining the term “qualified individual” to mean a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack,

or hold safe animal food as appropriate to the individuals assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

4. Raw Agricultural Commodity

We have added a definition of the term “raw agricultural commodity” to have the meaning given in section 201(r) of the FD&C Act. We decided to define this term in the rule to simplify the provisions in part 507 that refer to raw agricultural commodities.

5. Supply-Chain-Applied Control

We have added a definition of the term “supply-chain-applied control” to mean a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. We decided to define this term in the rule to simplify the provisions in part 507, and in this document, that refer to preventive controls applied by a supplier before receipt by a receiving facility.

6. Written Procedures for Receiving Raw Materials and Other Ingredients

We have added a definition of the term “written procedures for receiving raw materials and other ingredients” to mean written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use). We decided to define this term in the rule to simplify the provisions in part 507, and in this document, that refer to these procedures.

**IX. Subpart A: Comments on Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Animal Food**

In the 2013 proposed preventive controls rule for animal food we proposed that personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection

principles and should be informed of the danger of poor personal hygiene and insanitary practices. We asked if the recommendations should be requirements for employee education and training (78 FR 64736 at 64778). In addition, we requested comment on how best to implement section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group for human food with respect to training (78 FR 64736 at 64778). We requested comment on whether the rule should specify that each person engaged in animal food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) must receive training as appropriate to the person’s duties; specifying the frequency of training (*e.g.*, upon hiring and periodically thereafter); specify that training include the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as applied at the facility; and specify that records document required training of personnel and, if so, specify minimum requirements for the documentation (*e.g.*, the date of the training, the type of training, and the person(s) trained). We also requested comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both.

In the following paragraphs, we discuss comments that respond to our requests for comment on potential requirements for education and training and whether to establish any requirements in subpart B, subpart C, or both. After considering these comments, we are establishing requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding animal food, as well as the associated recordkeeping requirements in new § 507.4 in subpart A. The regulatory text makes clear that these requirements, established in subpart A, apply to individuals engaged in manufacturing, processing, packing, or holding animal food regardless of whether the individuals conduct these activities under the framework of the CGMPs established in subpart B or the framework for hazard analysis and risk-based preventive controls established in subparts C, D, and E. The regulatory text also makes clear that the qualification requirements apply to the recordkeeping requirements of subpart F. See table 5 for a description of these provisions.

TABLE 5—PROVISIONS FOR QUALIFICATIONS OF INDIVIDUALS WHO MANUFACTURE, PROCESS, PACK OR HOLD ANIMAL FOOD

Final section designation	Proposed section designation	Description
507.4(a)(1) .....	N/A	Applicability to individuals who manufacture, process, pack, or hold animal food subject to subparts B and F.
507.4(a)(2) .....	N/A	Applicability to individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F.
507.4(b)(1) .....	507.14(b)	Each individual engaged in manufacturing, processing, packing, or holding animal food must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties.
507.4(b)(2) .....	507.14(b)	Required training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene.
507.4(c) .....	507.14(c)	Additional qualifications of supervisory personnel.
507.4(d) .....	507.4(d)	Records of required training. The required records are subject to the recordkeeping requirements of subpart F.

*A. Applicability and Qualifications of All Individuals Engaged in Manufacturing, Processing, Packing, or Holding Animal Food (Final § 507.4(a), (b), and (d))*

(Comment 92) Some comments prefer that we continue to only provide recommendations for education and training and allow the animal food industry to determine the appropriate level of specific employee training that may be needed. Some comments say that we should allow facilities to conduct employee training in a flexible manner, with the facility determining the training content and frequency that is appropriate for the duties of a given employee as they relate to ensuring the safe production and distribution of animal food.

Some comments recommend that employees be trained “initially” and “periodically thereafter” but ask that we recognize the seasonal nature of a facility’s workforce. Some comments ask that the training include the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene as applied at the facility.

Some comments ask that training requirements be established in subpart B so that the requirements would also apply to establishments that manufacture, process, pack, or hold animal food, including establishments that are not subject to FSMA’s requirements for hazard analysis and risk-based preventive controls. Some comments that recommend establishing the training requirement in subpart B assert that training is more appropriately considered a prerequisite program than a preventive control that would belong in subpart C.

Other comments ask that the training and related recordkeeping requirements

for the facility’s preventive controls qualified individuals be established under subpart C because this is directly related to the facility’s food safety plan. Other comments ask that training requirements be established in both subpart B and subpart C. Other comments say that including requirements for education and training in both subparts B and C would be confusing.

(Response 92) We are establishing a series of requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding animal food in new § 507.4. First, to clarify how these qualification requirements apply to establishments subject to subparts B and F, we are requiring that the management of an establishment ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F are qualified to perform their assigned duties (§ 507.4(a)(1)). To clarify how these qualification requirements apply to facilities, we are requiring that the owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F are qualified to perform their assigned duties (§ 507.4(a)(2)).

We are not requiring training specific to the person’s assigned duties. Each establishment engaged in the manufacturing, processing, packing and holding of food for animal consumption would already have procedures in place to ensure that all individuals who manufacture, process, pack, or hold animal food know how to do their jobs. However, to emphasize that we expect all individuals who conduct such activities to know how to do their jobs, we are specifying that each individual engaged in manufacturing, processing,

packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual’s assigned duties (§ 507.4(b)(1)). To better align with the forthcoming FSVP rule, we are using the term “qualified individual” in new § 507.4(b)(1) and are defining the term “qualified individual” to mean a person who has the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. See the discussion of the term “preventive controls qualified individual” in section VIII.A.10, including a discussion of how we have changed the proposed term “qualified individual” to “preventive controls qualified individual” because we are establishing a new definition for “qualified individual,” with a meaning distinct from “preventive controls qualified individual.”

We also are requiring that each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof, receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the person’s assigned duties (see § 507.4(b)(2)). Records that document this required training must be established and maintained and are subject to the recordkeeping requirements of subpart F (§ 507.4(d)). The rule does not specify the frequency

of the required training. We expect that production employees will receive training before working in production operations. We expect that most facilities will also provide some form of refresher training.

We disagree that we should continue to only provide recommendations for education and training. Although the comments express concern about overly prescriptive requirements that may not consider variables that would affect an establishment's training program (such as training course content, training provider, effectiveness of the course and instructor and frequency of training per topic, an employee's type and length of experience, nature of formal education, and the animal food product type and point in the animal food supply chain at which the employee works with the animal food product), the training requirement we are establishing in the rule provides flexibility for each establishment to provide training, and determine the scope and frequency of the training, in a way that works best for the establishment.

We agree that it is appropriate to establish training requirements so that the requirements apply to all establishments that manufacture, process, pack, or hold animal food, including establishments that are not subject to FSMA's requirements for hazard analysis and risk-based preventive controls, and we are establishing the qualification and training requirements in subpart A to clarify the applicability of these requirements to all establishments and facilities subject to part 507. Although we agree that employees in facilities that are subject to the requirements for hazard analysis and risk-based preventive controls need to understand their responsibilities under the facility's food safety plan, we are setting forth a training requirement focused on the principles of animal food hygiene and animal food safety. We consider training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, to be fundamental to the concept of CGMPs. We agree that establishing a training requirement in both subpart B and subpart C could be confusing.

(Comment 93) Some comments agree that training should be documented and assert that those records should show the date of training, a description of the training, and the name of the person trained. However, comments ask that we allow flexibility in the way these records are kept. Other comments assert that requiring that records document

required training of personnel is burdensome, arbitrary, and capricious.

(Response 93) The rule requires that records that document training required by § 507.4(b)(2) be established and maintained without prescribing any content of those records. Although one approach to documenting training would be to provide the date of training, a description of the training, and the name of the person trained, the rule provides flexibility for each establishment to document its training in a way that works best for that establishment. We disagree that requiring records to document required training is burdensome, arbitrary, and capricious in light of the flexibility provided by the rule for the content of training records.

(Comment 94) Some comments agree that any requirements should include training appropriate to the person's duties but emphasize that the decision as to what is appropriate to the person's assigned duties should be determined by the establishment.

(Response 94) The requirement for employees to receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the person's assigned duties, provides flexibility for the establishment to provide training that is appropriate for its employees in light of each person's assigned duties. However, the rule does not require training specific to the person's assigned duties.

(Comment 95) Some comments assert that the training requirement would be an unreasonable burden for small businesses and that companies may incur substantial cost for the time that workers would be in training rather than in production. Some comments ask us to provide non-specific training recommendations for smaller processors that need flexibility to control the cost of training. Some comments assert that the training and education requirements must be accessible and flexible enough to allow employers to bring in temporary help when demand is high without causing a delay in hiring.

(Response 95) All employees will need enough training to do their job and understand the importance of hygiene for animal food safety. The training offered does not need to be expensive (e.g., offsite training or off-the-shelf purchased training) and we expect that much of the training will be provided in-house by knowledgeable employees. As discussed in Response 1, the FSPCA is developing a preventive controls training curriculum. These training materials will be available online, and

we expect these training materials to be useful to small businesses to use for in-house training.

#### *B. Additional Requirements Applicable to Supervisory Personnel (Final § 507.4(c))*

We proposed that responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel in § 507.14(c). We are finalizing this provision in § 507.4(c). We are correcting "all requirements of this subpart" to "all requirements of this part." As a conforming change for consistency with the provisions of § 507.4(b), we are replacing the phrase "competent supervisory personnel" with the phrase "supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production safe animal food."

#### **X. Subpart A: Comments on Proposed § 507.5—Exemptions**

We proposed to establish a series of exemptions from the requirements for hazard analysis and preventive controls that would be established in subpart C, with modified requirements in some cases.

Some comments support one or more of the proposed exemptions without change. For example, some comments note that the exemptions are specified in FSMA and, thus, reflect the intent of Congress. Some comments state that some exemptions (*i.e.*, those for products already subject to our regulations for the control of microbiological hazards for low-acid canned foods (LACF)) make sense because they are risk-based. Other comments that support one or more of the proposed exemptions ask us to clarify particulars associated with these exemptions or expand the scope of some of these exemptions. Other comments ask us to include additional exemptions in the rule.

In the remainder of this section, we discuss comments that ask us to clarify the proposed exemptions or that disagree with, or suggest one or more changes to, the proposed exemptions. We also discuss comments that ask us to include additional exemptions in the rule. After considering these comments, we have revised the proposed exemptions as shown in table 6 with editorial and conforming changes as shown in table 31. A key conforming change that affects all proposed exemptions from the requirements of subpart C is that the final exemptions are from the requirements of subpart E,

as well as subpart C. As discussed in section XL, the final rule establishes the requirements for a supply-chain program in subpart E, rather than within subpart C as proposed.

TABLE 6—REVISIONS TO THE PROPOSED EXEMPTIONS

Section	Exemption	Modification
507.5(e) .....	From the requirements of subpart C for on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the specified low-risk packing or holding activity/animal food combinations.	<ul style="list-style-type: none"> <li>• Changes consequential to the revised “farm” definition—<i>i.e.</i>, no longer identifying any packing or holding activities for any RACs.</li> <li>• Clarification that the modified requirements do not apply to on-farm packing or holding of food by a very small business if the only packing and holding activities subject to section 418 of the FD&amp;C Act that the business conducts are the listed low-risk packing or holding activity/animal food combinations.</li> <li>• Updated animal food categories consistent with the animal food categories included in table 1 in the section 103(c)(1)(C) RA.</li> <li>• Additions of low-risk packing or holding activity/animal food combinations as a result of an updated risk assessment.</li> </ul>
507.5(f) .....	From the requirements of subpart C for on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the specified low-risk manufacturing/processing activity/animal food combinations.	<ul style="list-style-type: none"> <li>• Changes consequential to the revised “farm” definition—<i>i.e.</i>:                             <ul style="list-style-type: none"> <li>• No longer distinguishing between manufacturing/processing activities conducted on a farm mixed-type facility’s own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility’s own RACs; and</li> <li>• Eliminating activities, conducted on others’ RACs, that would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding.</li> </ul> </li> <li>• Clarification that the modified requirements do not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the FD&amp;C Act that the business conducts are the listed low-risk manufacturing/processing activity/animal food combinations.</li> <li>• Updated animal food categories consistent with the animal food categories included in table 1 in the section 103(c)(1)(C) RA.</li> <li>• Additions of low-risk manufacturing/processing activity/animal food combinations as a result of an updated risk assessment.</li> </ul>
507.5(h) .....	From the requirements of subpart B for the holding and transportation of RACs.	Change from an exemption for specific activities ( <i>i.e.</i> , holding and transportation of RACs) to facilities solely engaged in those activities.

**A. General Comments on the Proposed Exemptions**

(Comment 96) Some comments ask us to provide the same flexibility for foreign small businesses as for domestic small businesses.

(Response 96) The exemptions apply to both foreign small businesses and domestic small businesses.

(Comment 97) Some comments ask us to clarify whether an establishment that is exempt from the requirements for hazard analysis and risk-based preventive controls in subpart C remains subject to the CGMP requirements in subpart B.

(Response 97) An establishment that is exempt from the requirements for hazard analysis and risk-based preventive controls in subparts C and E remains subject to the CGMP requirements in subpart B, unless that establishment is specifically exempt from subpart B under § 507.5(a) (which applies to farms and activities of “farm mixed-type facilities” that fall within the definition of “farm”); or § 507.5(h) (which applies to: (1) Establishments solely engaged in the holding or

transportation of one or more RACs; (2) hulling, shelling, and drying nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and (3) ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed)).

(Comment 98) Some comments request that we clearly articulate what activities are not covered and why; as well as what activities we are specifically exempting and why. This comment requests clarification about the differences between the categories of “not covered” and “exempt.”

(Response 98) We use the terms “not covered” and “exempt” interchangeably to describe what animal food operations or activities within an operation are not required to comply with all or parts of this rule. Farms, for example, are “not covered” by this rule, as established in § 507.5, which lists certain exemptions. As another example, a business meeting the very small business criteria is a qualified facility subject to the requirements of § 507.7, but “exempt” from the requirements of subparts C and E (see § 507.5(d)). Whether a particular exemption applies to an animal food

operation depends on the type of operation and the activities it is conducting. We believe the exemptions as codified provide enough specificity for a facility to determine whether it must comply with or is exempt from this final regulation, or certain provisions of the final regulation.

(Comment 99) One comment expressed the opinion that exemptions should be driven by risk of activities rather than by whether they are conducted on or off a farm.

(Response 99) Consistent with the statutory direction in section 103(c) of FSMA, including conducting a qualitative risk assessment, we have finalized exemptions for on-farm activity/animal food combinations conducted by farm-mixed-type facilities that are small or very small businesses as discussed further in sections VI and X.

**B. Proposed § 507.5(a)—Exemption for Facilities Not Required To Register Under Section 415 Regulations**

We proposed that this part does not apply to establishments, including “farms” (as defined in § 1.227 of this

chapter), that are not required to register under section 415 of the FD&C Act. However, we proposed that subpart B would apply to the packaging, packing, and holding of dried commodities if a “farm” or “farm mixed-type facility” dries/dehydrates raw agricultural commodities that are produce to create a distinct commodity.

After reviewing all of the comments concerning raw agricultural commodities as discussed elsewhere in this final rule, we have removed the requirement that subpart B would apply to the packaging, packing, and holding of dried commodities from a “farm” or “farm mixed-type facility” that dries/dehydrates RACs that are produce to create a distinct commodity. We have made this change because produce RACs are not typically dried or dehydrated to create distinct animal food commodities, as they are to create human food commodities (e.g., drying/dehydrating grapes to make raisins).

(Comment 100) One comment requests that we provide clarity and examples for animal food facilities that are exempt from facility registration and therefore exempt from compliance with part 507 because they are considered restaurants or retail food establishments.

(Response 100) Our food facility registration requirements are found in 21 CFR part 1, subpart H. Specifically, “restaurant” and “retail food establishment” are defined in 1.227(b). Additional information may be found in our “Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)” (Ref. 23). As discussed in section I.E. of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**, we are addressing the requirements of section 102(c) of FSMA in a separate rulemaking and issued a separate proposed rule to amend the definition of “retail food establishment” in the section 415 registration regulations and the section 414 recordkeeping regulations (80 FR 19160, April 9, 2015).

*C. Proposed § 507.5(b)—Exemption Applicable to Food Subject to 21 CFR Part 113—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers*

We proposed that activities in animal food facilities that are regulated under and are in compliance with § 500.23 and part 113 would be exempt from subpart C only with respect to microbiological hazards regulated under part 113. We further proposed that the facilities must comply with subparts C and F with regard to all other potential hazards and must comply with subparts A and B. We

requested comment on the criteria that should be used to determine whether a facility is in compliance with § 500.23 and part 113 (78 FR 64736 at 64762).

(Comment 101) Some comments express concern that the partial exemption for products subject to part 113 could generate confusion for both regulators and regulated facilities. These comments also assert that the partial exemption for products subject to part 113 would generate duplicative recordkeeping requirements under the two rules.

(Response 101) We acknowledge the potential for confusion and expect any confusion to decrease over time as both regulators and facilities gain experience with the new requirements. We also expect that in most instances a facility that is subject to § 500.23 and part 113, and that evaluates potential microbiological hazards as part of its hazard analysis, would conclude that the potential hazards are controlled by the targeted requirements of part 113 and conclude there are no significant microbiological hazards that require preventive controls to significantly minimize or prevent the hazards.

We disagree that the partial exemption for products subject to part 113 would generate duplicative recordkeeping requirements. The requirements of part 113 to control biological hazards are different from the requirements of subparts C and E to conduct a hazard evaluation for chemical and physical hazards, and implement preventive controls and associated preventive control management components to address significant chemical and physical hazards. Likewise, the records associated with the control of biological hazards under part 113 are not the same as the records associated with a hazard analysis, preventive controls, and associated preventive control management components for control of chemical and physical hazards. However, to the extent that a facility determines that existing records required by part 113 can be used to comply with the requirements of subparts C and E, a facility may rely on those records (see § 507.212).

(Comment 102) Some comments ask us to provide guidance to industry and the regulatory community regarding the criteria that will be used to determine when a facility is “in compliance with” part 113.

(Response 102) As an example, an LACF manufacturing facility that has ongoing problems controlling biological hazards may be better able to address biological hazards by preparing and implementing a written food safety

plan. As with facilities subject to our HACCP regulations, we expect that situations in which enforcement actions to ensure compliance with part 113 are insufficient to correct problems, and lead to a facility losing its exemption from the requirements of subparts C and E, will be rare and will depend on very specific circumstances. Therefore, at this time we do not anticipate issuing guidance on when violations of part 113 could lead to this outcome.

*D. Proposed § 507.5(c)—Exemption Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act*

We proposed that subpart C would not apply to activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety) of the FD&C Act (21 U.S.C. 350h).

(Comment 103) Some comments request that we broaden the exemption to operations that handle culls of raw, intact, fresh produce. One comment requested that fresh citrus be considered a low risk product or excluded from the rule entirely. This comment requested that culls should not be considered a by-product of fresh citrus production.

(Response 103) We decline these requests. We have included a provision under § 507.12 that exempts by-products of off-farm packing and holding of RACs for animal food use from most of part 507 if “the human food facility is subject to and in compliance with § 117.8 of part 117, and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.” The human food facility also must not further manufacture or process the by-products intended for use as animal food. The resulting animal food must be held and distributed in accordance with the CGMPs for the holding and distribution of human food by-products for use as animal food in § 507.28 and § 117.95. Thus, facilities subject to and in compliance with § 117.8 and applicable safety requirements of the FD&C Act and its implementing regulations, that pack or hold produce culls off-farm for use as animal food (without manufacturing or processing the culls) would be exempt from part 507, except for the limited holding and distribution CGMPs in § 507.28. Facilities that manufacture or process culls of raw, intact, fresh produce for use as animal food would be subject to part 507. Activities, such as packing fresh citrus, of a facility that is subject to section 419 of the FD&C Act are exempt from subparts C.

*E. Proposed § 507.5(d)—Exemption Applicable to a Qualified Facility*

We proposed that subpart C would not apply to a qualified facility, except as provided by subpart D (Withdrawal of an Exemption Applicable to a Qualified Facility), and that qualified facilities would be subject to the requirements in § 507.7.

(Comment 104) Some comments support the proposed exemption for a qualified facility. Other comments oppose this proposed exemption, asserting that it is not risk based and expressing concern that qualified facilities would cause significant food safety problems. Some comments ask us to strictly construct and narrowly apply the exemptions to as few businesses as possible.

Some comments do not agree that qualified facilities should be subject to modified requirements because even the modified requirements are burdensome. Some comments assert that qualified facilities having an average annual value of animal food sold during the previous 3-year period of \$10,000 or less should be exempt from all requirements related to hazard analysis and risk-based preventive controls, including modified requirements. One comment does not specify an amount of annual sales of animal food, but states that whether a facility is a qualified facility should be based on whether the facility has caused any reported injury or illness to humans or animals.

(Response 104) The exemption for qualified facilities, including the criteria for being a qualified facility and the applicability of modified requirements, is expressly directed by section 418(l) of the FD&C Act. In defining “very small business” to mean a business (including any subsidiaries or affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale), we constructed this exemption to apply to businesses that, collectively, produce less than 2 percent of the dollar value of animal food produced in the United States. This is comparable to the percentage of the human food supply that is exempt under the definition of very small business for human food (see section XI.B of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**). As previously discussed in section VIII.A.36, the businesses that will be exempt from the

requirements for hazard analysis and risk-based preventive controls, and will instead be subject to other requirements, will produce a small portion of the animal food at potential risk of causing foodborne illness (see the discussion at 79 FR 58476 at 58502).

(Comment 105) Some comments assert that a qualified facility should be exempt from the CGMP requirements of subpart B, as well as the requirements for hazard analysis and risk-based preventive controls in subpart C.

(Response 105) The exemption for qualified facilities is expressly directed by section 418(l) of the FD&C Act and is limited to an exemption from the requirements for hazard analysis and risk-based preventive controls in subparts C and E. The comments provide no basis for why new statutory requirements for hazard analysis and risk-based preventive controls should in any way impact CGMP requirements that apply to the manufacturing, processing, packing, and holding of animal food. CGMPs provide the basic requirements for ensuring production of safe animal food. Following the CGMPs is essential to properly address public (human and animal) health risks from very small facilities that are provided an exemption from subparts C and E in order to minimize the burden on such facilities.

(Comment 106) Some comments ask us to provide that a qualified facility may voluntarily choose to comply with the requirements for hazard analysis and preventive controls.

(Response 106) A qualified facility may voluntarily choose to comply with the requirements for hazard analysis and risk-based preventive controls without a specific provision authorizing it to do so. One way that a qualified facility could comply voluntarily would be to simply not submit the attestation that it is a qualified facility (see § 507.7(b) for the requirement for a qualified facility to submit an attestation regarding its status as a qualified facility). When we inspect the facility, we would inspect the facility for compliance with the requirements for hazard analysis and risk-based preventive controls. Another way for a facility to voluntarily comply would be to submit the attestation, and specify that it will satisfy the statutory documentation requirement through documentation of its food safety practices rather than documentation that it is in compliance with non-Federal food safety law.

(Comment 107) Some comments ask us to specify in guidance that a qualified facility is not required to prepare and implement a food safety plan.

(Response 107) We intend to recommend in guidance how a qualified facility could comply with the requirements in § 507.7 without satisfying all of the requirements in subparts C and E.

*F. Proposed § 507.5(e) and (f)—Exemptions Applicable to On-Farm Low-Risk Activity/Animal Food Combinations Conducted by a Small or Very Small Business*

As discussed in section VI.A, consistent with the statutory direction in section 103(c) of FSMA, including conducting a qualitative risk assessment, we proposed three exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very small businesses (proposed §§ 507.5(e), (f)(1), and (f)(2)).

1. General Comments on the Proposed Exemptions Applicable to On-Farm Low-Risk Activity/Animal Food Combinations Conducted by a Small or Very Small Business

(Comment 108) Some comments assert that conducting a low-risk activity/food combination should be sufficient to qualify any facility for exemption from subpart C, regardless of whether the activity is conducted on-farm or off-farm, or meets the economic threshold for a small or very small business.

(Response 108) The statute provides specific direction for those facilities that can qualify for this exemption. (See sections 418(l) and 418(o)(2) of the FD&C Act.) See also Response 104 in this final rule, and Responses 220 and 222 in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

(Comment 109) Some comments state that the exemptions for farming activities are confusing.

(Response 109) The activity/animal food combinations listed in § 507.5(e) are directed to an exemption for packing and holding activities, whereas the activity/animal food combinations listed in § 507.5(f) are directed to an exemption for manufacturing/processing activities. Although these exemptions are more complex than other exemptions (e.g., because they are directed to specific activities conducted on specific animal foods), the final “farm” definition has simplified them to the extent practicable. For example, under the “farm” definition in the 2013 proposed human preventive controls rule, whether an activity was packing or manufacturing/processing depended, in part, on whether the RACs being packed

were the farm's own RACs or others' RACs. In contrast, under the "farm" definition established in the final rule for preventive controls for human food published elsewhere in this **Federal Register**, packing RACs is a "packing" activity, regardless of ownership of the RACs being packed.

(Comment 110) Some comments note a distinction between the exemptions for on-farm low-risk activity/animal food combinations conducted by small and very small businesses and the exemption for qualified facilities. Specifically, the comments state that a farm mixed-type facility that only conducts low-risk activity/animal food combinations (such as grinding grains) would be exempt from the requirements of subpart C, whereas an off-farm qualified facility grinding grains, while exempt from the requirements of subpart C, would nonetheless be subject to the requirements for a qualified facility in § 507.7. These comments ask whether it would be better for a farm or farm mixed-type facility that satisfies criteria for a small or very small business, and also satisfies criteria for a qualified facility, to classify itself as a small or very small business or to classify itself as a qualified facility.

(Response 110) In light of the final "farm" definition, these comments no longer apply with respect to activities within the farm definition.

For activities conducted by a farm mixed-type facility, we acknowledge that the exemptions provided by § 507.5(e) and (f) for on-farm low-risk activity/animal food combinations are different from the exemption provided by § 507.5(a) for a qualified facility. A farm mixed-type facility that only conducts low-risk activity/animal food combinations listed in § 507.5(e) and (f) is fully exempt from the requirements of subparts C and E, and is not subject to the requirements for a qualified facility in § 507.7, even if that farm mixed-type facility is also a very small business (and, thus, also is a qualified facility). To make this clear, we have revised proposed § 507.5(e) to specify that § 507.7 does not apply to on-farm packing or holding of animal food by a very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk packing or holding activity/animal food combinations. Likewise, we have revised proposed § 507.5(f) to specify that § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the FD&C Act

that the business conducts are the listed low-risk manufacturing/processing activity/animal food combinations.

With these changes, a farm mixed-type facility that is a very small business and that only conducts the low-risk activity/animal food combinations listed in § 507.5(e) and/or (f) may find it advantageous to classify itself as a very small business eligible for the exemption in § 507.5(e) and/or (f) rather than as a qualified facility, which would be subject to the requirements in § 507.7.

(Comment 111) Some comments ask for a process to keep the list of low-risk activity/food combinations up to date, such as through guidance.

(Response 111) We decline this request. The exemptions established in this rule are binding, whereas any list of additional activity/animal food combinations established in a guidance document would not be binding. We established the list of activity/animal food combinations included in these exemptions through an extensive public process, including a request for comments on the section 103(c)(1)(C) draft RA. From this time forward, the process available to a person who wishes us to consider an additional activity/animal food combination is to submit a citizen petition in accordance with 21 CFR 10.30.

### 2. Proposed § 507.5(e)—Exemption Applicable to On-Farm Low-Risk Packing or Holding Activity/Animal Food Combinations Conducted by a Small or Very Small Business

We proposed that subpart C would not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership.

(Comment 112) Many comments state that it is common practice among farms to hold RACs from farms under different ownership and that classifying establishments as being within the "farm" definition, or outside the "farm" definition, based on who owns the RACs being packed is not a risk-based classification.

(Response 112) We proposed a revised definition of "farm" in the 2014 preventive controls supplemental notice for human food to include packing and holding of RACs grown on another farm not under the same ownership (79 FR 58524 at 58531 through 58532). As a

consequential change in light of the final "farm" definition established in the final rule for preventive controls for human food published elsewhere in this **Federal Register**, the exemption no longer identifies any packing or holding activities for any RACs (whether the farm's own RACs or others' RACs), because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls (subpart C) when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others' RACs. In light of the change in the "farm" definition, we have revised the section 103(c)(1)(C) RA, starting with the list of on-farm activity/animal food combinations outside the farm definition in table 1, to exclude packing and holding of RACs.

### 3. Proposed § 507.5(f)—Exemption Applicable to On-Farm Low-Risk Manufacturing/Processing Activity/Animal Food Combinations Conducted by a Small or Very Small Business

We proposed that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are those listed in the proposed exemption. The proposed exemption specified those activity/animal food combinations that would be exempt when conducted on a farm mixed-type facility's own RACs and those activity/animal food combinations that would be exempt when conducted on animal food other than the farm mixed-type facility's own RACs for distribution into commerce.

As a consequential change in light of the final "farm" definition, the final exemption no longer distinguishes between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on animal food other than the farm mixed-type facility's own RACs. As another consequential change, the exemption has been revised to eliminate activities, conducted on others' RACs, which no longer are classified as manufacturing/processing and instead are classified as harvesting, packing, or holding. In addition, we have revised the final exemption to list animal food categories consistent with the animal food categories included in table 1 in the section 103(c)(1)(C) RA (Ref. 3), modified in response to revisions of the "farm" definition. (See Response 112.) In constructing

categories of animal food based upon the new “farm” definition, we grouped together processed grain products (e.g., flour, grits, etc.) and grain by-products (e.g., brewers’ grain, distillers’ grain, and corn gluten meal). The category does not include culled products from processing grain for human food such as misshapen pasta. Pasta used in animal food falls under a new category (any other animal food that does not require time/temperature control for safety) that was added to include the wide range of possibilities for animal food that was originally processed to be human food, as well as other types of animal food not listed separately.

(Comment 113) Some comments ask us to include in the exemption a single list of low-risk manufacturing/processing activity/food combinations applicable to farm mixed-type facilities conducting activities on their own RACs and farm mixed-type facilities conducting activities on other’s RACs.

(Response 113) These comments no longer apply. As a consequence of the “farm” definition established by the final rule for preventive controls for human food published elsewhere in this **Federal Register**, the exemption no longer distinguishes between manufacturing/processing activities conducted on a farm mixed-type facility’s own RACs and manufacturing/processing activities conducted on animal food other than the farm mixed-type facility’s own RACs.

(Comment 114) Some comments ask us to include manufacturing of animal food from low risk ingredients as additional activity/animal food combinations in the exemption. Other comments support our conclusion that manufacturing animal food ready for consumption is not a low risk activity.

(Response 114) We evaluated manufacturing of animal food as one of the activity/animal food combinations within the qualitative risk assessment (Ref. 3). The 103(c)(1)(C) RA explains why we determined that manufacturing animal food ready for consumption is not a low-risk activity/animal food combination.

*G. Proposed § 507.5(g)—Exemption Applicable to Facilities Solely Engaged in Storage of Raw Agricultural Commodities Other Than Fruits and Vegetables Intended for Further Distribution or Processing*

We proposed that subpart C would not apply to facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. In the following paragraphs, we discuss comments that ask us to clarify how the

proposed exemption would apply to specific circumstances.

(Comment 115) Some comments ask whether this proposed exemption (proposed § 507.5(g)) would apply to facilities such as peanut buying points or bean elevators and assert that such commodities are analogous to grains and the activities conducted at such facilities are analogous to those performed by grain elevators.

(Response 115) We classify peanuts and beans (such as kidney beans, lima beans, and pinto beans) within the category of “fruits and vegetables”; we classify soybeans as grain (see the discussion of grains at 78 FR 64736 at 64764 and 79 FR 58476 at 5848, and fruits and vegetables at 78 FR 3646 at 3690 and proposed §§ 112.1 and 112.2 in the proposed produce safety rule). The exemption for facilities solely engaged in storage of RACs intended for further distribution or processing does not apply to facilities that store fruit and vegetable RACs and, thus, does not apply to facilities such as peanut buying points and bean elevators. As discussed in section IV.B, we have revised the “farm” definition to provide that an operation devoted only to the harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition, provided that the farms that grow or raise the majority of the RACs harvested, packed, and/or held by the operation own, or jointly own, a majority interest in the operation. With this revision, some operations dedicated to holding RACs, including fruit and vegetable RACs, will be within the “farm” definition.

Peanut buying points and bean elevators that do not meet the revised farm definition are storing RACs that are “fruits and vegetables” and do not meet the criteria for exemption under § 507.5(g). However, we would not expect such facilities to need an extensive food safety plan. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

(Comment 116) One comment states that genetically modified food should be added to the list of hazards that are seen as potential risks for animals.

(Response 116) We decline this request. We have not seen evidence that foods derived from genetically engineered plants differ from other foods in any meaningful or uniform way, or that, as a class, such foods present different or greater safety

concerns than their non-genetically engineered counterparts. We have a voluntary consultation process for foods derived from genetically engineered plants through which we engage with the developers of genetically engineered plants to help ensure the safety of the derived foods. Foods that have undergone this consultation process are as safe as foods from conventionally bred plants. Foods derived from genetically engineered plants, irrespective of the method of development, are subject to the same food safety and other regulatory requirements as foods derived from conventionally-bred plants. Therefore genetically engineered foods do not need to be singled out as a hazard.

(Comment 117) Some comments assert that the exemption for storage of raw agricultural commodities (other than fruits and vegetables) should extend to those distinct and physically separate portions of oilseed processing facilities that are devoted solely to RAC storage. According to these comments, in the overwhelming majority of cases the inclusion of a separate RAC storage area in the same building as the oilseed processing area will not introduce additional risk either to the processing area or to the operations that take place there and that storage areas, whether standing alone as a separate facility or incorporated into a larger processing facility, store RACs safely. These comments ask us to recognize that storage activities may include grain drying to standardize moisture levels and preserve product quality.

(Response 117) The activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs. In the 2014 supplemental notice, we explained that facilities that conduct operations similar to those conducted at grain elevators and silos, such as some facilities that hold oilseeds, may satisfy the criteria for exemption if activities other than storage are performed as a practical necessity for the distribution of RACs (see 79 FR 58476 at 58483 and the definition of “holding” in § 507.3). Examples of holding activities include drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (see § 507.3). Thus, the specific example of drying grains to standardize moisture levels and preserve product quality would fall within the definition of holding as a practical necessity for the distribution of RACs. A facility that stores oilseeds, and dries them as a practical necessity for the distribution of RACs, would be covered by the exemption in § 507.5(g).



However, we decline the request to modify the exemption in § 507.5(g) to also apply to distinct and physically separate storage areas that are used solely for storage of RACs (other than fruits and vegetables) intended for further distribution or processing. To the extent that the comments are asking us to do so to provide for facilities that conduct activities as a practical necessity for the distribution of RACs to be eligible for the exemption, doing so is not necessary in light of the definition of holding. To the extent that the comments are asking us to do so to provide for facilities that conduct manufacturing/processing activities in addition to holding activities, we disagree that doing so would be consistent with the statutory direction in FSMA. As previously discussed, section 418(m) of the FD&C Act provides in relevant part that we may by regulation exempt or modify the requirements for compliance under section 418 of the FD&C Act with respect to facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (78 FR 64736 at 64764). The plain meaning of “solely” is only, completely, entirely; without another or others; singly; alone (Ref. 24). Facilities that conduct manufacturing/processing activities in addition to holding activities are not “solely” engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution and processing.

(Comment 118) Some comments request that the language of § 507.5(g) explicitly state that the exemption from subpart C would apply to facilities that are solely engaged in the packing and holding of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. These comments indicate that packing is frequently involved when a facility distributes raw agricultural commodities that they have been holding. They cite the § 110.19(a) exemption from the human food CGMP regulation for establishments “engaged solely in the harvesting, storage, or distribution of one or more ‘raw agricultural commodities’” and remark that in application of the regulation, the activity of packing has been encompassed within the term “distribution.” In addition, some comments ask that the exemption proposed in § 507.5(g) be extended to an exemption from subpart B, as well as from subpart C.

(Response 118) We decline the request to add the term “packing” to § 507.5(g). As discussed in Response

117, the activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs. Under § 507.5(h), subpart B does not apply to the holding or transportation of one or more RACs. (See section X.H.)

*H. Proposed § 507.5(h)—Exemption Applicable to the Holding or Transportation of One or More Raw Agricultural Commodities*

We proposed to provide that subpart B would not apply to the holding or transportation of one or more RACs as defined in section 201(r) of the FD&C Act.

(Comment 119) Some comments ask us to include the term “packing” in § 507.5(h) to say “Subpart B of this part does not apply to the packing and holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.”

(Response 119) We decline the request to add the term “packing” to § 507.5(h). As discussed in Response 117, the activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs.

(Comment 120) Some comments ask us to clarify that CGMP requirements (such as using protective coverings where necessary and appropriate (§ 507.17(c))) do not apply to the bulk outdoor storage of RACs for further processing.

(Response 120) We are returning to the longstanding approach that the exemption applies to establishments “solely engaged” in specific activities. Under the exemption we are establishing in § 507.5(h)(1), those activities are holding and transportation of RACs. We explain why in the following paragraphs.

These comments appear to interpret the proposed exemption in a way that goes beyond the longstanding “RAC exemption” in the human food CGMPs in § 110.19 and is inconsistent with the intent in updating § 110.19 to adjust and clarify what activities fall within this exemption based on experience and changes in related areas of the law since issuance of this exemption from the CGMPs (78 FR 64736 at 64764 and 78 FR 3646 at 3710). The suggestion of these comments, *i.e.*, that CGMPs should not apply to the holding of RACs in a facility that manufactures, processes, or packs RACs—would not make sense in some circumstances and would create complex situations for establishments (in determining how to comply with the CGMP requirements) and for regulators (in determining how

to enforce the CGMP requirements). For example, it does not make sense for the part of a facility that holds RACs prior to processing to be exempt and the parts of the facility that are processing the RACs and storing them after processing to be covered. Likewise, it does not make sense for part of a transportation vehicle to be covered and part to be exempt.

By revising the proposed “RAC exemption” so that it applies only to establishments “solely engaged” in the storage or transportation of RACs, we are providing for a predictable framework for interpreting exemptions for facilities “solely engaged” in other activities. For example, as discussed in Comment 117, comments ask us to expand the exemption (in § 507.5(g)) from the requirements for hazard analysis and risk-based preventive controls for facilities that are “solely engaged” in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing to also apply to distinct and physically separate storage areas that are used solely for storage of such RACs. In our response, we noted that facilities that conduct manufacturing/processing activities in addition to holding activities are not “solely engaged” in the storage of such RACs (see Response 117). In addition, as discussed in Comment 146, comments ask us to apply the exemption (in § 507.10) from the requirements for hazard analysis and risk-based preventive controls for facilities that are “solely engaged” in the storage of unexposed packaged food to storage areas of facilities that also engage in food processing activities, *e.g.*, for distributors that are engaged in limited food processing, such as blending seeds to make bird food. In our response, we noted that such distributors are not “solely” engaged in the storage of unexposed packaged animal food (see Response 146).

The exemption we are establishing in this rule for establishments solely engaged in the storage or transportation of RACs remains consistent with our announced intent to adjust and clarify what activities fall within this exemption based, in part, on changes in related areas of the law since this exemption from the CGMP requirements was first issued. As discussed in section IV of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, we have made a number of changes to the “farm” definition, including changes that provide for an operation devoted to harvesting, packing, and/or holding of RACs to be a “farm” (*i.e.*, a “secondary activities

farm”) (and, thus, be exempt from the CGMP requirements under § 507.5(a)) even though the operation does not grow RACs (see § 507.3). With this revised “farm” definition, some establishments solely engaged in the “storage” of RACs will be exempt from the CGMP requirements because they are a “farm.” For further discussion on this provision, see section XI.J in the final rule for preventive controls for human food.

### *I. Comments Requesting Additional Exemptions*

(Comment 121) Some comments request additional exemptions from the requirements for hazard analysis and risk-based preventive controls in subpart C, the CGMP requirements of subpart B, or both.

(Response 121) We believe that our CGMP regulations, coupled with implementation of FSMA’s directives to focus more on preventing food safety problems than on reacting to problems after they occur, will play an important role in increasing animal food safety. We did not propose any exemptions or exceptions from the requirements of subpart C other than those authorized by section 103 of FSMA (78 FR 64736 at 64743 through 64744). We drew on our experience with the CGMP regulation for human food and changes in related areas of the FD&C Act since issuance of the CGMP regulation (78 FR 3646 at 3709 through 3711) to adjust and clarify what activities fall within a longstanding exclusion related to raw agricultural commodities (see § 110.19) and to modify the CGMPs for human food by-products for use as food for animals.

(Comment 122) Some comments state that facilities that hull, shell, and dry tree nuts without further processing could be characterized as establishments engaged solely engaged in the harvesting, storage, or distribution of one or more raw agricultural commodities. These comments express an expectation that since hulled or shelled dried nuts retain their raw agricultural commodity status, that facilities hulling, shelling and drying tree nuts without further processing would qualify for exemption under both proposed §§ 507.5(g) and 507.5(h).

(Response 122) Hulling and shelling of tree nuts (such as walnuts, almonds, and pistachios) are harvesting activities that are within the “farm” definition when conducted on a farm or farm mixed-type facility. Drying/dehydrating RACs without creating a distinct commodity (such as drying walnuts and hulls) is a holding activity that also is

within the “farm” definition when conducted on a farm or farm mixed-type facility. As discussed in section IV.B of the final rule for preventive controls for human food (published elsewhere in this issue of the **Federal Register**) we have revised the “farm” definition to provide that an operation, not conducted on a Primary Production Farm, devoted to the harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition (as a “secondary activities farm”), provided that the primary production farm(s) that grow or raise the majority of the RACs harvested, packed, and/or held by the secondary activities farm own, or jointly own, a majority interest in the operation. Non-farm facilities dedicated to the hulling, shelling, and drying of nuts and hulls perform the same activities as those performed by farms. When done on a primary production farm or by a secondary activities farm, those activities would not be subject to CGMPs. Furthermore, these activities do not transform the RAC into a processed food. Therefore, we have added regulatory text in § 507.5(h) to provide an exemption from subpart B for hulling, shelling, and drying nuts and hulls (without further manufacturing/processing) by a non-farm hulling/shelling/drying facility because of the similarity in the activities of a farm-owned operation and a non-farm owned facility. However, non-farm facilities are not exempt from subparts C and E under § 507.5(g) as they are not solely engaged in the storage of raw agricultural commodities. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

(Comment 123) Some comments state that ginning cotton to separate cotton fiber from cotton seed is a low-risk harvesting activity. Comments further note that since cotton seed used as animal food is a by-product from the production of cotton lint, the cotton seed coming from a ginning facility would not qualify as a human food by-product. The comments request that facilities whose entire operation consists of receiving and ginning cotton without further processing the cotton seeds be exempt from both subpart C under § 507.5(g) and subpart B under § 507.5(h).

(Response 123) Ginning cotton is a harvesting activity that is within the “farm” definition when conducted on a

farm or farm mixed-type facility. Drying/dehydrating the cottonseed without further processing is a holding activity that also is within the “farm” definition when conducted on a farm or farm mixed-type facility. (See Response 122 for a discussion on modification to the farm definition). When done on a primary production farm or by a secondary activities farm, these activities (ginning, drying, dehydrating) would not be subject to CGMPs, and these activities do not transform the RAC into a processed food. Therefore, we have added regulatory text in § 507.5(h)(2) to provide an exemption from subpart B for the ginning of cotton (without further manufacturing/processing) by a non-farm cotton ginning facility because of the similarity between a farm-owned operation and a non-farm owned facility (See Response 122). However, non-farm facilities are not exempt from subparts C and E under § 507.5(g) as they are not solely engaged in the storage of raw agricultural commodities. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

### **XI. Subpart A: Comments on Proposed § 507.7—Requirements That Apply to a Qualified Facility**

As previously discussed (78 FR 64736 at 64765), sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility must submit two types of documentation to us. The first type of required documentation relates to food safety practices at the facility, with two options for satisfying this documentation requirement. Under the first option, the qualified facility may choose to submit documentation that demonstrates that it has identified potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under the second option, the qualified facility may choose to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law. The second type of required

documentation relates to whether the facility satisfies the definition of a qualified facility.

If a qualified facility does not prepare documentation demonstrating that it has identified potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective, it must provide notification to consumers of certain facility information by one of two procedures, depending on whether an animal food packaging label is required on the animal food.

Consistent with the statutory direction of section 418(l) of the FD&C Act, we proposed the following requirements for qualified facilities: (1) Submission of certain documentation (proposed § 507.7(a)); (2) procedures for submission of the documentation (proposed § 507.7(b)); (3) the frequency of the submissions (proposed § 507.7(c)); (4) notification to consumers in certain circumstances (proposed § 507.7(d)); and (5) applicable records

that a qualified facility must maintain (proposed § 507.7(e)).

In the 2013 proposed preventive controls rule for animal food, we tentatively concluded that a certified statement would be acceptable for the purposes of satisfying the submission requirements of proposed § 507.7(a). We also requested comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility.

Some comments support one or more of the proposed requirements without change. For example, some comments state that our proposed interpretation of the statutory term “business address” is consistent with our use of the term “business address” in our regulations regarding information that must be included in a prior notice for imported food (§ 1.281). Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In this section, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. We also address comments discussing our tentative conclusion regarding the submission of certified statements to FDA, including submitting certified statements using the existing mechanism for registration of food facilities. After considering these comments, we have revised the proposed requirements as shown in table 7 with editorial and conforming changes as shown in table 31.

As discussed in Response 76, we have revised the definition of very small business to specify that it is based on an average (of sales plus market value of animal food held without sale) during the 3-year period preceding the applicable calendar year and, as a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis (see § 507.7(c)(1)).

TABLE 7—REVISIONS TO THE PROPOSED REQUIREMENTS FOR QUALIFIED FACILITIES

Section	Description	Revision
507.7(a)	Documentation to be submitted.	<ul style="list-style-type: none"> <li>Specify that the submitted documentation is an “attestation.”</li> <li>Add “tribal” as an example of applicable non-Federal food safety law.</li> </ul>
507.7(b)	Procedure for submission.	Update details regarding the electronic and paper submission of a form specific to the attestation requirement.
507.7(c)	Frequency of determination and submission.	<ul style="list-style-type: none"> <li>New requirement to determine and document status as a qualified facility on an annual basis no later than July 1 of each calendar year.</li> <li>Specify that a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019 must submit the attestation before beginning such operations.</li> <li>Specify that a facility must notify FDA of a change in status from “not a qualified facility” to “qualified facility” by July 31 of the applicable calendar year.</li> <li>Specify that when the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.</li> <li>Specify that the required biennial submissions of the attestations must be made during a timeframe that will coincide with the required biennial updates to facility registration.</li> </ul>
507.7(d)	Timeframe for compliance with the requirements of subparts C and E.	When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and E no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.
507.7(e)	Notification to consumers.	Conforming changes associated with the term “attestation.”
507.7(f)	Records	Conforming changes associated with the term “attestation.”

*A. Comments on Submission of a Certification Statement*

(Comment 124) Some comments ask us to clarify the distinction between the documentation that would be submitted to FDA and the records that a qualified facility relies on to support the submitted documentation.

Some comments agree with our tentative conclusion to use certified statements to satisfy the proposed

submission requirements, noting that it would save time and money and reduce the paperwork burden on qualified facilities. Some comments ask us to revise the proposed requirements to make this use of certified statements explicit in the regulatory text.

Other comments disagree with our tentative conclusion to use certified statements to satisfy the submission requirements. These comments focus on the importance of actual copies of

documents in determining compliance with the documentation requirements and assert that proof of qualification requires more than a checked box in an online registration database. Some comments ask us to require that a qualified facility affirm that it has the original documents on file and available for FDA inspection. Other comments assert that requiring qualified facilities to submit copies of the actual documentation would enable us to

easily review food safety plans or inspection reports and to target our compliance and enforcement activities to those qualified facilities that pose a greater risk because of inadequate prevention measures or deficient inspections.

(Response 124) We are affirming our tentative decision that we will not require a qualified facility to submit to FDA as part of its attestation the underlying documentation that establishes its compliance. We agree that the underlying records are needed to determine compliance with the documentation requirements and that a qualified facility must retain the documents it is relying on to support its attestation and make them available to us during inspection. We also agree that the regulatory text needs to be explicit regarding the required documentation and that we need to clearly distinguish between the documentation that would be submitted to FDA and the records that a qualified facility relies on to support the submitted documentation. Therefore, we have made the following three revisions to the proposed regulatory text.

First, we have revised proposed § 507.7(a) to specify that the submitted documentation is an “attestation.” Second, we have revised proposed § 507.7(b) to update details regarding the electronic and paper submission of a form specific to this attestation requirement. Third, we have revised proposed § 507.7(e) (final § 507.7(f)) to specify that you must maintain those records relied upon to support the “attestations” that are required by § 507.7(a).

We acknowledge that requiring submission of the actual documentation would enable us to easily review food safety plans or inspection reports and to target our compliance activities based on information that we see in those food safety plans or inspection reports. However, as discussed in Response 245, we are not requiring that other facilities submit a “facility profile” that would allow us to more broadly review food safety plans and target our compliance activities based on information that we see in those food safety plans and will instead explore other mechanisms to achieve the goals we described in the 2013 proposed preventive controls rule for animal food for a facility profile.

#### *B. General Comments on Requirements That Apply to a Qualified Facility*

(Comment 125) Some comments assert that the proposed requirements would create a costly burden for qualified facilities (e.g., registering and making submissions to FDA) that would

not be imposed on other types of exempted facilities. Some of these comments question whether the exemption for qualified facilities is meaningful in light of the significant burden imposed by the proposed requirements. Some comments contrast the proposed requirement for qualified facilities to submit documentation to FDA with proposed requirements for all other facilities to simply establish and maintain applicable records.

(Response 125) The submission requirements that we are establishing in this rule for qualified facilities reflect the statutory framework for qualified facilities (section 418(l)(2)(B) of the FD&C Act). Although the submission requirements only apply to qualified facilities, the reporting burden associated with submission of an attestation is much lower than the recordkeeping burden for facilities that are subject to the requirements for hazard analysis and risk-based preventive controls (see section LVIII).

(Comment 126) Some comments ask us to minimize setting different standards even though the requirements reflect express statutory provisions.

(Response 126) These comments appear to be referring to the statutory provisions of section 418(n)(3)(C) of the FD&C Act, which specify that the regulations we establish to implement section 418 of the FD&C Act acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods. We disagree that the statutory provisions of section 418(n)(3)(C) are directly relevant to the submission requirements of this rule for qualified facilities. The requirements for qualified facilities, but not other facilities, to submit documentation to FDA reflect different regulatory requirements. The different regulatory requirements are directed at different facilities, and do not set separate standards for particular animal foods. Regardless, even if the statutory provisions of section 418(n)(3)(C) were relevant to the submission requirements of qualified facilities, provisions of this rule that reflect express statutory provisions would not conflict with the statutory direction in section 418(n)(3)(C).

(Comment 127) Some comments emphasize that the requirements need to ensure adequate protection of public health and state that we should maintain and exercise oversight of qualified facilities. Some comments ask that we provide enough specificity so that qualified facilities know and understand their food safety responsibilities towards consumers.

(Response 127) A facility that satisfies criteria to be a qualified facility continues to be responsible to produce animal food that will not be adulterated under section 402 of the FD&C Act. Such a facility is also subject to the requirements of section 421 of the FD&C Act regarding frequency of inspection of all facilities and to the new administrative tools provided by FSMA, such as for suspension of registration (section 415 of the FD&C Act) and for mandatory recall (section 423 of the FD&C Act). As discussed in Response 77, we expect that most qualified facilities will be subject to the CGMP requirements of subpart B. When they are inspected, we will be ensuring they are in compliance with the CGMP requirements once the applicable compliance date is reached.

(Comment 128) Some comments ask which exemption a farm mixed-type facility should follow if it satisfies criteria for a qualified facility (§ 507.5(d)), as well as criteria for a very small business that only conducts on-farm low-risk activity/animal food combinations (specified in § 507.5(e) and (f)) and one comment suggests that FDA should allow such a facility to choose which exemption to follow.

(Response 128) We describe these comments in more detail in Comment 110. A farm mixed-type facility that is a very small business and that only conducts the low-risk activity/animal food combinations listed in § 507.5(e) and (f) may find it advantageous to classify itself as a very small business eligible for the exemption in § 507.5(e) and (f) (which is not subject to the requirements in § 507.7) rather than as a qualified facility (which is subject to the requirements in § 507.7).

(Comment 129) Some comments express concern about State access to the records that a qualified facility maintains to support its attestations, particularly when a State would conduct an inspection for compliance with part 507 under contract to FDA. These comments express concern about the time and resources necessary to verify the status of a facility as a qualified facility and note that previous mechanisms whereby we provide information to States in advance of inspection have been slow. These comments also express concern that if the state must verify the “qualified facility” status of all firms, including those that are not FDA contracts, this could delay their ability to conduct timely inspections and increase inspection time, reducing the number of inspections conducted.

(Response 129) We are sensitive to the time required for various inspection

activities and intend to communicate with States regarding our expectations for how to verify whether a facility is a qualified facility.

(Comment 130) Some comments point out that the proposed procedures for submission are silent on the process and timeframe for our review and approval of the submitted documentation and ask us to clarify this process and timeframe. Other comments ask us to clarify the consequences to a facility if its submission is found to be insufficient.

(Response 130) We will not be approving the submitted attestations. Instead, we intend to use the information to determine whether the facility should be inspected for compliance with the requirements for hazard analysis and risk-based preventive controls, or for compliance with the requirements for a qualified facility. During the inspection, we would ask to see the records that the facility maintains to support any submitted attestations.

(Comment 131) Some comments ask us to clarify whether a foreign facility would need to submit documentation of its status as qualified facility. These comments note that a foreign facility also would be required to provide information to an importer and assert that submitting information to both FDA and an importer would be a duplication of effort. These comments ask us to allow a foreign facility that is a qualified facility to submit information to either FDA or the importer, rather than to both FDA and the importer.

(Response 131) We decline this request. Documentation submitted to an importer would not reach FDA and, thus, could not satisfy the requirements of this rule. We are requiring submission of an attestation, on a form that can be submitted either electronically or on paper, rather than submission of the underlying information.

### C. Proposed § 507.7(a)—Documentation To Be Submitted

#### 1. Section 507.7(b)(1)—Documentation That the Facility Is a Qualified Facility

We proposed that a qualified facility must submit documentation that the facility is a qualified facility. We also proposed that for the purpose of determining whether a facility satisfies the definition of a qualified facility, the baseline year for calculating the adjustment for inflation is 2011. As discussed in Response 124, we have revised the provision to specify that the documentation that must be submitted is an attestation.

(Comment 132) Some comments ask us to clarify the documentation required to certify that an operation is a qualified facility. Some comments ask us to explicitly state that the documentation must include financial and sales records of the business and its subsidiaries or affiliates. Some comments ask us to clarify the types of records that would be required to be submitted by foreign establishments to support the classification of a foreign establishment as a “qualified facility.”

(Response 132) The submission to FDA will be an attestation rather than the records that the qualified facility relies on to support the attestation; however, you must maintain those records relied upon to support the “attestations” (see § 507.7(f)). As previously discussed, consistent with section 418(l)(2)(B)(ii) of the FD&C Act, we intend to issue guidance on the records that a facility could retain to demonstrate that it is a qualified facility (78 FR 64736 at 64767). As discussed in Response 124, we have revised the regulatory text to provide for qualified facilities to submit an attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law. We intend to focus on records demonstrating that a facility is a very small business (*i.e.*, financial records demonstrating that a business averages less than \$2,500,000 adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale)) rather than records demonstrating that the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users during a 3-year period exceeded the average annual monetary value of the food sold by the facility to all other purchasers. We expect that financial records demonstrating that a business is a very small business will be less burdensome for a qualified facility to maintain and require fewer resources for FDA to review.

During an inspection, we expect the facility to be able to show us how the facility is complying with the applicable food safety regulation (including relevant licenses, inspection reports, certificates, permits, credentials, or certifications), and producing safe animal food.

(Comment 133) Some comments ask how the adjustment for inflation will be calculated and how regulators such as the states will get this information.

(Response 133) We intend to use the Federal calculation for the Gross Domestic Product price deflator, as provided by the Bureau of Economic Analysis, to adjust for inflation. We will make the inflation-adjusted dollar value to the baseline very small business cutoffs (*e.g.* \$2,500,000 in 2011) available on our Internet site. We will update the values for the very small business exemptions and qualifications annually using this calculation.

#### 2. Proposed § 507.7(a)(2)(i)—First Option for Documentation: Food Safety Practices.

We proposed two options for satisfying the statutory documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act. Under the first option (the food safety practices option), a qualified facility could submit documentation demonstrating that it has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective. As discussed in Response 124, we have revised the provision to specify that the submission is an attestation.

(Comment 134) Some comments assert that the rule is vague about what the applicable documentation should include and how exhaustive it should be. Some comments ask whether documentation (such as a food safety plan) must address all operations at the establishment or only those that trigger the registration of the establishment as a facility. Some comments ask us to clarify the difference between having documentation to support food safety practices and attesting that the facility has such documentation. Other comments ask whether a qualified facility would need to have records documenting a risk analysis and monitoring.

(Response 134) If a qualified facility submits an attestation regarding its food safety practices, the documentation that the facility maintains for review during inspection must specify that the facility has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective (see § 507.7(a)(2)(i)). For example, a qualified facility that produces raw dog food might have documentation specifying that it has determined that *Salmonella* is a hazard requiring a preventive control, describing the process that will

control *Salmonella*, describing sanitation controls to prevent contamination of raw dog food with *Salmonella*, and describing an environmental monitoring program to verify that its sanitation controls are effective. Likewise, a qualified facility that makes a custom cattle food might have documentation specifying that it has determined that metal objects are a hazard requiring a preventive control and supporting the use of a magnet to remove metal objects from the cattle food, with procedures for monitoring the magnet's use if applicable.

As discussed in Response 124, a qualified facility that chooses the food safety practices option for complying with the submission requirements of this rule will attest to that by checking a statement on a form. In contrast, a food safety plan (or other documentation) that the qualified facility relies on to support the attestation will be a record subject to the recordkeeping requirements of subpart F.

### 3. Proposed § 507.7(a)(2)(ii)—Second Option for Documentation: Compliance With Other Applicable Non-Federal Food Safety Law

Under the second option for satisfying the statutory documentation requirement, a qualified facility could submit documentation that it is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. As discussed in Response 124, we have revised the provision to specify that the submission is an attestation. We also have revised the provision to add "tribal" as an example of applicable non-Federal food safety law to clarify for purposes of this rule that a qualified facility could submit an attestation that it is in compliance with tribal food safety law.

(Comment 135) Some comments object to the proposed provision. These comments point out that State and local requirements are inconsistent and assert that such requirements are not sufficiently rigorous to substitute for the FSMA requirement to conduct a hazard analysis and establish and execute a documented food safety plan. One comment asserts that the state laws may not provide the same level of protection to consumers.

(Response 135) The provision reflects the express statutory direction of section 418(l)(2)(B)(i)(II) of the FD&C Act. Most of these qualified facilities are subject to the CGMP requirements of subpart B and a facility that satisfies criteria to be a qualified facility continues to be

responsible to produce animal food that will not be adulterated under section 402 of the FD&C Act.

(Comment 136) Some comments ask us to specify that a qualified facility must document compliance with all applicable non-Federal food safety laws. One comment asks what evaluation FDA will conduct of any non-Federal food safety law before determining that compliance with such law constitutes compliance under FSMA for a qualified facility.

(Response 136) We decline this request. Section 418(l)(2)(B)(i)(II) of the FD&C Act refers to apply to compliance with "State, local, county, or other applicable non-Federal food safety law" (emphasis added). As discussed in Response 132, we have revised the regulatory text to provide for qualified facilities to submit an attestation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law. During an inspection, we expect the facility to be able to show us how the facility is complying with the applicable food safety regulation (including relevant licenses, inspection reports, certificates, permits, credentials, or certifications), and producing safe animal food.

(Comment 137) Some comments ask us to provide resources to the States to implement the proposed provision. These comments also ask us to develop and implement a strategic plan to provide resources (e.g. training, guidance) to State and local inspection agencies in advance of the anticipated increased burden on State and local inspection programs that will be created by the provision.

(Response 137) We do not believe that specific training for State or other government counterparts is necessary for the purposes of inspecting a qualified facility that attested to having documentation from a non-Federal regulatory authority. The State or other government counterpart would merely examine applicable documentation (such as a license, inspection report, certificate, permit, credentials, or certification by an appropriate agency (such as a State department of agriculture)), which is specified in the provision. After inspecting such documentation, the State or other government counterpart would focus on inspection for compliance with CGMPs.

### D. Proposed § 507.7(b)—Procedure for Submission

We proposed that the documentation must be submitted to FDA either electronically or by mail. As discussed in Response 124, we have revised the regulatory text to update details

regarding the electronic and paper submission of a specific form. We are developing paper and electronic versions of Form FDA 3942b, which is an information collection provision that is subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 to 3520). We intend to make the paper Form FDA 3942b available in the near future and invite comments consistent with procedures for approval of the form by OMB.

(Comment 138) Some comments recommend that any interface for electronic submission of certification statements post adequate notice of requirements the facility must meet and warnings detailing potential penalties (e.g., for fraudulent submission).

(Response 138) We intend that the electronic submission system will operate in a manner similar to the existing electronic submission system for registration of food facilities, including a certification statement advising the person signing the form that, under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. We intend to include a similar certification statement on paper forms that will be available for qualified facilities that choose to submit by paper rather than through the electronic system. The electronic and paper submission forms will focus on the attestation statements rather than on other requirements to which the facility is subject. The Small Entity Compliance Guide that we will issue in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121) will be better suited to helping qualified facilities understand the requirements of the rule than information presented on a submission form.

### E. Proposed § 507.7(c)—Frequency of Determination and Submission

We proposed that the documentation must be: (1) Submitted to FDA initially within 90 days of the applicable compliance date and (2) resubmitted at least every 2 years, or whenever there is a material change to the information applicable to determining the status of a facility.

(Comment 139) Some comments assert that the proposed timeframe of 90 days to submit the required documentation would not provide sufficient time to gather and submit the required documentation and ask us to extend the timeframe, e.g., to 120 or 180 days.

(Response 139) We are retaining the proposed timeframe for the initial

submission (within 90 days of the applicable compliance date). The only documentation that the qualified facility will need to submit is an attestation, which does not need to be gathered. Importantly, however, documentation supporting the attestation must be available for inspection by September 17, 2019. As discussed in Response 76, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. As a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis by no later than July 1 of each calendar year (see § 507.7(c)(1)).

In addition, we have revised proposed § 507.7(c)(1) (which we are finalizing as § 507.7(c)(2)(i)(A), (B), and (C)) to specify the timeframe for the initial submission for three distinct circumstances: (A) By December 16, 2019 for a facility that begins manufacturing, processing, packing, or holding animal food before September 17, 2019; (B) Before beginning operations, for a facility that begins manufacturing, processing, packing or holding animal food after September 17, 2019; or (C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section. See the discussion in Response 76 regarding the approach we intend to take in a number of circumstances that could lead to a facility having records to support its status as a qualified facility for fewer than 3 preceding calendar years.

We have revised the provision to specify that the required biennial submissions of the attestations must be made during a timeframe that will coincide with the required biennial updates to facility registration (see section 102 of FSMA), *i.e.*, during the period beginning on October 1 and ending on December 31, beginning in 2020. In determining that 2020 would be the first year for the required biennial submissions of the attestations, we first considered that the first submission of an attestation would be approximately December 2019 for qualified facilities that are operating as of the date of this final rule (*i.e.*, approximately 90 days after the date of publication of this rule). For qualified facilities that do not begin operations until after December 2019, the first biennial submission will be required in a timeframe less than 2 years, but once the qualified facility has made its first submission the subsequent biennial submissions will all be at 2-year intervals. Coordinating the biennial

submissions of the required attestations with the biennial registration will reduce the cumulative economic impact on the animal food industry of complying with two separate requirements because qualified facilities that choose to submit electronically will be able to submit electronically while accessing the same electronic portal used for facility registration.

(Comment 140) Some comments ask us to include an option within the system to notify us when a facility’s status as a “qualified facility” changes, *e.g.*, because its business expands or changes.

(Response 140) Notifying us when there is a material change in the facility’s status from “qualified facility” to “not a qualified facility” is a requirement rather than an option. We included this requirement in the proposed rule, and are establishing it in this final rule. We made editorial changes to the provision to make this clearer.

We also established a series of dates associated with the facility’s change in status from “qualified facility” to “not a qualified facility.” First, we are specifying that when the status of a facility changes from “qualified facility” to “not a qualified facility” based on the required annual determination, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year (see § 507.7(c)(3)). We have provided the facility with flexibility to wait until July 1 of a given calendar year to determine whether its status changes (see § 507.7(c)(1)); 30 days is an adequate timeframe to submit the form notifying us of the change in status.

Second, we are specifying that when the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and E no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility (see § 507.7(d)). In essence, this provision can provide a facility with up to a full year to comply with the full requirements for hazard analysis and risk-based preventive controls when the facility determines its change in status early in the calendar year. A facility that does not determine that change in status until the required date of July 1 would still have 6 months to comply with the full requirements for hazard analysis and risk-based preventive controls. As we have done in the case of a qualified exemption being withdrawn (see § 507.65(d)(1)), we are providing flexibility for a facility to comply in an alternative timeframe if agreed to by FDA and the facility.

(Comment 141) One comment asks us to specify that the required attestations be submitted every 5 years rather than every 2 years. This comment asserts that doing so would be consistent with the statutory direction of section 201 of FSMA (Targeting of Inspection Resources) for non-high risk food facilities. This comment also asserts that we did not provide specific reasons for the proposed 2-year timeframe and that resubmitting the attestations every 2 years will increase cost in time and labor.

(Response 141) We decline the request. The rule requires resubmission whenever there is a material change to the information that changes the status of a facility as a qualified facility. Therefore, if the facility’s sales change its status, so that it is no longer a qualified facility, the rule requires that facility to notify us when its status changes. (Note that the definition of very small business established in this rule bases the threshold dollar amount for a very small business on an average (of sales plus the market value of animal food held without sale) during the 3-year period preceding the applicable calendar year, rather than on annual sales plus market value. A biennial submission is adequate to otherwise require a qualified facility to affirmatively attest that it continues to satisfy the criteria for being a qualified facility. A biennial submission is not overly burdensome, because a facility can coordinate its biennial submission with its biennial update to its facility registration. The suggested 5-year submission based on the targeted inspection frequency for non-high risk animal food facilities implies that all qualified facilities produce such animal foods, which is not the case.

*F. Proposed § 507.7(d)—Notification to Consumers (Final § 507.7(e))*

We proposed that a qualified facility that does not submit documentation of its food safety practices must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address, or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities).

(Comment 142) One comment recommends that information giving the location of the manufacturing site, and not just the corporation contact information, be provided on the animal food labels. Other comments state that specifically for pet food and pet treats, the manufacturer should be required to include the co-packer information on

the product labels to include the co-packer's name, private label contact information, address, and co-packer's contact information (phone and/or email).

(Response 142) Section 418(l)(7) of the FD&C Act specifically mandates for a qualified facility that "the name and business address of the facility where the food was manufactured or processed," not the corporate contact information, be included on a label for a food for which a food packaging label is required. It does not require co-packer information. The statute makes no requirements for non-qualified facilities.

*G. Proposed § 507.7(e)—Records (Final § 507.7(f))*

We proposed that a qualified facility must maintain those records relied upon to support the required documentation. We also proposed that the records that a qualified facility must maintain would be subject to the requirements that would be established in subpart F of this rule. As discussed in Response 124, after considering comments we have revised the rule to specify that a qualified facility must maintain those records relied upon to support the required attestations (rather than the required documentation).

(Comment 143) Some comments ask us to explicitly specify that we have access to documents that establish a facility as a qualified facility. Some comments assert that a facility may reasonably assume that records such as

financial records would not be available to us because such records are excluded from the records that we have access to under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and as provided by § 1.362.

(Response 143) The rule explicitly specifies that we have access to records that are required by the rule (see § 507.200). If a facility relies on financial records to demonstrate its status as a qualified facility, we will have access to those financial records. The exemption referred to by the comments for financial records (§ 1.362) is narrowly targeted to records required by the section 414 recordkeeping regulations and does not apply to records required by this preventive controls rule for animal food.

**XII. Subpart A: Comments on Proposed § 507.10—Applicability of Part 507 to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food**

We proposed that subpart C would not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to ensure the safety of the animal food (proposed § 507.10(a)). We also proposed that a facility solely engaged in the storage of packaged animal food that is not exposed to the environment but requires time/temperature control for safety would be subject to the modified requirements

that would be established in proposed § 507.48 of subpart C (proposed § 507.10(b)).

Some comments support these proposed provisions without change. For example, one comment expresses the view that a facility solely engaged in the storage of packaged animal food that does not require time/temperature control for safety does not need to conduct its own hazard analysis, nor establish and implement preventive controls because there would be no hazards to trigger such activities. Other comments that support the proposed provisions ask us to clarify some aspects of the provisions or to clarify how the provisions will apply in particular circumstances. Other comments that support the proposed provisions ask us to broaden them.

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed provisions. After considering these comments, we have revised the proposed requirements as shown in table 8 with editorial and conforming changes as shown in table 31. A key conforming change that affects § 507.10 is that it includes an exemption from the requirements of subpart E, as well as subpart C. As discussed in section XL, the final rule establishes the requirements for a supply-chain program in subpart E, rather than within subpart C as proposed.

**TABLE 8—REVISIONS TO THE PROPOSED APPLICABILITY OF SUBPART C TO A FACILITY SOLELY ENGAGED IN THE STORAGE OF UNEXPOSED PACKAGED ANIMAL FOOD**

Section	Description	Revision
507.10(b) .....	Applicability of modified requirements in § 507.51 of subpart C.	Clarification that § 507.51 of subpart C only applies to those unexposed packaged animal foods that require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(Comment 144) Some comments ask us to clarify that temperature controls should be implemented when determined to be necessary by the facility or preventive controls qualified individual. Some comments ask us to clarify that if a facility stores both TCS food and non-TCS food (*i.e.*, unexposed packaged animal food that does not require time/temperature control for safety), then the modified requirements only apply for the portion of the facility that holds the TCS foods.

(Response 144) We have revised § 507.10(b) to clarify that a facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal

food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 of subpart C of this part for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(Comment 145) Some comments ask us to revise the regulatory text to be explicit that frozen unexposed packaged food is not a TCS food subject to modified requirements.

(Response 145) We decline this request. In the 2013 proposed animal food preventive controls rule, we

tentatively concluded that it would be rare for a frozen animal food to be a TCS food (78 FR 64736 at 64802), and we affirm that conclusion in this document. However, specifying in the regulatory text that a frozen animal food is not a TCS food would require us to conclude that a frozen animal food would "never" (rather than "rarely") be a TCS food, and we lack information to support "never."

(Comment 146) Some comments ask us to apply the exemption to storage areas of facilities that also engage in food processing activities, *e.g.*, for distributors that are engaged in limited food processing, such as blending seeds to make bird food. These comments



assert that the intent of the term “solely” is to make clear that a facility that conducts an activity subject to the exemption does not escape responsibility for complying with the requirements for hazard analysis and risk-based preventive controls when conducting activities that are not exempt.

(Response 146) We disagree with the comment’s interpretation of the term “solely.” The plain meaning of “solely” is only, completely, entirely; without another or others; singly; alone (Ref. 24). The facility described in the comment is not “solely” engaged in the storage of unexposed packaged animal food.

Such a facility must conduct a hazard analysis that addresses all activities conducted by the facility. The preventive controls that the facility would establish and implement would depend on the facility, the animal food, and the outcome of the facility’s hazard analysis and any preventive control management components associated with a facility’s preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system. A facility that stores unexposed packaged animal food that is not a TCS animal food could, for example, determine that no preventive controls and associated management components would be necessary. A facility that stores unexposed refrigerated packaged TCS animal food could, for example, determine that preventive controls and management components patterned after the modified requirements in § 507.51 are adequate to address significant hazards associated with that animal food.

(Comment 147) Some comments ask us to allow a facility to designate a storage area as a separate facility for purposes of compliance with the requirements for hazard analysis and risk-based preventive controls. In the comments’ view, an area solely engaged in the storage of unexposed packaged food could fall within the exemption in § 507.10 even though other areas would be subject to the requirements for hazard analysis and risk-based preventive controls.

(Response 147) We disagree that a designated storage area in an establishment that conducts manufacturing, processing, or packing in addition to storage can fall within the exemption for facilities “solely engaged in . . . storage.” The statute provides authority for us to exempt or modify the requirements for compliance with respect to “facilities” that are solely

engaged in the storage of packaged foods that are not exposed to the environment (section 418(m) of the FD&C Act). The statute defines “facility” as a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act (section 418(o)(2) of the FD&C Act). The section 415 registration regulations define facility as “any establishment, structure, or structures under one ownership at one general physical location . . .” The comment’s interpretation that we could view “areas” of registered facilities to be “facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment” is inconsistent with the statutory and regulatory framework under sections 415 and 418 of the FD&C Act.

(Comment 148) Some comments ask us to consider an alternative to the exemption for unexposed packaged foods when a facility conducts manufacturing, processing, packing, or holding activities in addition to storing unexposed packaged food. Specifically, these comments ask us to recognize that the minimal risks of storing unexposed packaged foods can be addressed through a combination of compliance with the modified requirements for TCS foods (if applicable) and the CGMPs in subpart B and state that doing so would be consistent with our discussion in the 2013 proposed animal food preventive controls rule.

(Response 148) These comments appear to suggest the outcome of a facility’s hazard analysis and food safety plan for storing unexposed packaged animal food, *i.e.*, that the only significant hazards are the potential for growth of pathogens in refrigerated unexposed packaged animal foods and that the preventive controls and preventive control management components specified in the modified requirements for TCS animal food are adequate to address such hazards. It is the responsibility of the facility’s preventive controls qualified individual to identify the significant hazards associated with the facility and the animal food it stores, as well as the appropriate preventive controls and preventive control management components. However, we agree that in some cases the approach suggested in these comments would be appropriate.

(Comment 149) Some comments assert that it is difficult to identify TCS foods. These comments ask us to work with industry and professional organizations to develop guidance on when the modified requirements apply.

(Response 149) This document does not include guidance on whether specific animal foods are TCS foods. We

will consider including guidance on animal foods that are TCS foods in the implementing guidances we are developing (see Response 1). A facility solely engaged in storage of unexposed packaged animal food can work with the manufacturer of the food to identify TCS food. Alternatively, such a facility could simply treat any refrigerated food as a TCS food.

### **XIII. Subpart A: Comments on Proposed § 507.12—Applicability of Part 507 to the Holding and Distribution of Human Food By-Products for Use as Animal Food.**

We proposed to add provisions for human food by-products for use as animal food. We proposed that the requirements of this part would not apply to by-products of human food production that are packed or held by that human food facility for distribution as animal food if: the facility is subject to and in compliance with subpart B of part 117 (the CGMPs in the proposed preventive controls rule for human food) and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations; and the facility does not further manufacture or process the by-products intended for use as animal food. Proposed § 507.12(b) would require that once the animal food was separated from the human food, the facility would need to comply with proposed §§ 507.28 and 117.95 of part 117 for the holding and distribution of that animal food. We also proposed § 117.95 be added to the proposed preventive controls rule for human food and asked for comment on whether the requirements should be placed in both § 117.95 and § 507.28.

Section 507.12 does not apply to human food by-products when contamination or other adulteration has occurred that is materially related to food safety. We handle requests for diversion of these products for animal food use on a case-by-case basis. Additional information on diversion of contaminated or adulterated food for animal food use is available in compliance policy guidances (CPG) CPG Sec. 675.100 “Diversion of Contaminated Food for Animal Use” and CPG Sec. 675.200 “Diversion of Adulterated Food to Acceptable Animal Feed Use” (Refs. 25 and 26). We asked for comment on whether we should include regulations for these types of requests.

Many comments generally support the concept that certain human food by-products intended for use as animal food which do not undergo further processing by the human food

manufacturer only need to comply with proposed § 507.28 for holding and distribution of human food by-products for use as animal food. Some of these comments note that human food by-products are an important source of animal food. Other comments agree but request changes and/or additional exemptions.

We have modified § 507.12 to clarify that the requirements of part 507 do not apply to off-farm packing and holding of RACs packed or held by a human food facility for distribution as animal food provided certain conditions are met. For off-farm packing and holding of produce (as defined in part 112 of this chapter), if the human food facility is subject to and in compliance with § 117.8 of part 117 of this chapter and in compliance with all applicable human food safety requirements of the FD&C Act and implementing regulations, and the human food facility does not further manufacture or process the by-products intended for use as animal food, then the requirements of part 507 do not apply to the by-products.

(Comment 150) Some comments request that the proposed provisions be included in both this rule and the final rule for preventive controls for human food so that it would be easier for human food processors to understand the requirements for human food by-products intended for use as animal food. One comment does not support placing these provisions in both of the final rules, preferring that all animal food provisions be in part 507, and that part 117 should pertain only to human food.

(Response 150) Section 117.95—“Holding and distribution of human food by-products for use as animal food” is established in this rule. Section 117.95 will appear in 21 CFR part 117, preventive controls for human food. The by-products holding and distribution provisions also will appear in § 507.28, the animal food CGMPs. The requirements of § 117.95 and § 507.28 are identical and appear in both places for the convenience of the facilities to which the provisions would apply.

(Comment 151) Two comments state it must be clear in the rule that not only by-products but also products which are already authorized for food like gelatin or collagen must be authorized for food for animals, without further requirements and additional CGMP implementation.

(Response 151) We understand this comment to be stating that a human food product that also may be used as an animal food should not be required to comply with part 507 if it is in compliance with human food

requirements. We agree with this comment. A facility that manufactures and sells a food just for human consumption is not subject to part 507, even if the purchaser of that food may use it for animal food.

If a facility manufactures, processes, packs, or holds human food and animal food, and is subject to subpart C of part 117, it can comply with subpart C of part 117 for the animal food, but needs to address any hazards unique to the animal food that require a preventive control, if applicable. Except as provided by § 507.12 for human food by-products, if a facility is required to comply with subpart B of part 507 and also subpart B of part 117 because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility (see the regulatory text for § 507.1(d)).

(Comment 152) Some comments request that facilities regulated by the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) not be required to comply with part 507 for animal-derived human food by-products intended for use as animal food. Some comments state the requirements are duplicative and are unnecessary because FSIS food safety requirements are already in place, and that oftentimes the FSIS establishment is unaware of what purpose or animal species the purchaser will use the by-product for as animal food.

(Response 152) Only animal food facilities that are required to register as a food facility under section 415 of the FD&C Act are required to comply with this rule. Establishments regulated exclusively throughout by FSIS under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, *i.e.*, establishments handling only meat, poultry, or certain egg products, are exempt from registration under section 415 of the FD&C Act (see § 1.226(g) (21 CFR 1.226(g))). Therefore, these establishments are not subject to this rule.

(Comment 153) Some comments state we did not provide support for the tentative conclusion that animal-derived by-products carry different risks than other by-products, and therefore did not provide a basis for why animal-derived by-products should be subject to all of part 507 while other human food by-products are subject to only § 507.28.

(Response 153) As explained in Response 152, animal-derived by-

products from establishments that are not required to register as food facilities would not be subject to part 507.

Facilities may be jointly regulated by FDA and FSIS if they produce some products that are under FDA jurisdiction and some that are under FSIS jurisdiction. Such facilities may be required to register as a food facility under section 415 of the FD&C Act. Examples of facilities jointly regulated by FDA and FSIS include FSIS establishments that also process animal food (such as certain pet food), and facilities that process meat and nonmeat products (such as frozen entrees, some of which contain meat and are regulated by FSIS, and some of which do not contain meat but which contain seafood or vegetables that are regulated by FDA).

FSIS establishments that are required to register with FDA because they also process FDA-regulated human food, must follow §§ 507.28 and 117.95 for the holding and distribution of their FDA-regulated human food by-products for use as animal food, if the establishments meet the requirements of § 507.12(a). FSIS establishments that are required to register with FDA because they also process FDA-regulated animal food must comply with the provisions in the preventive controls rule for animal food (part 507).

(Comment 154) Some comments assert that requiring FSIS-regulated establishments to comply with part 507 would result in more by-products being diverted to other disposal methods which might have an economic or environmental impact.

(Response 154) We do not agree that compliance with part 507 will likely result in substantially less use of human food by-products as animal food because it applies only to those establishments that are required to register under section 415 of the FD&C Act. Furthermore, other disposal methods for these products may be more cost prohibitive than compliance with these regulations.

(Comment 155) One comment requests the wording in proposed § 507.12 be revised to explicitly exclude animal-derived human food by-products for use as animal food because of pathogen risk.

(Response 155) Animal-derived human food by-products have a long history of use in the animal food industry. These human food by-products typically are sold from the human food facility to an animal food manufacturer/processor, such as a pet food manufacturer, that uses the by-products as an ingredient in a finished animal food. These manufacturers/processors are required to comply with

part 507 and must address any potential pathogens. Furthermore, 21 CFR 589.2000 prohibits the use of mammalian protein in the manufacture of animal food given to ruminant animals, such as cows, sheep, and goats, and regulations issued under the Swine Health Protection Act (7 U.S.C. 3801 *et seq.*) are intended to ensure that food waste containing meat does not contain active disease organisms that pose a risk to swine who eat it (see 9 CFR part 166).

(Comment 156) A few comments state that USDA, not FDA, should issue any regulations concerning the food safety of animal-derived by-products intended for use as animal food.

(Response 156) The FD&C Act gives FDA certain authority to regulate food, which includes food for animals. As explained in section XV of the 2013 proposed preventive controls rule for animal food, the FD&C Act authorizes FDA to issue CGMP and preventive controls regulations to enhance the safety of animal food, including human food by-products that are intended for use as animal food. We decline to address what USDA's role in animal food safety should be as is it out of the scope of this rulemaking.

(Comment 157) One comment suggests an alternative approach to animal-derived human food by-products. The comment suggests that we consider a provision that would allow the purchaser to take legal responsibility for evaluating and mitigating risk associated with by-products intended for use as animal food if both parties agree.

(Response 157) For facilities subject to subpart C, the supply-chain program in subpart E is required when the receiving facility's hazard analysis identifies a hazard requiring a supply-chain-applied control and the receiving facility's manufacturing/processing will not control the hazard. However, when a manufacturer/processor identifies a hazard requiring a preventive control, but can demonstrate and document that the hazard will be controlled by an entity in its distribution chain (*e.g.*, its customer), then the manufacturer/processor is not required to implement a preventive control (see §§ 507.36 and 507.37). For a discussion of these provisions, see section XXVII. For facilities exempt from the requirements of subpart C, we are aware that parties may enter into purchase contracts that include specifications or information for the animal food purchased.

(Comment 158) The comments support seafood, dietary supplements, and infant formula by-products intended for use as animal food without further processing be subject only to the

holding and distribution provisions in proposed § 507.28.

(Response 158) We agree with these comments. We did not receive comments indicating by-products from these human foods have specific problems if used as animal food. Facilities that process seafood, dietary supplements, and infant formula that meet the requirements of § 507.12(a) must follow the requirements of § 507.28 and § 117.95 for human food by-products for use as animal food.

(Comment 159) Some comments state that all human food by-products, including those further processed, should only have to comply with the holding and distribution requirements in proposed § 507.28. Other comments support the requirement that human food by-products which are further processed should be required to comply with all of proposed part 507. Some comments request clarification about what constitutes further processing.

(Response 159) We decline the request to exempt human food by-products that are further processed from the requirements of part 507 because following CGMPs for the processing will help ensure the animal food's safety and because processing can introduce hazards requiring preventive controls. Further processing includes any manufacturing/processing as defined in § 507.3 and includes activities such as cooking, freezing, pelleting, and milling. Some passive activities such as dewatering by holding a by-product in a container with a screened bottom which allows water to escape, or holding in a perforated container which allows natural drying to occur are not considered further processing. Holding by-products at particular temperature to facilitate easier transportation of the by-products is not considered further processing; however, cooking or freezing a by-product to prevent deterioration or adulteration is considered further processing. Facilities holding human food by-products for use as animal food must follow the requirements of § 507.28.

(Comment 160) Some comments state we should not include diversion requests for contaminated or adulterated human food to animal food in the regulations; that the information contained in the guidance documents should remain in guidance and be handled on a case-by-case basis. However, some comments request that the existing compliance policy guidances be reviewed and updated and provide suggested changes.

(Response 160) We have not included regulations for diversion of contaminated or adulterated human

food for animal food use in this final rule. We will continue to handle diversion requests on an individual basis. We will consider reviewing and revising the current compliance policy guidances, CPG Sec. 675.100, "Diversion of Contaminated Food for Animal Use" and CPG Sec. 675.200, "Diversion of Adulterated Food to Acceptable Animal Feed Use" (Refs. 25 and 26).

(Comment 161) One comment requests clarification on whether these provisions would apply to retail outlets such as grocery stores or bakeries. One comment asserts that when a pig farmer gets outdated milk from a dairy processing bottling plant after the plant takes it back from grocery stores that the dairy processor (the human food manufacturer) would be exempt from the animal food preventive controls final rule.

(Response 161) Retail food establishments such as grocery stores and bakeries are not required to register as food facilities (see §§ 1.226(c) and 1.227(b)(11)) and as a result are not required to comply with part 507. However, the products they distribute for animal food must not be adulterated.

If milk has been returned to a processing plant because it is contaminated or adulterated, the facility must follow our compliance policy guidances for requests to divert human food for use as animal food (Refs. 25 and 26). If the returned milk is not contaminated or adulterated, but is returned for a quality reason, the facility must follow the holding and distribution requirements of § 507.28 and § 117.95, but would be exempt from the other provisions in subpart B and subpart C of part 507.

(Comment 162) One comment requests clarification on whether a facility that is producing human food by-products intended for animal food that fall under proposed § 507.12 has to state in its food safety plan that § 507.12 applies.

(Response 162) If the human food processor meets the requirements in § 507.12(a), the facility only needs to comply with § 507.28 and § 117.95, for the holding and distribution of the human food by-products for use as animal food. The facility does not need to include this information in its food safety plan for the human food, but may choose to include it so that employees and other individuals viewing the food safety plan understand what regulatory requirements the human food processor is applying to those human food by-products intended for animal food.

#### XIV. Subpart B: General Comments on Proposed Subpart B—Current Good Manufacturing Practice

In the 2014 supplemental proposed rule we revised the proposed CGMPs to be more appropriate for the animal food industry. Following are comments on the proposed CGMP requirements.

(Comment 163) Some comments state that the risks for pet food, especially with respect to pathogens, are different than the risks for livestock feed, and therefore FDA should issue two sets of CGMPs. Some comments say that CGMPs for pet food should be modeled after the human food CGMPs because of the high level of care people provide and demand for their pets, pets may eat or sleep with humans, and pet owners often store pet food close to human food.

(Response 163) We believe the single set of CGMPs can serve as baseline standards for producing safe animal food across all types of animal food facilities and animal food. We considered the diverse needs of industry and the ultimate goal of animal food safety as we finalized the CGMP regulations. We believe the final requirements are flexible enough to be applied appropriately in various animal food production settings. For example, § 507.19(b) contains requirements for the cleaning of animal food-contact surfaces of equipment and utensils to protect against contamination of animal food. We do not specify exactly how this is to be done (except some requirements for cleaning with wet processing of animal food), knowing that what constitutes adequate cleaning will depend on the plant and the animal food. (See Response 182).

As discussed in the 2013 proposed rule for preventive controls for animal food, in 2003 we introduced the concept of the Animal Feed Safety System (AFSS) which was intended to address the safety of all animal food at all stages of production and use. After obtaining input from the general public, State regulatory officials, industry, veterinarians, and consumers, the AFSS working group began developing a proposed rule for process controls for animal food, prior to FSMA, that was intended to apply to all animal food (including pet food, livestock feed, and raw materials and other ingredients) (78 FR 64736 at 64740).

When we revised the proposed CGMPs in the 2014 supplemental notice, we not only consulted the human food CGMPs and their development history, but also reviewed the draft AFSS process controls proposed rule. We also reviewed

CGMPs developed by organizations such as the British Standards Institute's Publicly Available Specification (PAS) 222 and the Association of American Feed Control Officials (AAFCO) model GMPs for feed and feed ingredients (which are adopted by many states for regulation of animal food) (Refs. 27 and 28). Both PAS 222 and AAFCO GMPs apply to pet food and other animal food such as feed for livestock. Many of the raw materials and other ingredients used in making finished animal food are used by multiple types of animal food manufacturers producing a variety of animal food products. It would not be feasible to enforce different sets of standards for pet food and livestock feed in a plant supplying the same ingredients to a pet food manufacturer and a livestock feed manufacturer. We expect our CGMP requirements to be applied appropriately in all facilities manufacturing and processing animal food.

(Comment 164) Some comments say that CGMP requirements for animal food in general are not appropriate for some products used in animal food. Comments provide examples such as rendered products, which are thermally processed before being used as ingredients in animal food; humic products because raw mined materials are low risk; and oilseed products because they have not been associated with any significant food safety risks and are intermediate ingredients that will undergo a subsequent kill step.

(Response 164) We understand that some ingredients utilized in the production of animal food may pose a low risk. Nevertheless, facilities that are required to register under section 415 of the FD&C Act and are suppliers of ingredients used in animal food will be required to meet the CGMP requirements being finalized in this rule. We believe these CGMPs provide a great deal of flexibility in establishing baseline standards for safely manufacturing, processing, packing, or holding the wide diversity of ingredients used in animal food.

(Comment 165) One comment suggests that a new section be added at the end of subpart B that would eliminate the need to comply with the CGMPs if a facility showed that the hazard analysis and risk-based preventive controls required by subpart C had been properly conducted, implemented and validated.

(Response 165) We decline this request. The requested change is counter to the intent of this regulation, that the CGMPs in subpart B provide baseline safety and sanitation standards, while hazards specific to a facility and

the animal food it produces are identified and controlled under subpart C. We consider CGMPs to be a prerequisite program important for effective preventive controls, and believe that the CGMPs being finalized in this rule provide enough flexibility for a facility to use CGMPs to address certain hazards so they do not become hazards that would require a preventive control.

(Comment 166) One comment from a foreign government says that minimum requirements for recordkeeping and traceability, which are recommended in the CODEX Code of Practice on Good Animal Feeding, might be appropriate in subpart B so that they would apply to establishments exempt from subpart C.

(Response 166) We agree that traceability and associated recordkeeping are important tools for a facility to use for tracing animal food in the event of a recall or foodborne illness outbreak. Recordkeeping requirements currently exist in the Bioterrorism Act, and implementing regulations in part 1 subpart J for persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. In addition, the responsible party at any food facility required to register under section 415 of the FD&C Act (domestic and foreign) is subject to the RFR requirements under section 417 of the FD&C Act. Section 417 requires under certain circumstances that the responsible party notify the previous source and subsequent recipient of the article of reportable food, providing traceability.

(Comment 167) Some comments request that we use the term "adulteration" instead of "contamination" in subpart B of the final rule because "adulteration" of food is the regulatory standard for action, whereas contamination is currently undefined. These comments state that the term contamination should carry a different meaning than in part 117 because what is considered a contaminant in human food may differ from what is considered a contaminant in animal food.

(Response 167) We decline this request. Section 402(a)(3) and (4) of the FD&C Act were added to expand our bases for initiating enforcement proceedings against adulterated food, particularly to allow us to act where a food has been prepared, packed, or held under insanitary conditions, whereby it may have become contaminated. In other words, a food need not be shown to contain contaminants to be adulterated; a showing that the food was prepared, packed, or held under

conditions whereby it may become contaminated is sufficient to prove adulteration. Thus, the word “contamination” serves a necessary purpose in the context of adulteration. The CGMPs in this final rule are intended to help protect against the contamination of animal food, so that it will not become adulterated.

The word “contamination” is used widely in FDA regulations, including our Current Good Manufacturing Practice for Medicated Feeds (21 CFR part 225), Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR part 113), and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (21 CFR part 110, and updated and included in the final rule for preventive controls for human food, 21 CFR part 117, published elsewhere in this **Federal Register**). In addition, “contamination” is used in Codex Good Practices for the Feed Industry and PAS 222 (Ref. 27). Because of the wide use of the term throughout current FDA regulations and in international standards, we conclude that industry is familiar with the word “contamination” and it is an appropriate word to use in this final rule.

We recognize that it may not always be possible to prevent contamination of animal food. Therefore, we have changed the regulatory text throughout subpart B to stress that the goal of the regulations is to “protect against” or “minimize” the contamination of animal food. We recognize that what is considered contamination of human food may not be considered contamination in animal food.

(Comment 168) Some comments object to the use of the terms “sanitize” and “sanitation” in the CGMPs, saying that the destruction of microorganisms is not always necessary in animal food facilities and therefore “cleaning” or “housekeeping” should be used instead of “sanitizing.” Some of these comments also ask that we change the title of proposed § 507.19 from “Sanitation” to “Cleaning and Housekeeping.”

(Response 168) We decline this request. We use the term “sanitation” in a general way that we believe is well understood by the animal food industry and does not mean the destruction of microorganisms. For example, the term “sanitation” is defined in PAS-222 (Ref. 27). When the destruction of vegetative cells of pathogens and substantial reduction of numbers of other undesirable microorganisms is required, we use the terms “sanitize” or “sanitizing,” not “sanitation,” which is

consistent with how these terms are used throughout our current regulations for human and animal food. The only requirement for sanitizing in subpart B is in regards to wet processing (see regulatory text for § 507.19(b)(2)). Therefore, we believe that “sanitation” is a word that is commonly understood by industry and is used in this final rule in a way that is consistent with how it is used in our other regulations relating to human and animal food.

(Comment 169) Some comments request that we use “tools” instead of “utensils” in the CGMPs to better fit the terminology used in the animal food industry.

(Response 169) We decline this request. We recognize that “utensil” is not commonly used in the animal food industry; however, we believe it is well understood. The term “utensil” is used in PAS-222 and Codex Good Practices for the Feed Industry, as well as in the CGMPs for human food in part 110 and in the revised CGMPs in the final rule for preventive controls for human food, part 117 (Refs. 27 and 29). Further, because “tools” is broadly used to refer to such things as construction equipment, software, educational material, and even laws and regulations, we believe it is not a good substitute for “utensils.”

(Comment 170) A number of comments request that wherever we require measures to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, that we delete animal food-contact surfaces and animal food-packaging materials because the focus should be solely on the animal food.

(Response 170) We decline this request. While the ultimate goal of the CGMP requirements is to protect against contamination of animal food, we believe that protecting animal food-contact surfaces and animal food-packaging material from contamination is a necessary step to achieve this goal because the surfaces and packaging can be a source of contamination.

#### **XV. Subpart B: Comments on Proposed § 507.14—Personnel**

We proposed that plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food. We are finalizing this provision with the discussed changes in § 507.14(a). We have changed “plant” to

“establishment” for clarity. We are finalizing the proposed list of methods for maintaining cleanliness that were proposed in § 507.14(a)(1) through (5) in new § 507.14(b)(1) through (5). We have added paragraph (b) to read: “the methods for conforming to hygienic practices and maintaining cleanliness include.”

(Comment 171) Some comments ask us to remove “all” because it is too extreme and prescriptive.

(Response 171) We have revised the regulatory text to delete “all”. We disagree that the term “all” is too extreme and prescriptive, but conclude that the term “all” is not necessary to communicate the intent of the requirement.

#### *A. Proposed § 507.14(a)(1)—Personal Cleanliness (Final § 507.14(b)(1))*

We proposed that the methods for maintaining cleanliness include maintaining adequate personal cleanliness. We did not receive comments specific to this provision and are finalizing it as proposed.

#### *B. Proposed § 507.14(a)(2)—Hand Washing (Final § 507.14(b)(2))*

We proposed that the methods for maintaining cleanliness include washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to prevent contamination.

(Comment 172) One comment disagrees with FDA’s decision to revise the language from the 2013 proposed rule by removing the parenthetical statement about sanitizing hands if necessary to protect against contamination with undesirable organisms. The comment recommends that FDA add a qualifying statement that if hand washing facilities are not readily available, the use of hand sanitizers is permitted.

(Response 172) We decline this request. We deleted the parenthetical statement because we did not intend to require hand sanitizing after hand washing. We are providing flexibility for plant management to determine if hand sanitizing after washing is necessary to protect against contamination of animal food with undesirable microorganisms. We recognize that there may be some situations where hand washing facilities are not readily available. The use of waterless hand cleaners (including hand sanitizers) may be adequate under these circumstances.

*C. Proposed § 507.14(a)(3)—Unsecured Jewelry and Other Objects (Final § 507.14(b)(3))*

We proposed that personnel be required to remove or secure jewelry and other objects that might fall into animal food, equipment, or containers.

(Comment 173) One comment says this requirement is unnecessary since the proposed CGMPs contain numerous other provisions that require facilities to protect against the adulteration of products. The focus placed on jewelry and other items that may potentially fall into products is unwarranted due to the limited risk of such occurrences.

(Response 173) We believe that a specific provision to protect against jewelry and other personal items falling into animal food is appropriate, and is not redundant to other requirements in the CGMPs that are intended to protect against adulteration of animal food.

*D. Proposed § 507.14(a)(4)—Storing Clothing and Personal Belongings (Final § 507.14(b)(4))*

We proposed requiring personnel to store clothing and other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned.

(Comment 174) One comment says that the requirement is not practical or necessary to ensure the safety of animal food. The comment states that the temperature in a facility can be highly variable, so it would be unreasonable to require an employee to store clothing outside of areas where animal food is exposed.

(Response 174) We understand that personnel may need layers of clothing in certain plants that are exposed to varying temperatures. However, when clothing is removed, it needs to be stored away from exposed animal food so it does not become a source of contamination. We believe storing clothing and other personal belongings in areas other than where animal food is exposed is a reasonable protection.

*E. Proposed § 507.14(a)(5)—Taking Other Necessary Precautions (Final § 507.14(b)(5))*

We proposed that personnel must take any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 175) One comment requests that we provide examples in a guidance document for the requirement to take “any other necessary precautions to protect against contamination of animal food, animal food contact

surfaces, or animal food packaging materials.”

(Response 175) We believe this provision indicates that the listed requirements are not meant to be exhaustive and provides needed flexibility for the diverse animal food industry to implement precautions specific to their operations to protect against the contamination of animal food. We will consider providing examples in any future guidance.

**XVI. Subpart B: Comments on Proposed § 507.17—Plant and Grounds**

*A. Proposed § 507.17(a)—Grounds Surrounding an Animal Food Plant*

We proposed that the grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food, including provisions to keep areas from being a harborage for pests, maintaining areas so they are not a source of contamination, adequately draining areas, and treating and disposing of waste so it is not a source of contamination.

(Comment 176) One comment says that the term “surrounding” the plant is too ambiguous, and that we should specify the distance from a plant that must be controlled to prevent animal food contamination.

(Response 176) We decline to specify a distance from the plant because the area that could impact plant operations is highly variable from plant to plant. We have replaced the word “surrounding” with the word “around,” meaning the grounds of the plant under control of the plant management that could impact plant operations.

(Comment 177) Some comments say that the requirements are highly prescriptive and should be more flexible. Other comments state that the general language that requires the grounds to be kept in a condition that will protect against the contamination of animal food is sufficient and that the specific requirements should be recommendations.

(Response 177) The specific requirements provide the baseline expectations we have for plants to maintain their grounds in a way that does not result in the contamination of animal food. The specific requirements are common to most plants and provide necessary information to the plant management about what it must do to comply with this final rule. However, the requirements do not preclude a plant from addressing unique circumstances that could lead to the contamination of animal food.

*B. Proposed § 507.17(b)(1)—Adequate Space Between Equipment, Walls, and Stored Materials*

We proposed that the buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. We also proposed that the plant must provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment.

(Comment 178) Two comments disagree with this requirement. One comment says that the focus is on equipment design and not protecting against animal food contamination. The other comment suggests simplifying the requirement to provide access between equipment and walls.

(Response 178) We believe protecting animal food from contamination requires proper plant design. We decline the request to change the requirement by deleting the reference to stored materials because we do not agree that stored materials should be allowed to prevent employees from performing their duties or inhibit the cleaning and maintenance of equipment. We did modify the language in paragraph (b) to replace “buildings, structures, fixtures, and other physical facilities of the plant” with “the plant” because the plant would include its buildings, structures, fixtures, and physical facilities.

*C. Proposed § 507.17(b)(2)—Dripping and Condensation*

We proposed that the plant must be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination.

(Comment 179) One comment asks that we allow for facilities to be “constructed or maintained,” rather than “constructed” only, to ensure that drip or condensate does not serve as a source of animal food contamination. Another comment asks that the requirement be deleted, since it is generally not relevant and is redundant to the opening statement in proposed paragraph (b). Other comments say that requirements pertaining to the construction of buildings and structures are too prescriptive and should specify only that the plant be constructed in such a manner as to protect against adulteration of animal food.

(Response 179) We decline the requests to revise or delete this requirement. The requirements in (b)(1) to (5) are some of the specific requirements that we believe are needed to meet the general requirement in paragraph (b) that the plant be designed and constructed to reduce the potential for contamination. We believe it is important to specify that fixtures, ducts, and pipes be constructed so that they do not serve as a source of contamination because condensate and drip may serve as a source of contamination. As specified in § 507.20(b)(3), plumbing must be maintained to avoid being a source of contamination to animal food. In addition, as specified in 507.19(a), the fixtures and physical facilities of the plant must be kept in good repair to prevent animal food from becoming adulterated. This would include fixtures, ducts, and pipes. Thus, we agree that one way to manage dripping and condensation is through maintenance or repair to the plumbing or structure, and do not intend that existing plants must be redesigned or reconstructed.

*D. Proposed § 507.17(b)(3)—Ventilation*

We proposed that the plant must provide adequate ventilation or control equipment to minimize vapors (for example, steam) and fumes in areas where they may contaminate animal food, and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food.

(Comment 180) One comment says that while steam is a key manufacturing component, it is unlikely to be a source of potentially hazardous contaminants. Several comments state that steam is not commonly used in animal food processing, and should not be specified in the rule, or language stating “where appropriate and necessary” should be included in the regulatory text. Other comments suggest additional alternative language.

(Response 180) We agree that not all plants use steam and the phrase “where appropriate and necessary” provides that distinction and have added it to the regulatory text. We also recognize that animal food facilities commonly rely on natural ventilation. As a result, we have added the parenthetical (mechanical or natural) to the regulatory text to read: “Provide adequate ventilation (mechanical or natural) . . .”

*E. Proposed § 507.17(b)(4)—Lighting*

We proposed that the plant must provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured,

processed, packed, or held, and areas where equipment or utensils are cleaned. We received no comments on this provision and are finalizing it as proposed.

*F. Proposed § 507.17(b)(5)—Glass*

We proposed that the plant must provide safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage. We did not receive specific comments on this paragraph. However, for clarity, we have replaced the term “safety-type” with “shatter-resistant.”

*G. Proposed § 507.17(b)(6)—Outdoor Storage*

We proposed that animal food stored outdoors in bulk be protected by any effective means, including using protective coverings, controlling areas over and around the bulk animal food to eliminate harborage for pests, and checking on a regular basis for pests and pest infestation.

(Comment 181) Several comments say that protecting animal food stored outdoors is better addressed in proposed § 507.19 (Sanitation). One comment says that at livestock facilities and farms animal food such as hay, silage, grain, human food by-products, and other commodities are commonly stored outside with no cover. Another comment requests that the regulation be revised to recommend rather than require the provisions.

(Response 181) While we disagree with the recommendation to move this requirement to § 507.19 (Sanitation), we moved it from proposed paragraph (b) to new paragraph (c) in § 507.17 because paragraph (b) pertains to buildings and structures and this requirement is about animal food stored outside of the building or structure. We have revised the regulatory text in paragraph (c)(1) to read “Using protective coverings where necessary and appropriate” to account for the situations that may not require protective coverings. In addition, we have added checking for product condition related to the safety of the animal food in paragraph (c)(3) to ensure that if the animal food is not covered, animal food safety is maintained. We decline to specify under what circumstance protective coverage is required (such as, to protect against adverse weather conditions) since there could be several reasons for needing protective coverage to help protect against contamination of the animal food.

**XVII. Subpart B: Comments on Proposed § 507.19—Sanitation**

*A. Proposed § 507.19(a)—Buildings*

We proposed that buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming contaminated. We received no comments on this provision, however we are replacing “contaminated” with the broader standard “adulterated” as proposed in the 2013 proposed preventive controls rule for animal food.

*B. Proposed § 507.19(b)—Cleaning*

We proposed that animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, and that when necessary, equipment be disassembled for thorough cleaning.

(Comment 182) Two comments state that the proposed provision is too prescriptive because of the requirement to disassemble equipment for cleaning when necessary.

(Response 182) We believe the language provides flexibility for plants to prevent contamination of animal food contact and non-contact surfaces of utensils and equipment. The language “when necessary” provides the plant the option whether to disassemble the equipment for cleaning based on the manufacturer’s knowledge and experience of when this cleaning procedure is necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

*C. Proposed § 507.19(b)(1)—Wet Cleaning*

We proposed that when it is necessary to wet-clean animal food-contact surfaces used for manufacturing, processing, packing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use.

(Comment 183) One comment states that “low-moisture animal food” is not defined, so for clarity we should either define it or replace it with “safe moisture level animal food” because “safe moisture level” is already defined in the proposed rule.

(Response 183) We agree that the term “low-moisture” is not well known when applied to the animal food industry as a whole and we have removed the term. We believe that in most cases, animal

food contact surfaces must be thoroughly dried after wet cleaning because the moisture could provide an environment for growth of undesirable microorganisms. However, we also understand that in some situations, for example in wet processing areas, it would not be necessary to dry surfaces thoroughly before subsequent use in order to protect against contamination. Therefore, we have inserted “when necessary,” so that the requirement is appropriate for all types of animal food facilities.

(Comment 184) Two comments note that the proposed rule includes explicit requirements for wet cleaning, but none for dry cleaning. One comment suggests adding language to paragraph (b) for dry cleaning, including vacuuming or sweeping. The second comment suggests adding language for dry cleaning when used solely for low-moisture feed ingredients.

(Response 184) We decline these requests. The regulatory text in paragraph (b) requires that utensils and equipment be cleaned and maintained, but it does not specify the exact procedures. Adequate cleanout of so-called dry feeds has been an important CGMP requirement applicable to medicated feed for more than 40 years and, as such, some of the animal food industry is well aware of this practice. The dry cleaning procedures suggested in the comments would be allowable methods of cleaning and maintaining where appropriate to protect against the contamination of animal food. We do not believe additional language is necessary in the regulatory text for dry cleaning. The provisions in paragraph (b)(1) for wet cleaning are in addition to the more general requirements in paragraph (b) to help ensure that water from the wet-cleaning process does not result in subsequent contamination of animal food.

#### *D. Proposed § 507.19(b)(2)—Wet Processing*

We proposed that in wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(Comment 185) One comment says the proposed requirements for cleaning in wet processing areas should be more flexible and suggests the additional wording “as necessary to protect against adulteration of animal food.”

(Response 185) We believe this requirement is sufficiently flexible because it applies only when necessary to protect against the introduction of undesirable microorganisms into animal food.

#### *E. Proposed § 507.19(c)—Cleaning Compounds and Sanitizing Agents*

We proposed that cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use. We received no comments on this provision and are finalizing it as proposed.

#### *F. Proposed § 507.19(d)(1)—Toxic Materials*

We proposed that only certain toxic materials may be used or stored in a plant where animal food is manufactured, processed, or exposed, *i.e.*, those that are required to maintain clean and sanitary conditions, those necessary for use in laboratory testing procedures, those necessary for plant and equipment maintenance and operation, and those necessary for use in the plant’s operations.

(Comment 186) Some comments say that the proposed regulation would require an absolute prohibition of any potentially toxic materials that are stored but not used by an animal food plant. The comments note that animal food plants that hold and distribute materials such as fertilizers and pesticides would either need to discontinue this practice or construct new storage buildings, which may be expensive. Several comments suggest alternative language to allow toxic materials to be held and distributed in a way that would not require significant physical improvements to the plant.

(Response 186) We agree that it might be common for an animal food plant to have toxic materials not identified in paragraph (d)(1), such as fertilizers or other non-plant chemicals, as part of its business inventory. However, we disagree with the comments that state the provisions in the rule would require new investments in storage buildings. The intent of the provision is to keep toxic chemical categories not listed in paragraph (d)(1) out of the plant area so animal food is not exposed. We revised the regulatory text to add paragraph (d)(3), which reads “Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.” We expect that this will result in toxic materials not identified in paragraph (d)(1) being separated from animal food either by sufficient space or

a sufficient physical barrier such that they are not able to contaminate the animal food. With this clarification, we do not believe that establishments will need to make significant investments to their buildings and structures to comply with these requirements.

#### *G. Proposed § 507.19(d)(2)—Identification, Use, and Storage of Toxic Materials*

We proposed that toxic materials described in paragraph (d)(1) of this section (for example, cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 187) A number of comments object to the use of “toxic” in proposed paragraph (d)(2). Several comments suggest that “cleaning materials” rather than “toxic cleaning compounds” be used in paragraph (d)(2) because any substance may be considered “toxic” if handled or used inappropriately. One comment asks that the term “toxic materials” be deleted and requirements established instead for the control of substances that are not approved for use in animal food.

(Response 187) We decline the request. The term “toxic” is important to specify that this paragraph applies to toxic cleaning compounds. The term “cleaning compounds” would be too general and might include materials that would not need to be handled as specified in these requirements to protect against the contamination of animal food. For example, water could be considered a cleaning compound, but it is not considered toxic at regular use levels and we would not expect a plant to treat its use of cleaning water in a manner consistent with this requirement. We decline the request to substitute “substances that are not approved for use in animal food” for “toxic materials.” Not all animal food ingredients have been or must be preapproved by the Agency before being used to produce animal food. Additionally, ingredients that have not been approved by the Agency would not necessarily be toxic.

#### *H. Proposed § 507.19(e)—Pest Control*

We proposed that effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of insecticides and rodenticides in the plant is permitted only under precautions and restrictions that will



protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. We received no comments on this provision. We have replaced the words “insecticides and rodenticides” with “pesticides” for simplicity and because we have defined pest as “any objectionable animals or insects including birds, rodents, flies, and larvae.” Thus, pests are not limited to insects and rodents.

#### *I. Proposed § 507.19(f)—Trash and Garbage*

We proposed that trash and garbage must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests. We received no comments on this provision; however we are removing the term “garbage.” (See Response 227).

### **XVIII. Subpart B: Comments on Proposed § 507.20—Water Supply and Plumbing**

#### *A. Proposed § 507.20(a)—Water Supply (Final § 507.20(a)(1)–(4))*

We proposed that the water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing or processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(Comment 188) One comment suggests that we develop an enforcement plan for water quality that takes into account the intended use of the animal food being manufactured. Another comment says that many of the details contained in this paragraph of the proposed regulation should be handled as guidance rather than regulation.

(Response 188) We believe that the details contained in this paragraph should remain requirements because they are important to helping ensure the safety of animal food and to provide the regulated facility with information

about what is expected of the water supply for the plant and the animal food being manufactured, processed, packed or held. We will consider including water supply in any future guidance.

(Comment 189) Two comments say that the requirements pertaining to the water supply are overly prescriptive and we should require only that the water supply be adequate for the operations. Two comments suggest that the requirement about the reuse of water be reworded to provide more clarification on the recycling of water within the plant.

(Response 189) We believe the source of the water is relevant to ensuring that animal food is protected from contamination. We also believe specifying that water be safe for its intended use, and that it be provided at a suitable temperature and pressure where it is needed for manufacturing, processing, cleaning, and hand washing helps protect against animal food contamination. With respect to reuse of water, we believe our statement that water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food allows flexibility for recycling water within the plant. Additional clarification could have the unintended effect of reducing flexibility.

#### *B. Proposed § 507.20(b)—Plumbing*

We proposed that plumbing be designed, installed, and maintained to carry adequate quantities of water to required locations throughout the plant; properly convey sewage and liquid disposable waste from the plant; avoid being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies, equipment, or utensils, or creating an unsanitary condition; provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and ensure there is no backflow or cross-connections between piping for water for processing and for waste water.

(Comment 190) One comment says we are proposing to establish specific requirements for plumbing design, installation, and maintenance that are not necessary to prevent the adulteration of animal food, and suggests deleting the plumbing design section entirely. Two comments say that floor drains are not the only way to remove water or other fluids from floors, and suggest we allow other options such as vacuuming, mopping, or fans.

(Response 190) We decline these requests. We believe these are basic and necessary requirements for helping ensure production of safe animal food. The regulatory text requires adequate floor drainage for areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Plants that do not perform these activities as part of their normal operations would not be expected to have floor drainage and vacuuming or mopping may be adequate.

#### *C. Proposed § 507.20(c)—Sewage*

We proposed that sewage must be disposed of through an adequate sewerage system or through other adequate means.

(Comment 191) Some comments say that the requirement to provide an adequate sewer system is covered by the requirement in proposed § 507.20(b)(2) for plumbing and that one of the requirements should be deleted to eliminate this redundancy.

(Response 191) The requirement in paragraph (b)(2) is intended to make sure the plumbing in the plant is sufficient to remove sewage and liquid disposable waste from the points at which it is generated within the plant, while the requirement in paragraph (c) is intended to make sure that the sewage and liquid disposable waste created by the plant is delivered to a wastewater system, such as a sewer or septic system, which has a capacity adequate to ensure that this wastewater does not contaminate the animal food.

#### *D. Proposed § 507.20(d)—Toilet Facilities*

We proposed that each plant must provide employees with adequate, readily accessible toilet facilities, and that the toilet facilities be kept clean and not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 192) Some comments suggest adding “as appropriate” to the requirement to provide adequate toilet facilities for plant employees.

(Response 192) We decline this request. We understand that there may be an exception where toilet facilities are not inside a plant, but we believe it is important that toilet facilities are available near the plant for employee use, and the requirement as proposed provides this flexibility.

#### *E. Proposed § 507.20(e)—Hand-Washing Facilities*

We proposed that each plant must provide hand-washing facilities

designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 193) Some comments suggest adding the words "as appropriate" to the requirement to provide flexibility for those plants that may not need hand-washing facilities. Another comment asks that we add an option that allows for the use of hand sanitizing in plants that may not need hand-washing facilities.

(Response 193) We understand that there may not be running water in every plant, but we believe it is important that hand-washing facilities be available to employees. We understand that in some cases hand-washing facilities might consist of waterless hand cleaners (including hand sanitizers).

### **XIX. Subpart B: Comments on Proposed § 507.22—Equipment and Utensils**

#### *A. Proposed § 507.22(a)(1)—Plant Equipment and Utensils*

We proposed that all plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained.

(Comment 194) Some comments suggest that this be a recommendation rather than a requirement because it is too prescriptive and applies to all equipment in a plant, rather than only to equipment used in the production of animal food.

(Response 194) We decline this request. We believe that all plant equipment with the potential to contaminate animal food must be cleanable and maintained. To clarify this requirement, we have added language stating that this requirement applies to equipment and utensils used in manufacturing, processing, packing, and holding animal food, as well as equipment and utensils that do not come in contact with animal food but could still serve as a source of contamination of animal food.

#### *B. Proposed § 507.22(a)(2)—Design of Equipment and Utensils*

We proposed that the design, construction, and use of equipment and utensils must preclude the contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(Comment 195) Some comments say that this requirement is too prescriptive because equipment and utensils are designed and constructed by entities independent of the animal food

manufacturers/processors. Some comments also say that we should clarify that we are not requiring the use of food-grade lubricants.

(Response 195) We understand that plants do not normally design and construct the equipment they use. However, we believe it is the plant's responsibility to select equipment and utensils that when used will not adulterate animal food. We have revised the text to clarify that the presence of non-food grade lubricants, fuel, metal fragments, contaminated water, or other contaminants in animal food may render it adulterated. We also have revised the wording for easier reading. We are not requiring that only food grade lubricants be used in the plant, but food grade lubricants must be used on equipment that comes in contact with animal food. When a non-food grade lubricant is used on non-food contact equipment, it must not adulterate the animal food. We have added the term "non-food grade" for lubricants to clarify this.

#### *C. Proposed § 507.22(a)(3)—Equipment Installation*

We proposed that equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and adjacent spaces. This provision has been revised to be a requirement, not a recommendation as it is a requirement, not guidance.

(Comment 196) One comment suggests that we combine proposed §§ 507.22(a)(1) and 507.22(a)(3).

(Response 196) We decline this request. The first provision requires that equipment be properly designed and constructed, and the second requires that it be installed in a way that facilitates cleaning and maintenance. We have revised the wording in (a)(3) for clarity.

#### *D. Proposed § 507.22(a)(4)—Animal Food Contact Surfaces*

We proposed that animal food-contact surfaces must be made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, and sanitizing agents; be made of nontoxic materials; and maintained to protect animal food from being contaminated.

(Comment 197) Some comments ask us to specify that food-contact surfaces must be designed to withstand cleaning procedures.

(Response 197) We have revised the regulatory text to include cleaning procedures. For example animal food-contact surfaces must be designed to withstand the actions of scrubbing

utensils that could damage the equipment.

#### *E. Proposed § 507.22(a)(5)—Non-Animal Food Contact Equipment (Final § 507.22(a)(1))*

We proposed that equipment in the animal food in manufacturing/processing area, that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition.

(Comment 198) One comment says that this requirement should be deleted because it is highly prescriptive, redundant to proposed paragraph (a)(1), and not performance based or necessary. Further, the comment states FDA's focus should be on whether the area is adequately cleaned, not on whether equipment that does not come in contact with animal food is properly designed.

(Response 198) We disagree that the requirement is too prescriptive. However, we agree that there is some redundancy between proposed paragraphs (a)(1) and (a)(5). We have removed proposed paragraph (a)(5) and have modified the regulatory text in paragraph (a)(1) as discussed in section XIX.A.

#### *F. Proposed § 507.22(b)—System Design and Construction*

We proposed that holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way that does not contaminate animal food.

(Comment 199) Several comments suggest that this requirement be revised or deleted to allow plants the flexibility to maintain their equipment in a manner that is appropriate for their facility, and because it is redundant to proposed § 507.22(a)(1) through (4).

(Response 199) We decline to revise or eliminate this provision. The requirements in § 507.22(a) are specific to individual pieces of equipment. The requirement in § 507.22(b) is meant to address entire systems that may contain multiple pieces of equipment. While an individual piece of equipment may be designed, constructed and maintained so that it protects against the contamination of animal food, when that piece of equipment becomes part of a system, its use in the system must be in a manner that protects against the contamination of animal food. (See Response 167.)

*G. Proposed § 507.22(c)—Monitoring Cold Storage Temperatures*

We proposed that each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-monitoring device.

(Comment 200) Some comments state requiring monitoring devices for each compartment goes too far. Facilities should have flexibility in controlling temperatures in freezers and cold storage compartments. One comment says this requirement should not require the use of continuous temperature-monitoring devices.

(Response 200) We believe that a temperature-measuring device for each compartment is necessary because the temperature may be different in each compartment. We have replaced the term “temperature-monitoring device” with “temperature-measuring device” as we do not intend the establishment to use a continuous monitoring device or temperature recording device.

*H. Proposed § 507.22(d)—Instruments*

We proposed that instruments and controls used for measuring, regulating, or recording temperatures, pH,  $a_w$ , or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses. We received no comments on this provision and are finalizing it as proposed.

*I. Proposed § 507.22(e)—Compressed Air*

We proposed that compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way so animal food is not contaminated. We received no comments on this provision and are finalizing it as proposed with the revision “to protect against the contamination of animal food.” (See Response 167.)

**XX. Subpart B: Comments on Proposed § 507.25—Plant Operations***A. Proposed § 507.25(a)(1)—CGMPs*

We proposed that plant management must ensure that all operations in the manufacturing, processing, packing, and holding of animal food are conducted in accordance with the CGMP requirements of this subpart. We received no comments on this provision. We are revising paragraph (a) to read “Management of the establishment must ensure that:” based on the definition of “plant” (see section VIII.A.23).

*B. Proposed § 507.25(a)(2)—Identifying Contents of Containers*

We proposed that plant management must ensure that containers holding animal food, including raw materials, other ingredients, or rework, accurately identify the contents.

(Comment 201) Some comments suggest that we revise the proposed requirements by clarifying that the contents of containers, not the containers themselves, are accurately identified, and that we clarify that bulk silos and bins are not required to be placarded, because this is impractical and not industry practice.

(Response 201) We agree that the animal food in the containers is what must be identified and have clarified the language in the regulatory text to require management to ensure animal food, including raw materials, other ingredients, or rework is accurately identified. We recognize that a variety of systems are used by establishments to identify animal food within the plant including labeling, computer systems, paper records, chalkboards, and other methods. It is necessary that plant personnel be able to accurately identify animal food, including raw materials, other ingredients, or rework within the plant so that animal food is not commingled, substituted, or incorrectly formulated in a manner that results in adulterated animal food.

*C. Proposed § 507.25(a)(3)—Labeling of Finished Product (Final § 507.27(b))*

We proposed that plant management must ensure that the labeling for finished animal food product contains information and instructions for safely using the product for the intended animal species.

(Comment 202) Many comments suggest that instead of specifying that labeling for the finished animal food product contains information and instructions for safely using the product for the intended animal species we specify only that labeling for finished animal food products conforms to requirements in existing FDA regulations. One comment asks that we clarify that finished product means the product that the animal receives.

(Response 202) We decline the request. We do not intend “finished animal food product” to mean only product that the animal receives. A finished animal food product could be ready-to-eat animal food or it could be an ingredient or mixture of ingredients that will be further processed, mixed, or blended before it is suitable for feeding to animals.

Labeling containing information and instructions for safe use is important for

both the person feeding the animal(s) and the downstream facilities that may use an ingredient or mixture of ingredients to further process, mix, or blend into an animal food product. Some animal food products may pose a food safety concern for some species for which the food is not intended, or may pose a food safety concern for an intended species if not used properly. For example, the manufacturer of a copper product might include the use levels for food for different species or a labeling statement specifying the maximum safe level of copper in an animal food intended for sheep.

We have moved this requirement to paragraph (b) in § 507.27 “Holding and Distribution.” We believe that this move helps to clarify that the labeling is intended for finished animal food leaving the plant. We have renumbered the other requirements in this section accordingly.

*D. Proposed § 507.25(a)(4)—Animal Food Packaging Material (Final § 507.25(a)(3))*

We proposed that plant management must ensure that animal food-packaging materials are safe and suitable.

(Comment 203) One comment suggests that instead of requiring that animal food-packaging materials are safe and suitable, we require that they are safe and suitable for the intended use.

(Response 203) We disagree that this clarification is needed because the intended use is inherent in the current wording of this regulation.

*E. Proposed § 507.25(a)(5)—Responsibility for Overall Plant Cleanliness (Final § 507.25(a)(4))*

We proposed that plant management must ensure that overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function.

(Comment 204) One comment suggests that we require that the competent individuals responsible for overall cleanliness of the plant be “qualified competent individuals.”

(Response 204) As discussed in Response 92, we expect all individuals who perform activities required under part 507 to know how to do their jobs; thus, we are establishing new § 507.4(b), which specifies that all individuals who perform activities required under part 507 must be “qualified individuals” as that term is defined in § 507.3 (*i.e.*, a person who has the necessary education, training, and experience to perform an activity required under part 507). A qualified individual may be, but is not required to be, an employee of the establishment.

*F. Proposed § 507.25(a)(6)—Contamination Precautions (Final § 507.25(a)(5))*

We proposed that plant management must ensure that reasonable precautions are taken so that plant operations do not contribute to the contamination of animal food, animal food-contact surfaces, and animal food packaging materials. We received no comments on this provision. We did replace the term “reasonable” with the term “adequate” to be more consistent with the rest of the regulatory text in subpart B.

*G. Proposed § 507.25(a)(7)—Testing Procedures (Final § 507.25(a)(6))*

We proposed that plant management must ensure that chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination.

(Comment 205) Some comments say that the need for chemical, microbial, or extraneous-material testing should be determined by a facility when identifying hazards and controls under subpart C, and therefore it should not be required under CGMPs. One comment says that it should be deleted because it is already addressed under the testing provisions in subpart C.

(Response 205) The CGMP regulations in subpart B are intended to establish baseline requirements that apply to all plants that manufacture, process, pack, or hold animal food (and thus are required to register as food facilities in accordance with § 415 of the FD&C Act). Using testing procedures, where necessary, to identify sanitation failures or to identify contaminated animal food may be an important component of manufacturing, processing, packing, or holding animal food. This type of testing may be independent of the requirements of subpart C, hazard analysis and risk based preventive controls, and therefore we have included it in the CGMP regulations. The provision provides flexibility for management to determine when testing is required by providing that testing be used “where necessary.”

*H. Proposed § 507.25(a)(8)—Contaminated Product (Final § 507.25(a)(7))*

We proposed that plant management must ensure that animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food. Whatever methods

are used to dispose of adulterated animal food, the methods should comply with state and local requirements.

(Comment 206) One comment requests that if we require reconditioning of an animal found to be adulterated, that we clarify that such a requirement does not apply to grains subject to the review inspection provisions provided for by 7 CFR 800.125 and 800.135.

(Response 206) In most cases, grains subject to the review inspection provisions provided for by 7 CFR 800.125 and 800.135 are RACs that are being held or transported and subpart B (including § 507.25(a)(7)) would not apply to the grains (see § 507.5(h)). In addition this provision only applies to animal food that has actually been found to be adulterated. The provisions provided for by 7 CFR 800.125 and 800.135 are administered by USDA’s Federal Grain Inspection Service and relate to their mission of facilitating the marketing of grains and related commodities.

*I. Proposed § 507.25(a)(9)—Protecting Against Contamination (Final § 507.25(a)(8))*

We proposed that plant management must ensure that all animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the contamination of animal food.

(Comment 207) Some comments suggest that we remove the requirement to minimize the potential for the growth of undesirable microorganisms, so that the requirement would be to minimize contamination of animal food or protecting against adulteration of animal food.

(Response 207) We decline this request. In addition to other contaminants, we conclude that it is important for an establishment to address undesirable microorganisms because they are a common source of contamination (78 FR 64736 at 64747).

*J. Proposed § 507.25(b)(1)—Raw Materials and Ingredients*

We proposed that raw materials and ingredients must be inspected to ensure that they are suitable for manufacturing/processing into animal food and handled under conditions that protect against contamination and minimize deterioration. We are revising the phrase “raw materials and ingredients” to read “raw materials and other ingredients” to make it clear that raw materials are ingredients.

(Comment 208) Some comments ask that we insert “as appropriate and necessary” into the requirement to inspect raw materials and ingredients to ensure that they are suitable for manufacturing/processing into animal food. Another comment says that “minimize deterioration” and “deterioration” are highly subjective and should be deleted.

(Response 208) We decline the requests. However, we have revised the regulatory text by replacing “inspected” with “examined.” We believe that the use of the word “examined” provides more clarity for the animal food industry because the term “inspected” often implies a regulatory activity. We believe such an examination is necessary to protect against contamination of animal food. An examination of raw materials and other ingredients may include basic activities such as a simple visual examination of the product (e.g., looking for broken bags), or performing a chemical or microbial analysis. Deterioration of animal food includes the loss of palatability or nutritive value typically associated with the animal food and we believe this could be a safety concern because animals are often fed the same food containing the same ingredients for prolonged periods of time. As a result, food refusal or consumption of animal food containing fewer nutrients than the animal food is expected to provide may result in poor animal productivity or health issues. Furthermore, deterioration can indicate that the animal food has been held under conditions that would also support the growth of undesirable microorganisms.

*K. Proposed § 507.25(b)(1)(i)—Shipping Containers*

We proposed that shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be inspected upon receipt to determine whether contamination or deterioration of animal food has occurred.

(Comment 209) Some comments say that inspection of shipping containers should be as appropriate and necessary, or at a frequency appropriate and necessary.

(Response 209) We decline this request. We have revised the regulatory text by replacing “inspected” with “examined.” We believe this change better conveys our intent that incoming containers consistently be checked to make sure there is no gross visible contamination or deterioration of animal food.

*L. Proposed § 507.25(b)(1)(ii)—Raw Materials*

We proposed that raw materials must be cleaned as necessary to minimize soil or other contamination.

(Comment 210) Many comments say that it is not always necessary to minimize soil contamination of raw materials because livestock routinely ingest soil when consuming pasture plants, hay, and other feeds without adverse consequences. Recommendations are to delete reference to soil or else insert “as appropriate.”

(Response 210) We agree. We have revised the regulatory text to remove the words “soil or other” from the requirement.

*M. Proposed § 507.25(b)(1)(iii)—Raw Materials*

We proposed that raw materials and ingredients must be stored under conditions that will protect against contamination and deterioration.

(Comment 211) One comment suggests that the requirement that raw materials be stored under conditions that will protect against contamination and deterioration be qualified to say “unreasonable contamination” and “excessive deterioration” to be more appropriate for raw materials that will be rendered. One comment asks that we delete “and deterioration.” Another comment suggests that a new section be added to require that air flow be controlled so that contamination does not spread from the raw material areas into the finished product areas of the plant.

(Response 211) We believe the rule as proposed is clear, and that the qualifiers suggested do not help reduce subjectivity and may create confusion about what is considered unreasonable or excessive. We decline to add a requirement that specifically addresses air flow, because ventilation is addressed in § 507.17(b)(3). Also, the broad language requires that raw materials and other ingredients must be stored under conditions that will protect against contamination, which would include protection from airborne contaminants. We have determined, however, that it is logical from a food safety standpoint to include rework in this provision. Therefore, we have incorporated proposed § 507.25(b)(3) into this requirement.

*N. Proposed § 507.25(b)(2)—Raw Materials Susceptible to Mycotoxins*

We proposed that raw materials and ingredients susceptible to contamination with mycotoxins or other

natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans.

(Comment 212) Several comments suggest that we eliminate this requirement because this activity belongs in subpart C, not subpart B. Other comments say that the requirement could be interpreted to mean that every load of incoming cereal grains must be evaluated for mycotoxins, which would not always be necessary. Other suggestions are to remove “evaluated” from the requirement, leaving only the requirement that raw materials and ingredients susceptible to mycotoxin contamination be used in a manner that does not result in harm to humans or animals.

(Response 212) We are locating requirements that are common to most establishments and plants and serve as a baseline for animal food safety in subpart B, current good manufacturing practice. Also, we do not intend that every load of grain received must be tested before it can be used. We intend for “evaluation” to be broad and flexible enough to consider any information that allows the plant to use the raw materials and other ingredients in a manner that does not result in harm to humans or animals. For example, an evaluation could be based on a general review of the weather conditions during the growing season and whether it could result in mycotoxins.

(Comment 213) One comment disagrees with our decision in the 2014 supplemental proposed rule to remove a requirement in § 507.25(b)(2) of the 2013 proposed rule for preventive controls for animal food that raw materials and ingredients not contain microorganisms injurious to human or animal health. This comment says that we should have modified the regulatory text to require that raw materials that are expected to contain levels of microorganisms that may be injurious to animal or human health, such as materials to be rendered, be stored and handled in a way that prevents contaminating the facility and finished product, and that the materials be treated (e.g., heat treated) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(Response 213) Incoming raw materials and other ingredients may contain microorganisms injurious to human or animal health. As we stated in the 2014 supplemental notice for animal food, we proposed to remove this requirement because we did not intend that incoming raw materials and

other ingredients must be tested for pathogens. Instead, we have included requirements that are meant to minimize the growth of undesirable microorganisms, and protect animal food from the contamination with undesirable microorganisms from raw materials and other ingredients, including those that may be injurious to human or animal health. We believe these requirements are sufficient to help ensure the safety of animal food.

*O. Proposed § 507.25(b)(3)—Raw Materials and Rework (Final § 507.25(b)(1)(iii))*

We proposed that raw materials and ingredients and all rework must be held in containers designed and constructed in a way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated.

(Comment 214) Some comments say that requiring that rework be held under conditions that will minimize the potential for growth of undesirable microorganisms is too prescriptive, and suggest that the requirement be modified to require that all rework must be held in a manner that prevents the animal food from becoming adulterated. Some comments say that this requirement should be addressed in subpart C rather than subpart B.

(Response 214) We disagree that the requirement should be addressed in subpart C instead of subpart B because we consider this to be a baseline requirement that should apply to all establishments that manufacture, process, pack, or hold animal food. However, we have decided that proposed paragraph (b)(3) contains requirements that are similar to proposed § 507.25(b)(1)(iii). We have moved this provision and included it in paragraph (b)(1)(iii) in the final rule.

*P. Proposed § 507.25(b)(4)—Frozen Raw Materials (Final § 507.25(b)(3))*

We proposed that raw materials and ingredients, if frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(Comment 215) One comment says that the requirement to keep frozen raw materials frozen or thaw them in a manner that minimizes the potential for the growth of undesirable microorganisms is redundant to other requirements in § 507.25(b)(1) and therefore should be deleted.

(Response 215) We decline this request. The requirements in § 507.25(b)(1) and 507.25(b)(1)(iii) address raw material and other ingredient inspection, storage and handling in general. This requirement speaks specifically to the storage and handling of frozen raw materials. We believe it is important for those establishments that use frozen raw material to thaw that material safely to minimize the potential for the growth of undesirable microorganisms during the thawing process.

*Q. Proposed § 507.25(c)(1)—Appropriate Conditions for Animal Food*

We proposed that animal food must be maintained under conditions, *e.g.*, appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding.

(Comment 216) Some comments say that the requirement to hold and manufacture products at a temperatures and relative humidity that will minimize the potential for growth of undesirable microorganisms should be deleted because it is not relevant to most animal food facilities. With this deletion, the requirement would be that animal food be maintained under conditions that would prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding.

(Response 216) Temperature and relative humidity are examples of conditions and may not apply to all plants and animal food. This requirement is important for animal food safety in plants that produce animal food that must be handled under specific processing, packing or holding conditions to prevent the growth of undesirable microorganisms and adulteration.

*R. Proposed § 507.25(c)(2)—Control of Undesirable Microorganisms*

We proposed that measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling  $a_w$ ) must be adequate to prevent adulteration of animal food.

(Comment 217) Most of the comments say that measures to significantly minimize or prevent the growth of undesirable microorganisms should be addressed under subpart C, and that this

requirement should be removed from the CGMPs. One comment recommends deleting only the examples of measures that might be taken. Another comment recommends deleting the term “significantly” as this term is not defined and is difficult to quantify.

(Response 217) We disagree that the requirement should be addressed in subpart C instead of subpart B. We consider controlling undesirable microorganisms to be a baseline requirement that should apply to all establishments that manufacture, process, pack, or hold animal food. We also decline the request to remove the examples of measures that can be used to significantly minimize or prevent the growth of undesirable microorganisms because they are examples of practical solutions already used by industry. We decline to delete the term “significantly.” The term “significantly minimize” is defined in § 507.3 and means to reduce to an acceptable level, including to eliminate.

*S. Proposed § 507.25(c)(3)—Work-in-Process and Rework*

We proposed that work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms.

(Comment 218) Some comments request that we delete “and the growth of undesirable microorganisms” and require only that work-in-process and rework be handled in such a way that it is protected against adulteration.

(Response 218) We decline this request. Because undesirable microorganisms are a common source of contamination of animal food, including work-in-process and rework, we have decided to specify that establishments must protect against the growth of undesirable microorganisms, as well as other contamination.

*T. Proposed § 507.25(c)(4)—Processing Steps*

We proposed that steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food.

(Comment 219) One comment suggests that we revise the requirement to say that steps be performed in a way that protects against animal food adulteration rather than protects against animal food contamination. Another comment suggests that the requirement be deleted because it is redundant to other requirements in the proposed rule.

(Response 219) As discussed in Response 167, we believe contamination

is the better word to use in this context. These specific requirements provide a level of detail that we believe is important because these activities are common in the animal food industry and can contribute to the contamination of animal food. We believe that this requirement for these activities is not redundant to other requirements in this final rule.

*U. Proposed § 507.25(c)(5)—Processing Operations*

We proposed that filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms.

(Comment 220) One comment requests that we delete “and the growth of undesirable microorganisms” and require only that operations be performed in such a way that the animal food is protected against adulteration. Another comment suggests that the requirement be deleted because it is redundant, but does not identify the redundant section.

(Response 220) As discussed in Response 167, we believe contamination is the better word to use in this context. These specific requirements, including the requirement for the protection against the growth of undesirable microorganisms, provide a level of detail that we believe is important because these activities are common in the animal food industry and can contribute to the contamination of animal food. We believe that these requirements for these activities are not redundant with other requirements in this final rule.

*V. Proposed § 507.25(c)(6)—Controlling Water Activity ( $a_w$ )*

We proposed that animal food that relies on the control of water activity for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(Comment 221) Some comments request that we delete the requirement because controlling water activity belongs in subpart C, not in the CGMP regulations. Another comment says that controlling moisture level is not sufficient and the requirement should be revised to require that animal food that relies on the control of water activity for preventing the growth of undesirable microorganisms be processed to and maintained at a suitable water activity, not a safe moisture level. We also received comments asserting that water activity may not be the only factor responsible for preventing the growth of undesirable

microorganisms in dry products and that we should modify the regulatory text to take into account other synergistic barriers for microbial growth and toxin formation.

(Response 221) We disagree that controlling water activity belongs in subpart C. While not all animal food establishments rely on the control of water activity for preventing the growth of undesirable microorganisms in their animal food, we have determined it is important to have this requirement in CGMP regulations for those establishments that do, considering the potential public health significance of undesirable microorganisms. We agree that the term “safe water activity level” is more commonly understood by the animal food industry than “safe moisture level” and we have revised the regulatory text accordingly. We agree with the comment that water activity may not be the only factor responsible for preventing growth of undesirable microorganisms in certain animal food and have revised the regulatory text to clarify that such products rely “principally” on the control of water activity.

*W. Proposed § 507.25(c)(7)—Controlling pH*

We proposed that animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH.

(Comment 222) Some comments request that we delete this proposed requirement because controlling pH belongs in subpart C, not in subpart B. One comment also says that it is too prescriptive and duplicative of protections against adulteration in other proposed sections of subpart B.

(Response 222) We decline the request. While not all animal food establishments principally rely on the control of pH for preventing the growth of undesirable microorganisms in their animal food, we have determined it is important to have this requirement in the CGMP regulations for those establishments that do, considering the potential public health significance of undesirable microorganisms.

**X. Proposed § 507.25(c)(8)—Ice**

We proposed that when ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

(Comment 223) One comment suggests that this requirement be deleted because ice is rarely used in the

manufacturing/processing of animal food.

(Response 223) We decline this request. We have established this requirement to help ensure that when ice is used for the manufacture of animal food, the ice is made from water that is safe so that it does not contaminate the animal food it contacts.

**XXI. Subpart B: Comments on Proposed § 507.27—Holding and Distribution**

*A. Proposed § 507.27(a)—Holding and Distribution*

We proposed that animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration.

(Comment 224) A few comments request that we remove “minimize deterioration” from this requirement. These comments say that although deterioration may lead to animals refusing food, an animal’s refusal of food does not necessarily mean that the food has deteriorated. The comments suggest that we instead use the phrase “ensure product integrity throughout the intended shelf life,” or that we clarify the definition of deterioration if we do not remove it.

(Response 224) We decline this request. We believe it is important that animal food be held and distributed in manner that does not lead to deterioration. Deterioration of animal food includes the loss of palatability or nutritive value typically associated with the animal food and we believe this could be a safety concern because animals are often fed the same food containing the same ingredients for prolonged periods of time. As a result, food refusal or consumption of animal food containing fewer nutrients than the animal food is expected to provide may result in poor animal productivity or health issues. Furthermore, deterioration can indicate that the animal food has been held under conditions that would also support the growth of undesirable microorganisms.

*B. Proposed § 507.27(a)(1)—Containers*

We proposed that containers used for holding animal food for distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent contamination of animal food.

(Comment 225) A few comments request that the terms “designed” and “constructed of appropriate material,” which may have different interpretations, be replaced by “fit for purpose” a term recognized by the animal food industry.

(Response 225) We decline the request. We believe the terms “designed” and “constructed of appropriate material” are well understood by the animal food industry and “fit for purpose” does not improve clarity.

(Comment 226) A few comments note containers used to hold animal food may include bins, totes or other intermediate storage containers, each of which may require differing levels and frequency of cleaning. Some of these comments ask that we add the phrase “where necessary” when discussing cleaning to provide flexibility.

(Response 226) We agree that containers used to hold animal food will require different cleaning methods and frequency of cleaning. These differences may result from the types of containers used, the amount and type of animal food held, the frequency at which containers are reused, as well as other factors. As a result, we agree that it is appropriate to include language that indicates that different methods and frequencies of cleaning may be appropriate to protect against contamination of the animal food and we have revised the regulatory text to add “as necessary” after cleaned.

*C. Proposed § 507.27(a)(2)—Protection From Contamination*

We proposed that animal food held for distribution must be held in a way that prevents contamination from sources such as trash and garbage.

(Comment 227) A few comments request that the phrase “from sources such as trash and garbage” be deleted. A few comments request that the term “garbage” not be used because some products that may be considered garbage may actually be suitable for use as animal food. Some of these comments suggested alternative language.

(Response 227) We agree in part with this comment. The mistaken inclusion of trash or garbage into animal food could be a potential source of contamination. The terms “trash” and “garbage” are intended in their general sense and refer to items that are not suitable for animal food, or are not intended for animal food. However, under the Swine Health Protection Act, “garbage” as defined by the act is prohibited for use as food for swine, unless it is treated to kill disease organisms. For this reason, and because the terms can be considered synonyms, we are removing the term “garbage” throughout subpart B to avoid confusion.

*D. Proposed § 507.27(a)(3)—Labeling of Animal Food Held for Distribution (Final § 507.27(b))*

We proposed that labeling identifying the product by the common or usual name must be affixed to or accompany the animal food.

(Comment 228) Some comments support the labeling requirement because accurate identification of animal food throughout the distribution chain is an important food safety step and loss of identity can have serious animal and human health implications. One comment suggests that this requirement be revised to specify that the proposed labeling be required during holding and distribution of both packaged animal food and bulk animal food. One comment says that FDA's primary interest should be identification, not labeling, because labeling for animal food being held for distribution in bulk is impractical. The comment also notes that plants may use a central computer system or other method to identify animal food location. A few comments suggest that we should require that animal food held for distribution be labeled as required by regulations for finished products.

(Response 228) We agree that animal food may be identified in the plant through methods other than labeling. We expect that while animal food is being processed in the plant that the animal food is accurately identified as required in § 507.25(a)(2) of this final rule.

We have moved the requirement that labeling must include information and instructions for safely using the animal food product for the intended animal species from proposed § 507.25(a)(3) "Plant operations" in the 2014 supplemental proposed rule to § 507.27(b) of "Holding and distribution" to clarify that this labeling information must be included when the product is ready for distribution. We think that placing the labeling requirements for animal food products ready for distribution under "Holding and distribution" will help reduce confusion and make these requirements for labeling for distribution easier to find in the final rule. Labeling that meets applicable FDA labeling regulations must accompany or be affixed to the animal food and that the labeling must include, when applicable, information and instructions for safely using the product for the intended animal species. We have added the clarification that it is "when applicable," understanding that not all animal food product will need information on its safe use. We have

deleted the requirement that labeling that identifies the product by the common or usual name must be affixed to or accompany the animal food in this section because it is already covered by current FDA regulations.

*E. Proposed § 507.27(b)—Shipping Containers (Final § 507.27(c))*

We proposed that shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

(Comment 229) Some comments state that the requirement to inspect shipping containers is not practical because containers are frequently reused without intervening cleaning or because the animal food is distributed in dedicated containers or vehicles. One comment says that it is pointless to inspect the containers when the product being distributed may be decayed and may be dumped on the ground for the animals to eat. Other comments state that sometimes nobody is available to inspect the vehicle when third-party transportation is used and that third-party transportation vehicles may already contain animal food or by-products because they are used to pick up from several facilities. Some comments say that contractual provisions specify how third-party shipping container may be used, and therefore inspection prior to each load would not be necessary to manage this risk.

(Response 229) Though we disagree with the comments, we are revising the regulatory text in §§ 507.27 and 507.28 to replace the word "inspected" with "examined". We believe that the use of the word "examined" provides more clarity for the animal food industry because the term "inspected" often implies a regulatory activity. This does not mean that the shipping container must be cleaned prior to each use. The plant or facility is responsible for examining shipping containers and bulk vehicles that it uses to transport the animal food (e.g., the facility transports the animal food, or arranges with a third-party to distribute the animal food to the facility's customer). We expect the plant or facility personnel involved in the process of loading the product into the shipping container or vehicle to be aware of the condition of the shipping container or vehicle, and consider whether its condition would contaminate the animal food. This examination could include viewing the shipping container or vehicle to observe whether there are any unusual residues in it that may contaminate the animal

food, or it could be simply knowing what the shipping container or vehicle had previously been used for and because of that, whether the container needed to be cleaned prior to use. We do not expect a plant or facility to examine the shipping container or bulk vehicle when a customer transports the animal food or arranges for a third-party to pick up the animal food. However, a plant or facility may choose to examine a customer's shipping container or bulk vehicle as a business decision to ensure that shipping container or bulk vehicle will not lead to the contamination or adulteration of the animal food.

*F. Proposed § 507.27(c)—Returned Animal Food (Final § 507.27(d))*

We proposed that animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed. We received no comments on this requirement and are finalizing it as proposed.

*G. Proposed § 507.27(d)—Unpackaged Bulk Animal Food (Final § 507.27(e))*

We proposed that unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food. We received no comment on this requirement and are finalizing it as proposed with one wording change. We have added the term "unsafe" to modify cross contamination to make it clear that this requirement applies to cross contamination that would result in unsafe animal food.

**XXII. Subpart B: Comments on Proposed § 507.28—Holding and Distribution of Human Food By-Products for Use as Animal Food**

We proposed to add provisions for human food by-products for use as animal food. We proposed that the requirements of this part (with the exception of proposed § 507.28) would not apply to by-products of human food production that are packed and held by that facility for distribution as animal food if certain requirements were met (see discussion in section XIII). The facility would only need to comply with proposed § 507.28 of this part and proposed § 117.95 of part 117 (which contains identical requirements).

*A. Proposed § 507.28(a)—Contamination*

We proposed that human food by-products held for distribution as animal food must be held under conditions that will protect against contamination.



(Comment 230) Multiple comments request that the term “human food by-products,” not “animal food,” be used throughout §§ 507.28 and 117.95 (of part 117). These comments note that it is important to make clear that human food by-products do not change from human food to animal food until they are transferred to someone with the intent to use it as an animal food.

(Response 230) We disagree that human food by-products are not animal food until they have been transferred to someone with the intent to use it as animal food. Furthermore, we think that the use of the term “human food by-products” would be more confusing here because not all human food by-products are intended for use as animal food. However, we have revised the regulatory text to use the term “human food by-products for use as animal food” throughout this section to differentiate it from other requirements in parts 117 and 507. The purpose of these provisions in §§ 507.28 and 117.95 is to ensure that when the processor is holding and distributing human food by-products for use as animal food, the by-products are recognized as human food by-products for use as animal food by all employees and treated as such.

#### *B. Proposed § 507.28(a)(1)—Containers*

We proposed that containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food.

(Comment 231) Some comments state that the provisions about containers are too prescriptive because by-products may be held and conveyed in ways that do not use containers (such as using storage silos, augers, pipes, chutes or conveyor belts to convey product directly to transportation vehicles). Some comments request clarification on cleaning the containers because they are frequently reused for holding by-product without intervening cleaning procedures.

(Response 231) We agree that human food by-products for use as animal food may be held and conveyed using equipment instead of containers. We have revised the regulatory text to add “equipment” in addition to containers, and have added the words “convey” and “cleaned as necessary” (see regulatory text for §§ 507.28(a)(1) and 117.95(a)(1)). We expect containers and equipment to be cleaned at a frequency that protects against contamination of human food by-products for use as animal food by contaminants that could be harmful to the public (human and

animal) health. This may not require cleaning after each use.

#### *C. Proposed § 507.28(a)(2)—Protection From Contamination*

We proposed that animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage. As discussed in Response 227, we have revised the regulatory text to remove the term garbage. We did not receive additional comments related to this paragraph and are finalizing the proposed language with changes previously discussed. (See Responses 227 and 230.)

#### *D. Proposed § 507.28(a)(3)—Labeling*

We proposed that labeling identifying the product by the common or usual name must be affixed to or accompany animal food.

(Comment 232) Some comments state that by-products only need to be reasonably identified while they are being held by the facility and state that once they are ready for distribution, they should be labeled in conformance with applicable regulatory requirements. One comment states that what is considered the “common and usual name” varies between the human food industry, the animal food industry, producers and regulators. This comment suggests that FDA work with regulatory partners to provide guidance on the proper “common and usual name” of by-products to promote consistency.

(Response 232) We agree in part with these comments. As with animal food subject to all of part 507, we expect that while human food by-product for use as animal food is being held in the human food facility, it is accurately identified. (See Response 201.) We have revised the regulatory text to clarify that the human food by-product for use as animal food must be accurately identified while held in the human food facility (see § 507.28(a)(3) of the final rule). We retained the requirement that when the human food by-product for use as animal food is distributed, it must have labeling that identifies the common or usual name of the product affixed to or accompanying it (see § 507.28(b) of the final rule).

Our CPG Sec. 665.100 discusses common or usual names for animal food ingredients (Ref. 25). There are also industry and other regulatory resources that may assist facilities in determining the common or usual name of the animal food. For example, USDA maintains the National Nutrient Database for Standard Reference, a database that includes a list of names for human food items (Ref. 30). We will take into consideration these comments

when determining whether to issue additional guidance about the common or usual name of animal food.

(Comment 233) One comment requests that FDA require human food manufacturers to document the recipient’s intended use of the by-products so the by-products do not become ingredients of human food. This comment also requests that these by-products be required to be labeled with the statement “For Use as Animal Feed Only.”

(Response 233) We decline these requests. Human food is produced under human food regulations, such as CGMPs, and HACCP regulations for juice and seafood, and facilities must meet the applicable requirements for food that is manufactured, processed, packed, or held to ensure the safety of that human food. This requirement in § 507.28 is meant only for human food by-products for use as animal food that are only held and distributed (*i.e.* not further processed). Human food by-products may be used as human food ingredients as long as they are in compliance with the applicable human food regulations. However, we would not object if a facility labels the human food by-products for use as animal food “For Use as Animal Food Only.”

#### *E. Proposed § 507.28(b)—Shipping Containers*

We proposed that shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food. This provision is paragraph (c) of this section in the final rule.

(Comment 234) We received the same comments on § 507.28(c) as § 507.27(c). (See Comment 229.)

(Response 234) We are revising the regulatory text in §§ 507.28(c) and 117.95(c). (See Response 229.)

### **XXIII. Subpart C: Comments on Overall Framework for Hazard Analysis and Risk-Based Preventive Controls**

In the 2014 supplemental notice for preventive controls for animal food, we proposed a series of changes to proposed subpart C and reopened the comment period specifically with respect to these changes. The proposed changes included: (1) Eliminating the term “hazard reasonably likely to occur” throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term); (2) adding a new defined term, “significant hazard,” and, in general, using this new term instead of “hazard reasonably likely to occur” throughout the re-

proposed regulations; (3) defining “known or reasonably foreseeable hazard” in place of “reasonably foreseeable hazard” and clarifying that the new term means a hazard “that has the potential to be associated with the facility or the food” rather than “a potential . . . hazard that may be

associated with the facility or the food”; and (4) providing additional flexibility to address concerns about rewriting existing plans or programs to conform with the requirement of the preventive controls rule.

We received many comments on the overall framework for hazard analysis

and risk-based preventive controls. We discuss each of these comments in the discussion of the specific regulatory text applicable to each comment. We show highlights of the changes we made after considering these comments in table 9.

TABLE 9—REVISIONS TO THE OVERALL FRAMEWORK FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Section	Description	Revision
507.3	Definition of “significant hazard”	Revise the proposed term “significant hazard” to “hazard requiring a preventive control” and revise the definition to emphasize the role of risk in determining whether a hazard requires a preventive control.
507.3	Definition of “corrections”	Define the term “correction” to distinguish “corrections” from “corrective actions.”
507.34(c)(1), 507.39(a), 507.40, 507.45(a), 507.47(a), 507.49(a), 507.49(b).	Flexibility in preventive controls and preventive control management components for monitoring, corrective actions and corrections, and verification.	Clarify that preventive control management components depend on the role of a preventive control in the facility’s food safety system, as well as the nature of the preventive control.
507.33(b)(1)	Hazard identification	Emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).
507.33(b)(2)		
507.40(c)(2)	Monitoring records	Provide for the use of “exception records” for monitoring preventive controls.
507.42(a)	Corrective action procedures	Clarify that corrective action procedures depend on the nature of the hazard.
507.42(c)	Corrections	Provide for additional circumstances when corrections, rather than corrective actions, are warranted.
507.47(c)	Preventive controls that do not require validation.	Clarify that a list of preventive controls that do not require validation is not an exhaustive list.
507.49(a)(5)	Activities to verify implementation and effectiveness.	Clarify that there could be alternative verification activities of implementation and effectiveness other than those that we specify in the rule.
507.49(b)	Written procedures for verification of implementation and effectiveness.	Clarify that written procedures for verification of implementation and effectiveness are established and implemented as appropriate to the role of the preventive control in the facility’s food safety system, as well as appropriate to the facility, the animal food, and the nature of the preventive control.
507.50(b)	Reanalysis	Provide for reanalysis of an applicable portion of the food safety plan (rather than the complete food safety plan) in specified circumstances.

**XXIV. Subpart C: Comments on Proposed § 507.31—Food Safety Plan**

We proposed requirements for a food safety plan. Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following sections, we discuss comments that ask us to clarify the proposed requirements, or disagree with, or suggest one or more changes to the proposed requirements. After considering these comments, we are finalizing the provisions as proposed, with editorial and conforming changes as shown in table 31.

We proposed that the food safety plan be under the oversight of one or more “qualified individuals.” As discussed in section VIII.A.24, we have changed the proposed term “qualified individual” to

“preventive controls qualified individual” because we are establishing a new definition for “qualified individual,” with a meaning distinct from “preventive controls qualified individual.” To minimize the potential for confusion for when the term “qualified individual” refers to the proposed meaning of the term and when the term “qualified individual” refers to the meaning of that term as finalized in this rule, in the remainder of this document we substitute the new term “preventive controls qualified individual” for the proposed term “qualified individual,” even though the proposed rule used the term “qualified individual.” Likewise, we substitute the new term “preventive controls qualified individual” for the proposed term “qualified individual” when describing the comments to the proposed rule, even though those comments use the term “qualified individual.”

We proposed that several other provisions of subpart C be under the oversight of a “qualified individual” (now “preventive controls qualified individual”), and also proposed requirements that would apply to the “qualified individual” (now “preventive controls qualified individual”). See, e.g., §§ 507.47, 507.49, 507.50, 507.51, 507.53, and 507.55). As discussed in the preceding paragraph, in the remainder of this document, we substitute the new term “preventive controls qualified individual” for the proposed term “qualified individual,” when describing these proposed provisions and the comments to these proposed provisions.

**A. Proposed § 507.31(a)—Requirement for a Food Safety Plan**

We proposed that you must prepare, or have prepared, and implement a written food safety plan.

(Comment 235) Some comments ask us to develop a final preventive controls

rule with separate requirements for food safety plans for manufacturers of livestock food and for manufacturers of food for other animal species.

(Response 235) We decline this request. The required elements of the food safety plan listed in § 507.31(c) apply to each type of animal food manufactured at a facility. Animal food types or production method types may be grouped together if the hazards, preventive controls, parameters, and management components (monitoring, corrective actions and corrections, and verification) necessary to ensure the effectiveness of the preventive controls are essentially identical. We have provided additional flexibility within the required elements of the food safety plan in the final rule. Therefore the same requirements for a food safety plan are applicable to a facility that makes food for livestock and one that makes food for other animal species.

(Comment 236) Some comments ask us to add regulatory text to this section stating that an existing written food safety plan, including any plan intended to satisfy the requirements of a foreign jurisdiction or that complies with existing standards developed by other organizations (such as PAS 222 (Ref. 27)), satisfies the requirements of this section if it contains the information specified by § 507.31(c).

(Response 236) To the extent that an existing food safety plan includes all required information, a facility can use such plans to meet the requirements of this rule. We expect that many existing plans will need only minor supplementation to fully comply with these requirements. Relying on existing records, with supplementation as necessary to satisfy the requirements of the preventive controls rule, is acceptable (see § 507.212).

(Comment 237) Some comments agree with our previous statements that facilities should be able to group animal food types or production method types if hazards, control measures, parameters, and required procedures, such as monitoring, are identical (78 FR 64736 at 64779). Some comments ask us to emphasize that each facility needs only one food safety plan, regardless of how many animal species it makes food for, or how many different types of food it makes. These comments further state that facilities are under the impression that any given facility will need multiple food safety plans if they make many food types or make food for multiple animal species.

(Response 237) We are requiring that a facility have a written food safety plan that covers all types of animal food it manufactures, processes, packs, or holds

and all of the animal species for which the food is intended. We recognize that, to the extent that the controls are the same, there may be common controls that broadly apply to some or all of a facility's animal food products.

However, any product-, process-, or animal species-specific differences must be carefully delineated and observed in practice.

In some facilities with limited types of animal food products or animal species for which the food is intended, the written food safety plan may contain a single set of procedures that addresses all of the products produced. For other facilities, there may not be a practical way to group the products and the written food safety plan may need to contain more than one set of procedures to address all of its products.

(Comment 238) Some comments ask us to emphasize that "written" means "any type of recordable and reproducible format" (e.g., as paper or electronic documents). Some comments ask us to specify that the components of the food safety plan need not be in a single document or stored in one place.

(Response 238) A "written" food safety plan can be either a paper document or an electronic document, as provided for by § 507.202(a). The final rule specifies that required information (which would include the food safety plan) does not need to be kept in one set of records (see § 507.212(b)), and a food safety plan may be prepared as a set of documents kept in different locations within the facility (e.g., based on where they will be used), provided that each set of documents is onsite. As provided in the recordkeeping provisions, electronic records are considered to be onsite if they are accessible from an onsite location.

(Comment 239) Some comments ask us to provide that the food safety plan be handled at the corporate level rather than the facility level if a corporation owns many facilities.

(Response 239) A corporation may designate an individual at the corporate level as the owner, operator, or agent in charge of a particular facility. In addition, an employee of the corporation, whether at headquarters or at another facility owned by the corporation, may provide input into a particular facility's food safety plan. As previously discussed, the food safety plan does need to be facility specific (see the discussion of the facility-based nature of the food safety plan in the 2013 proposed preventive controls rule for animal food, 78 FR 64736 at 64780). For example, even if a corporation makes similar products at two separate facilities, it is unlikely that the two

facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility may affect its approach to preventive controls.

(Comment 240) Some comments assert that a food safety plan should only be required for high-risk processing facilities because adhering to CGMPs is sufficient for low-risk facilities. Some comments assert that FSMA does not authorize us to require farms to develop food safety plans.

(Response 240) We decline the request to establish additional exemptions based on risk, other than the exemptions for on-farm low-risk activity/animal food combinations provided by section 103(c)(1)(D) of FSMA (§ 507.5(e) and (f)). The applicability of the requirements of the preventive controls rule to facilities that are required to register is required by the statute (see the definition of facility in section 418(o)(2) of the FD&C Act). Section 418(h) of the FD&C Act requires that a facility prepare and implement a food safety plan, unless an exemption applies. Neither FSMA nor this rule establishes an exemption for "low-risk" facilities, including "low-risk" facilities that are regularly inspected by State, local, or tribal government Agencies. A farm is not subject to this rule for activities within the "farm" definition. A farm mixed-type facility that is a small or very small business and only conducts the low-risk activity/animal food combinations specified in § 507.5(e) and (f) is exempt from the requirements of subparts C and E, including the requirement for a food safety plan.

(Comment 241) Some comments ask us to clarify that a food safety plan is not required when a facility is exempt as a qualified facility (§ 507.7(a)) or as a facility solely engaged in the storage of packaged food that is not exposed to the environment (§ 507.10)

(Response 241) A qualified facility is exempt from the requirements of subparts C and E, including the requirement to prepare and implement a food safety plan, and is instead subject to the requirements in § 507.7. Likewise, a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is exempt from the requirements of subparts C and E, including the requirement to prepare and implement a food safety plan. See Response 242 for unexposed, packaged TCS animal food.

(Comment 242) Some comments ask us to clarify that a food safety plan is not required for facilities that store unexposed, refrigerated, packaged TCS animal foods.

(Response 242) We agree that a facility “solely engaged” in the storage of unexposed, refrigerated, packaged TCS animal food is exempt from the requirements of subparts C and E, including the requirement to prepare and implement a food safety plan, and instead is subject to the modified requirements in § 507.51 (see § 507.10). However, if a facility engages in other activities in addition to the storage of unexposed, refrigerated, packaged TCS animal food, the exemption does not apply. In such a case, the facility must prepare and implement a food safety plan. However, the modified requirements of § 507.51 can be informative with respect to what the food safety plan could include regarding the storage of unexposed, refrigerated, packaged TCS animal food.

*B. Proposed § 507.31(b)—Preparation of the Food Safety Plan by a Preventive Controls Qualified Individual*

We proposed that the food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(Comment 243) Some comments ask us to provide for a group of qualified individuals to prepare, or oversee the preparation of, a food safety plan.

(Response 243) The proposed regulatory text included in the 2014 supplemental notice provides for the food safety plan to be prepared, or its preparation overseen, by one or more preventive controls qualified individuals, and we are finalizing it as proposed.

*C. Proposed § 507.31(c)—Contents of a Food Safety Plan*

We proposed that the written food safety plan must include the written hazard analysis, preventive controls (including the supplier program and recall plan), procedures for monitoring the implementation of the preventive controls, corrective action procedures, and verification procedures. As discussed in more detail in section XL, we have revised the phrase “supplier program” to “supply-chain program” throughout the regulatory text. In the remainder of this document, we use the phrase “supply-chain program” in section headings and when referring to the provisions of the final rule. We continue to use the term “supplier program” when describing the proposed provisions and the comments regarding the proposed provisions.

(Comment 244) Some comments ask us to specify that sanitation controls must be in the food safety plan. Some comments ask us to require that the food safety plan include the qualifications of the preventive controls qualified individual.

(Response 244) Sanitation controls are one type of preventive control. As appropriate to the facility and the animal food (e.g., to control hazards such as environmental pathogens), sanitation controls for cleanliness of animal food-contact surfaces and prevention of cross contamination are required to be in the food safety plan (§ 507.34(c)(2)).

We are requiring that you document all applicable training taken by the preventive controls qualified individual (see § 507.53(d)). This documentation must be established and maintained (see § 507.55(a)(6)).

*D. Proposed § 507.31(d)—Records*

We proposed that the food safety plan is a record that is subject to the recordkeeping requirements of subpart F. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

*E. Comments on Potential Requirements for Submission of a Facility Profile to FDA*

We requested comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan (78 FR 64736 at 64809). This information, which could be referred to as a “facility profile,” could be submitted through an electronic form using a menu selection approach at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. We described potential benefits to having a facility’s food safety plan in advance of an inspection, such as aiding in the efficient oversight of preventive controls by allowing us to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards). We noted that facilities could benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. We requested comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. We also requested comment on any additional benefits that might be obtained from using such an approach

and any potential concerns with this approach.

We noted that we had previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (**Federal Register** of May 11, 2012, 77 FR 27779). In contrast to the voluntary submission of food facility profile information described in that document, in the 2013 proposed preventive controls rule for animal food we requested comment on whether the submission of such information should be required.

(Comment 245) Some comments state that submission of a facility profile would be useful and support requiring such a submission. However, most of the comments that addressed our request for comments on such a submission express concern. Some comments assert that requiring submission of a facility profile is outside of FDA’s statutory authority under FSMA. Other comments assert that submitting a facility profile would not advance food safety goals or have a commensurate benefit to food safety. Some comments express concern about protection of confidential information. Other comments express concerns that we would misinterpret the submitted information in the absence of discussion with the facility. Some comments assert that receiving and evaluating the submitted information would be too time-consuming for FDA, whereas other comments assert that submitting the information would be too time-consuming for the facility. Some comments state that a subset of the information that would be submitted could be found in the Establishment Inspection Reports. Some comments assert that we could use information already available through the RFR to identify facilities that have needed to address a serious food safety violation and target our inspectional resources to those facilities. Some comments state that a facility profile is a not a static document and would be very difficult to keep up to date. Other comments state that such a profile would be of limited or no use to FDA because information regarding hazards and preventive controls is best assessed in the context of a full food safety plan and related documentation. These comments further state that food safety plans will constantly evolve as facilities undertake new activities and refine their processes; a profile would present only a static picture of the food safety measures in place at a given time; FDA has already implemented changes to the

registration process that require facilities to provide more information about the activities at the facility. One comment asks us to refrain from requiring written or electronic submission of facility profiles.

(Response 245) We have decided that we will not establish a requirement for submission of a facility profile. We will explore other mechanisms to achieve the goals we described in the 2013 proposed preventive controls rule for animal food.

**XXV. Subpart C: Comments on Proposed § 507.33—Hazard Analysis**

We proposed requirements for hazard analysis, including hazard identification

and hazard evaluation. Some comments support the proposed requirements without change. For example, some comments support our proposal for the hazard analysis to address “known or reasonably foreseeable hazards” because this is consistent with Codex. Other comments agree that the hazard analysis should address both the severity of the potential hazard and the probability that the hazard will be present in an animal food product. Other comments state that testing for environmental pathogens may be impractical in certain situations for facilities in chemical plants that also produce food additives and that the proposed requirements for hazard

evaluation make it clear that in such facilities environmental monitoring would not be required. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 10 with editorial and conforming changes as shown in table 31.

TABLE 10—REVISIONS TO THE PROPOSED REQUIREMENTS FOR HAZARD ANALYSIS

Section	Description	Revision
507.33(a)(1) .....	Requirement for a hazard analysis	Specify that a facility must “conduct a hazard analysis” to identify and evaluate known or reasonably foreseeable hazards, rather than merely specify that a facility must “identify and evaluate” known or reasonably foreseeable hazards.
507.33(a)(2) .....	Requirement for the hazard analysis to be written.	Clarify that the hazard analysis must be written, regardless of its outcome.
507.33(b)(1) and (b)(2) .....	Hazard identification .....	Emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).
507.33(b)(1)(ii) .....	Hazard identification .....	Replace “imbalances” with “deficiencies or toxicities” and provide examples of these hazards.
507.33(b)(1)(iii) .....	Hazard identification .....	Add examples of physical hazards.
507.33(c)(2) .....	Hazard evaluation .....	Provide that hazard evaluation does not need to include an evaluation of environmental pathogens whenever finished animal food is exposed to the environment prior to packaging if the packaged food includes a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.
507.33(d)(10) .....	Hazard evaluation .....	Provide an example of “other relevant factor” that the hazard evaluation must consider (the example is the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins)).

*A. Proposed § 507.33(a)—Requirement for a Written Hazard Analysis*

We proposed that you must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are significant hazards. We also proposed that the hazard analysis must be written.

As discussed in Response 62, we have revised the term “significant hazard” to “hazard requiring a preventive control.” In addition, we have revised the regulatory text to specify that the outcome of a hazard analysis is to determine whether there are any hazards requiring a preventive control.

(Comment 246) Some comments ask us to specify that the rule requires a written hazard analysis even if the hazard analysis concludes that no hazards exist.

(Response 246) As proposed, the regulatory text would require a written hazard analysis even if the hazard analysis concludes that no hazards exist. To make this clearer, we have made two revisions to the regulatory text. First, we have revised the regulatory text to specify that a facility must “conduct a hazard analysis” to identify and evaluate known or reasonably foreseeable hazards, rather than merely specify that a facility must “identify and evaluate” known or reasonably foreseeable hazards. Second, we have revised the regulatory text to specify that the hazard analysis must be written regardless of its outcome.

(Comment 247) Some comments assert that a facility should not be able to conclude that no hazard exists in its production process and that any such conclusion reached should be a “red flag” to FDA investigators.

(Response 247) The purpose of a hazard analysis is to identify and evaluate known or reasonably foreseeable hazards to determine

whether there are any hazards requiring a preventive control. If a facility appropriately determines, under the oversight of a preventive controls qualified individual, that no such hazards exist, then that is the outcome of its hazard analysis, and the facility must document that outcome in its written hazard analysis.

We expect that there will be many circumstances in which a facility appropriately determines that certain biological, chemical, or physical hazards are not hazards requiring a preventive control that must be addressed in the food safety plan. The provisions of the rule that allow a facility to appropriately determine that a particular hazard is not a hazard requiring a preventive control in certain animal food products are not equivalent to an exemption from the rule. For example, a facility that appropriately determines that there are no hazards requiring a preventive control associated with its animal food products

must document that determination in its written hazard analysis (§ 507.33); however, no preventive controls, including supplier verification activities, and associated management components would be required in such a situation. There are several types of animal food products for which a facility may determine that there are no hazards requiring a preventive control. Such products include, but are not limited to: alfalfa cubes, vegetable oils, and molasses.

However, we agree that our investigators should take appropriate steps to evaluate a facility's hazard analysis when the outcome is that there are no hazards requiring a preventive control. We expect that our investigators would both review the facility's written hazard analysis and discuss the outcome with the facility. During the initial stages of implementation, we also expect that our investigators will ask subject matter experts in our Center for Veterinary Medicine (CVM) to review such a hazard analysis. Over time, as our investigators gain experience with appropriate determinations that there are no hazards requiring a preventive control, we expect that there will be fewer circumstances in which our investigators would consult CVM about such an outcome.

(Comment 248) Some comments ask us to require that the hazard analysis be re-evaluated every 3 years and updated as needed.

(Response 248) The written hazard analysis is one component of the food safety plan, and the food safety plan is subject to reanalysis at least once every 3 years, and sooner under certain circumstances (see § 507.50).

(Comment 249) Some comments ask us to modify the provision to specify that the hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility, *including hazards in the raw materials and ingredients used in the animal food* (emphasis added).

(Response 249) We decline this request. Other provisions in the requirements for hazard analysis specify that the hazard evaluation must consider raw materials and ingredients (see § 507.33(d)(3)). It is not necessary to repeat the specific requirements associated with the hazard evaluation in the provision that directs each facility to conduct a hazard analysis.

(Comment 250) Some comments state that the standard for hazard analysis in the preventive controls rule should both align with the re-proposed requirements for hazard analysis set forth in the

supplemental FSVP notice and be consistent with the statutory standard for hazard analysis in section 418(b)(1) of the FD&C Act.

(Response 250) We have aligned the requirements of the animal food preventive controls rule and the proposed FSVP rule to the extent practicable, consistent with the applicable statutory requirements.

#### *B. Proposed § 507.33(b)—Hazard Identification*

We proposed that the hazard identification must consider hazards that include biological, chemical, and physical hazards. We proposed examples of biological hazards (*e.g.*, microbiological hazards such as parasites, environmental pathogens, and other pathogens) and chemical hazards (*e.g.*, radiological hazards and substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances).

In the preamble for the 2013 proposed preventive controls rule for animal food, we explained that nutrient imbalance hazards can result from excessive levels of a nutrient in animal food resulting in toxicity to the animal, or a nutrient deficiency in the animal food that can compromise the health of an animal and provided examples (78 FR 64736 at 64782). These nutrient imbalance hazards are of particular concern for animals that consume one animal food type as their sole source of nutrition. Because different species have different nutritional needs, certain quantities of a nutrient that are needed by one species of animal could pose a health risk to another species of animal.

In the preamble for the 2013 proposed preventive controls rule for animal food we also provided examples of physical hazards (*e.g.*, stones, glass, or metal fragments that could inadvertently be introduced into animal food) (78 FR 64736 at 64782) but did not include these examples in the proposed regulatory text.

We also proposed that the hazard identification must consider hazards that may be present in the animal food if they occur naturally or may be unintentionally introduced. In the 2014 preventive controls supplemental notice for animal food we proposed to add that the hazard analysis also must consider hazards that may be intentionally introduced for purposes of economic gain (proposed § 507.33(b)(2)(iii)).

(Comment 251) As discussed in Comment 62, some comments express concern that the rule would refer to multiple levels of hazards (*i.e.*, “hazard,” “known or reasonably

foreseeable hazard,” and “significant hazard” (which we now refer to as “hazard requiring a preventive control”) and ask us to provide sufficient clarity to be able to distinguish between these types of hazards.

(Response 251) As discussed in Response 62, we have revised the requirements for hazard identification to emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).

(Comment 252) Some comments ask us to include examples of physical hazards in the regulatory text.

(Response 252) We have added stones, glass, and metal fragments as examples of physical hazards in the regulatory text. This is consistent with the regulatory text for biological and chemical hazards, even though the hazards listed in section 418(b)(1) of the FD&C Act include examples of chemical and biological hazards but do not include examples of physical hazards.

(Comment 253) Some comments ask us to separately list some hazards (such as parasites and drug residues) rather than include them as examples of biological hazards and chemical hazards.

(Response 253) We decline this request. Although section 418(b)(1)(A) of the FD&C Act lists such items separately, we believe it is clearer to acknowledge that some of the hazards listed in the statute are in fact a subset of the broader categories of biological and chemical hazards.

(Comment 254) Some comments ask us to rephrase the requirement for hazard identification to specify “The hazard analysis must identify hazards” rather than “The hazard identification must consider hazards.”

(Response 254) We decline this request. The provision is directed to the first step of a hazard analysis, *i.e.*, hazard identification, rather than to the overall hazard analysis (which is addressed in § 507.33(a)). The purpose of the hazard identification is to consider the types of hazards listed as a step in determining whether there are any hazards requiring a preventive control; the suggestion of the comments implies that such hazards will always be identified. As discussed in Response 247, the outcome of a hazard analysis for an animal food product could be that there are no hazards requiring a preventive control.

(Comment 255) Some comments ask us to revise the chemical hazard examples by replacing the term “nutrient imbalances” with “nutrient deficiencies or toxicities.”

(Response 255) We agree that the suggested revision adds clarity and have modified the regulatory text to replace “nutrient imbalances” with “nutrient deficiencies or toxicities,” and provide examples, such as “inadequate thiamine in cat food,” “excessive vitamin D in dog food”, and “excessive copper in food for sheep.”

(Comment 256) Some comments assert that nutrient imbalances should not be addressed in an animal food safety plan because they pose no threat to humans.

(Response 256) We disagree with these comments. The preventive controls rule for animal food is intended to protect animal health, as well as human health. Section 418 of the FD&C Act, which authorizes the preventive controls rules, applies to facilities registered under section 415 of the FD&C Act, which includes facilities that manufacture, process, pack, and hold animal food.

(Comment 257) Some comments assert that while serious, ongoing imbalances of nutrients such as copper and selenium must be avoided with checks and balances, and perhaps product testing, there could be a multitude of other incidents that could occur without serious consequences and to address every possible scenario, by species, when the Agency is aware of a limited number of rare cases, is unreasonable. Some comments state that the notion that nutrient deficiencies or toxicities for animals are hazards likely to occur in the manufacture of animal food seems like a poor fit in this set of food safety regulations.

(Response 257) The Agency has a history of animal food incidents resulting in recall of animal food and in animal illnesses and deaths from nutrient deficiencies or toxicities.

From 2012 to 2014, FDA received multiple reports through its RFR that were attributable to animal food associated with nutrient deficiencies or toxicities. For example, during the 2010/2011 reporting period, 3.57 percent of 224 primary (industry and voluntary) RFR entries were associated with nutrient deficiencies or toxicities in animal food. During the 2012/2013 period, 2.97 percent of 202 entries were attributable to nutrient imbalances or toxicities in animal food (Refs. 14 and 16). Reports included low levels of thiamine in cat food; high levels of vitamin D in dog food; low levels of vitamin D in food for swine; high levels of vitamin D in food for guinea pigs, fish, and other animal species; high levels of calcium and phosphorus in food for broiler chickens and turkeys causing the death of several hundred

young birds (Refs. 13 to 16); high levels of salt in food for broilers; high levels of protein/urea in food for cattle; and high levels of copper in food for sheep. Many of these animal foods with nutrient imbalances (deficiencies or toxicities) resulted in a recall of the affected animal food (Refs. 31 to 39).

Moreover, an analysis of thiamin levels in randomly selected commercial canned cat foods was conducted during a period from December 2012 through January 2013 (Ref. 40). The study found 13.3 percent of the cat foods tested fell below the minimum set for thiamine by AAFCO and 15.6 percent were below the recommended allowance of the National Research Council.

We also disagree with the implication that facilities must address every possible hazard. Facilities must identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring a preventive control.

(Comment 258) Some comments suggest that nutrient imbalances should be addressed through CGMPs.

(Response 258) We disagree with these comments. We consider nutrient deficiencies and toxicities to be a type of chemical hazard that are appropriately addressed through preventive controls. If a facility identifies a nutrient deficiency or toxicity as a hazard that is known or reasonably foreseeable in an animal food and is a hazard that requires a preventive control, the facility must implement preventive controls for that hazard. The facility has flexibility in determining what preventive controls it needs to implement to control the hazard. Preventive controls for identified nutrient toxicity or deficiency hazards can include CGMPs, but the specific CGMP needs to be included in the food safety plan (or for a qualified facility, the documentation supporting an attestation under § 507.7(a)(2)).

(Comment 259) Some comments ask us to consider revising the proposed rule to include food allergens in animal food much in the same way that they have been proposed in the human food rule.

(Response 259) We decline this request. We are not aware of evidence indicating that foodborne allergens pose a significant health risk to animals (78 FR 64736 at 64771). Animals with actual food allergies typically have digestive disorders or dermatologic conditions, not the anaphylactic reaction that humans have to the major food allergens (defined in section 201(qq) of the FD&C Act).

(Comment 260) Some comments assert that physical hazards in animal food are not likely to cause any serious injuries to humans as the contaminant is not assimilated into edible tissue.

(Response 260) We disagree with these comments. The rule defines the term hazard to include a physical agent that has the potential to cause injury or illness in animals, as well as humans. Physical hazards in animal food can cause illness or injury in animals.

(Comment 261) Some comments ask us to delete “decomposition” from the list of chemical hazards in this provision.

(Response 261) We decline this request. As discussed previously, decomposition of animal food consists of microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death (see 78 FR 64736 at 64782).

(Comment 262) Some comments assert that we should not require all food safety plans to specifically address the likelihood of radiological hazards.

(Response 262) The rule only requires that a facility consider whether radiological hazards are known or reasonably foreseeable, and we have described situations where radiological hazards could be considered to be known or reasonably foreseeable. A facility that appropriately determines that no radiological hazards are known or reasonably foreseeable would document that determination in its written hazard analysis but would not need to establish preventive controls and associated preventive control management components to address radiological hazards.

(Comment 263) Some comments assert that predictable intentional hazards should be in the food safety plan but unexpected intentional hazards should be part of a food defense plan.

(Response 263) This rule only requires a facility to consider intentionally introduced hazards when such hazards are introduced for purposes of economic gain. Hazards that may be intentionally introduced by acts of terrorism are the subject of the 2013 proposed intentional adulteration rule (78 FR 78014, December 24, 2013), which applies only to human foods.

(Comment 264) Some comments disagree that the animal food preventive controls rule should address hazards that are intentionally introduced for purposes of economic gain (economically motivated adulteration).

Some of these comments assert that economically motivated adulteration is not a good fit for the hazard analysis and preventive controls framework because it is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards. Some comments state that traditional food safety hazards are primarily both identified and addressed at the facility level, but economically motivated adulteration is typically handled by the corporate parent company, where supply-chain management programs are typically located. These comments also assert that food safety-related economically motivated adulteration is extremely rare and that predicting economically motivated adulteration to prevent it is extremely difficult. Some comments assert there will be no measurable benefit to food safety by imposing requirements to consider economically motivated adulteration as part of a food safety plan and that doing so will consume limited resources without a corresponding increase in consumer protection. Other comments assert that there is no need to require a facility to identify hazards intentionally introduced for purposes of economic gain because the misbranding and adulteration provisions of the FD&C Act already sufficiently provide safeguards against economic gain.

(Response 264) We agree with the comments that state that the requirement to consider hazards intentionally introduced for purposes of economic gain is narrow. Such hazards will be identified in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. In addition, we define hazards to only include those agents that have the potential to cause illness or injury. Economically motivated adulteration that affects product integrity or quality, for example, but not animal food safety, is out of the scope of this rule. We continue to believe that there is benefit in taking this preventive approach to economically motivated adulteration and not relying solely on enforcing the preexisting misbranding and adulteration provisions of the FD&C Act after a violation occurs.

As discussed in sections XL through XLVII, we are finalizing supply-chain program provisions. It is consistent with the framework of this rule for a facility to address hazards requiring a preventive control that may be intentionally introduced for purposes of economic gain through the facility's supply-chain program.

(Comment 265) Some comments express concern about identifying hazards that may be intentionally introduced for purposes of economic gain because there are potentially an unlimited number of unknown or yet-to-be identified hazards that could be intentionally introduced for purposes of economic gain by an unscrupulous supplier. These comments disagree with our attempt to narrow the field of potential scenarios for economically motivated adulteration to circumstances where there has been a pattern of such adulteration in the past.

Some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration is both too broad and too narrow at the same time. These comments assert that our attempt is too broad, because we expect facilities to consider patterns of adulteration from the past "even though the past occurrences may not be associated with the specific supplier or the specific food product" and a requirement to consider every potential product and potential supplier makes the task open ended. These comments further assert that our attempt is too narrow, because a focus on patterns of adulteration in the past is unlikely to reveal potential future instances of economically motivated adulteration and because those intending to defraud purchasers for economic gain are trying to avoid detection. According to these comments, once an animal food safety related instance of economically motivated adulteration is uncovered, perpetrators quickly move to carry out their fraudulent activities in a different way. Some comments assert that there are alternative ways to control hazards that may be intentionally introduced for purposes of economic gain without specific regulatory requirements, such as by having an effective supplier approval program with appropriate qualification and verification activities; through business-to-business relations, expectations, and contracts; and through a vulnerability assessment and control plan tailored specifically to economically motivated adulteration.

(Response 265) We disagree that the requirement is too broad. A facility must conduct a hazard analysis for each type of animal food manufactured, processed, packed, or held at the facility. There is no requirement to consider every potential product or potential supplier. We also disagree that the requirement is too narrow. Some individuals intending to defraud purchasers for economic gain will develop entirely novel ways of adulterating food to suit their purposes.

We agree that these circumstances may not lend themselves to the preventive approach required here. We encourage, but do not mandate, that facilities adopt other measures they deem appropriate to mitigate the risks of economically motivated adulteration that this rulemaking does not address. Still, the repeated use of melamine over the years, in animal foods and in foods for people, demonstrates that patterns of economically motivated adulteration can emerge and should be considered as part of a hazard analysis.

(Comment 266) Some comments ask us to limit the requirement to identify hazards that may be introduced for purposes of economic gain to only those hazards that pose a risk to public health for which there has been a pattern in the past. Some comments assert that in those few instances where a hazard was intentionally introduced the underlying intention was to defraud rather than to cause harm, and the food safety hazard was an unintended consequence. Some comments ask us to focus the hazard identification solely on inbound products, because it is obvious that hazards introduced by the facility itself will not be prevented through a hazard analysis. Some comments ask us to narrow the scope of the requirement by specifying that facilities focus on three situations: (1) Situations in which there has been a pattern of similar adulteration in the past; (2) animal foods or ingredients for which quality assurance methods may not sufficiently characterize the animal food or ingredient to assure its identity, and; (3) animal foods or ingredients for which there are substitutes that are likely to be harmful that would be considered obvious to one skilled in food science.

(Response 266) We decline to make the changes suggested in these comments because they are unnecessary. Because of our definition of hazard, the requirement is already limited to economically motivated adulteration that is reasonably likely to cause illness or injury. Under the final rule, a facility does not need to identify a hazard related to economically motivated adulteration when there is no risk to public health or when the economically motivated adulteration is not known or reasonably foreseeable.

We agree that the three circumstances suggested by the comments are an appropriate focus for facilities who seek guidance on how to approach the requirements, but decline the request to specify these limitations of the scope in the regulatory text. As already noted, some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration



is both too broad and too narrow at the same time. (See Comment 265.) Although we continue to believe that the instances in which a facility will identify a hazard intentionally introduced for economic gain will be rare, we also consider that limiting the scope of the requirement in the regulatory text would be both prejudging the future and inconsistent with the public health objectives of this rule.

(Comment 267) Some comments ask us to allow implementation of the major provisions in FSMA before establishing requirements to address economically motivated adulteration. These comments assert that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. In addition, because economically motivated adulteration is typically addressed through product specifications, supplier relationships, and good business practices, implementation of these other provisions of the animal food preventive controls rule are likely to have a positive effect on preventing economically motivated adulteration.

(Response 267) We disagree that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. Hazards intentionally introduced for economic gain are addressed here with the same preventive framework as every other hazard. As such, we do not see a compelling reason to delay implementation of the requirements to address economically motivated adulteration.

*C. Proposed § 507.33(c) and (d)—Evaluation of Whether a Hazard Requires a Preventive Control*

We proposed that the hazard analysis must include an evaluation of the identified hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls; and environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment that would significantly minimize the pathogen (proposed § 507.33(c)(2)). We also proposed that the hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended consumer: (1) The formulation of the animal food; (2) the condition, function, and design of the facility and equipment; (3) raw materials and ingredients; (4) transportation practices; (5)

manufacturing/processing procedures; (6) packaging activities and labeling activities; (7) storage and distribution; (8) intended or reasonably foreseeable use; (9) sanitation, including employee hygiene; and (10) any other relevant factors (proposed § 507.33(d)(1) through (10)).

(Comment 268) Some comments ask us to revise the requirement to include an evaluation of environmental pathogens to avoid the implication that an intervention is needed when there may be other controls (such as pH or formulation) that would significantly minimize or prevent the pathogen. These comments suggest that we revise the provision to require that a hazard evaluation include an evaluation of environmental pathogens whenever a food is exposed to the environment prior to packaging and the packaged food does not receive a treatment “or otherwise include a control measure” that would significantly minimize the pathogen.

(Response 268) We have revised the provision on the hazard evaluation for environmental pathogens to specify that the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. We agree that controls such as formulation can function as a “kill step” and that the provision should make clear that such controls can be used in lieu of “treatment.”

(Comment 269) Some comments ask us to clarify what we meant by “other relevant factors” and note that natural disasters (which we previously discussed) (78 FR 64736 at 64785) are “usually exceptional events” that are best managed in a facility crisis management plan. Other comments ask us to specify that the hazard evaluation must consider any relevant geographic, temporal, agricultural, or other factors that may affect the severity or probability of the hazard.

(Response 269) We included “other relevant factors” to emphasize that the list of factors in the provision is not an exhaustive list and that a facility is responsible for considering those factors that play a role in its determination of whether a potential hazard is a hazard requiring a preventive control, regardless of whether those factors are listed in the provision. A facility that already addresses circumstances such as natural disasters in other plans may consider the applicable part of those plans to be part of its food safety plan (see § 507.212).

We agree that geographic, temporal, and agricultural factors are examples of

“other relevant factors.” For example, hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some RACs are more of a problem in some years than in others. We have added the temporal nature of some hazards associated with some RACs as an example of “other relevant factors” to consider (see § 507.33(d)(10)).

(Comment 270) Some comments ask us to specify that the hazard evaluation be more specific about issues relevant to raw materials and ingredients, including how raw materials are selected and shipped, how suppliers are evaluated, and how shipments are inspected on receipt.

(Response 270) We decline this request. When a hazard requiring a preventive control in a raw material or other ingredient is controlled before receipt, the receiving facility would address such specifics in the supply-chain program that would be required as a preventive control (see subpart E).

(Comment 271) Some comments assert that the proposed requirements for hazard evaluation could be interpreted in many ways. For example, a facility could conclude that the presence of a hand sink or boot dip prior to entering the processing area will reduce the likelihood of environmental pathogens and that environmental pathogens are not a significant hazard, whereas a regulator could interpret this provision to mean that a facility must always consider an environmental pathogen to be a significant hazard when the criteria in the provision are met, unless the facility can provide evidence to the contrary.

(Response 271) We agree that the requirements for hazard evaluation are subject to alternative interpretations. This is often the case, particularly when a regulation is new. The provision specifies that a facility must evaluate whether an environmental pathogen is a hazard requiring a preventive control in particular circumstances, *i.e.*, whenever a finished animal food (for which an environmental pathogen is identified as a hazard) is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. The written hazard analysis must be prepared (or its preparation overseen by) a preventive controls qualified individual (see § 507.31(b) and (c)(1)). The preventive controls qualified individual for a facility that determines that an environmental pathogen is not a hazard requiring a preventive control in

such circumstances must document that determination, and a regulator would consider the adequacy of the documented determination before reaching a conclusion as to whether the facility had failed to satisfy the requirements. However, the use of a hand sink or boot dip prior to entering the processing areas to reduce the likelihood of environmental pathogens may also be considered to be part of the sanitation controls for the environmental pathogen.

(Comment 272) Some comments ask us to focus on language that will clearly differentiate between functions, processes, and controls for facilities with food safety plans that identify microbial hazards and those that do not identify microbial hazards, and other known or reasonably foreseeable hazards. These comments assert that sanitation of objects and surfaces may be appropriate for the former, but not necessarily for the latter.

(Response 272) The facility is responsible for conducting a hazard analysis, and if hazards are identified that require a preventive control, the facility must consider the effect of sanitation on the safety of the finished animal food for the intended animal (see § 507.33(d)). Based on the outcome of its hazard evaluation, the facility may determine that sanitation is not an appropriate preventive control for the hazards it identified.

(Comment 273) Some comments assert that a food safety plan and hazard analysis should not include numerous hazards and hazard analysis steps. Some comments assert that hazard analysis should not be as detailed (stringent) for animal food as it is for human food. These comments maintain that prerequisite programs, which reduce the likelihood of a potential hazard to the point where the hazard is not reasonably likely to occur, would satisfy the requirement that the hazard be adequately controlled, making it unnecessary for a facility to include the identified hazards in its hazard analysis and preventive controls. Other comments assert that many hazards can be exclusively controlled through prerequisite programs without a need for CCPs.

(Response 273) While known and reasonably foreseeable hazards and the

outcome of a hazard analysis for human food and animal food may not be identical, in each case the purpose of a hazard analysis is to identify and evaluate known or reasonably foreseeable hazards for the type of food manufactured, processed, packed, or held to determine whether there are any hazards requiring a preventive control. As previously discussed in the 2013 animal food preventive control proposed rule (78 FR 64736 at 64781), the process of identifying and evaluating the hazards that may occur for specific types of animal food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of animal food. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific animal food products when required. If a facility identifies a hazard requiring a preventive control, the facility must determine an appropriate preventive control and include that preventive control in its food safety plan. A facility that establishes other controls (such as those that the comments describe as “prerequisite programs”) for hazards that are not, based on the outcome of the facility’s hazard analysis, “hazards requiring a preventive control” would not need to establish preventive control management components for such controls. However, some controls previously established in “prerequisite programs” would be considered “preventive controls.” We provide some flexibility for facilities with respect to how they manage preventive controls, and the preventive control management components may be different for hazards that have been managed as “prerequisite programs” compared to those managed with CCPs. The same principles would apply for the hazards a facility identifies as needing a preventive control.

(Comment 274) Some comments assert that the statutory language within FSMA does not mandate that covered animal food and pet food facilities implement regulatory HACCP plans. These comments further urge us to remove reference to HACCP.

(Response 274) We agree that section 103 of FSMA does not mandate HACCP

regulations; however, we have concluded that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. For discussion, see section II.C.2. of the 2013 proposed preventive controls rule for human food (78 FR 3646 at 3660).

(Comment 275) Some comments ask us to allow consideration of both severity and probability in the scientific hazard analysis as this would be consistent with international standards.

(Response 275) Section 507.33(c)(1) requires that a hazard evaluation must include an assessment of the severity of the injury or illness if a hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

For additional discussion of comments on hazard analysis, see section XXV in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

**XXVI. Subpart C: Comments on Proposed § 507.36—Preventive Controls (Final § 507.34)**

We proposed requirements to identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act. Some comments support the proposed requirements without change. For example, some comments agree that preventive controls must be written and include process controls, sanitation controls, a recall plan, and other controls as appropriate and necessary. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 11, with editorial and conforming changes as shown in table 31.

TABLE 11—REVISIONS TO THE PROPOSED REQUIREMENTS FOR PREVENTIVE CONTROLS

Section	Description	Revision
507.34(c)(1)	Process controls	Clarify that the requirements for process controls depend on the role of the process control in the food safety system.

*A. Proposed § 507.36(a)—Requirement To Identify and Implement Preventive Controls (Final § 507.34(a))*

We proposed that you must identify and implement preventive controls, including at critical control points, if any, to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act. We also proposed that these preventive controls include controls at CCPs, if there are any CCPs, and controls, other than those at CCPs, that are also appropriate for animal food safety.

Some comments support the flexibility provided to facilities to implement preventive controls that are appropriate to the facility and the animal food. Other comments support the clarification, in the 2014 supplemental notice, that not all preventive controls are established at CCPs and that some food safety plans will not have CCPs. We are finalizing the provision as proposed with the editorial and conforming changes in table 31.

*B. Proposed § 507.36(b)—Requirement for Written Preventive Controls (Final § 507.34(b))*

We proposed that preventive controls must be written.

(Comment 276) Some comments ask us to clarify whether documentation of treatment by a “custom processor” would be accepted as a “written preventive control” when the “custom processor” controls the hazard.

(Response 276) The question posed by these comments highlights the difference between the records required in the food safety plan and the records documenting the implementation of the food safety plan. The “written preventive controls” are part of the food safety plan, whereas the records documenting treatment are implementation records.

Implementation records documenting treatment, whether by a facility or its “custom processor,” would not satisfy the requirements for written preventive controls. However, specifying that the preventive control for a specific hazard is a particular treatment by a “custom processor,” along with information that describes the treatment, would satisfy the requirement for written preventive controls.

*C. Proposed § 507.36(c)(1)—Process Controls (Final § 507.34(c)(1))*

We proposed that preventive controls include process controls as appropriate

to the facility and the animal food. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal foods. Process controls must include, as appropriate to the applicable control, parameters associated with the control of the hazard, and the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(Comment 277) Some comments state that assigning a parameter and associated minimum and maximum values for some process controls (such as refrigeration (including freezing), or water activity) may be possible, but not be necessary for food safety. These comments ask us to require minimum and maximum values to be assessed against the applicable food safety need, or otherwise make clear that the implications of not controlling minimum and maximum values must be assessed in light of the circumstances. Other comments express concern that “as appropriate to the applicable control” could be interpreted as suggesting that if it is merely feasible to establish parameters for a process control, they must be established. Other comments express concern that the proposed requirement suggests that if a parameter is not “controlled,” a regulator could conclude that the facility is not in compliance with the rule because it necessarily has not significantly minimized or prevented a significant hazard.

Some comments recommend incorporating recognition that the degree of rigor in application of subpart C parameters should be applied on a sliding scale, commensurate with the nature of the risk and the preventive control used. The comments request that the language in this section is altered to indicate that the parameters will not always be applicable.

(Response 277) See Response 293. We have revised the regulatory text to specify that process controls must include parameters and minimum or maximum values as appropriate to both the nature of the applicable control and its role in the facility’s food safety system. We decline the request to indicate that parameters of subpart C will not always be applicable, as the revised regulatory text provides adequate flexibility for a facility to determine what preventive controls, including process controls, are appropriate to the facility and its animal

food, if a hazard requiring a preventive control is identified.

(Comment 278) Some comments ask us to delete the phrase “to significantly minimize or prevent a significant hazard.”

(Response 278) We decline this request. “Significantly minimize or prevent a significant hazard” (which we have revised to “significantly minimize or prevent a hazard requiring a process control”) is the standard for controlling the hazards. Although the phrase could be viewed as redundant with the standard in the requirement to identify and implement preventive controls (§ 507.34(a)(1)), repeating that standard in the requirements for parameters and the minimum or maximum values associated with control of the hazard emphasizes the standard, which is appropriate for process controls.

*D. Proposed § 507.36(c)(2)—Sanitation Controls (Final § 507.34(c)(2))*

We proposed that preventive controls include, as appropriate to the facility and the animal food, sanitation controls that include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. We also proposed that sanitation controls must include procedures, practices, and processes for the cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment, and procedures for the prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

(Comment 279) One comment states that sanitation is not always a feasible step for facilities handling animal food, especially in dry blending facilities and dry storage operations. The comment asks us to remove the reference to “sanitary condition” and replace it with language consistent with the GMP section such as “to ensure the facility is adequately cleaned and properly maintained to significantly minimize or prevent hazards.”

(Response 279) We decline this request. The sanitation controls are flexible so that a facility can determine what sanitation controls are necessary for their facility and animal food if they identify a hazard requiring sanitation controls as a preventive control. Replacing the term “sanitary condition” with the suggested language would not improve the flexibility of the sanitation control requirements.

(Comment 280) Some comments assert that sanitation controls are not necessary to prevent any hazards in distribution facilities where animal food-contact surfaces are not present. Other comments assert that sanitation controls should be required in all cases (rather than “as appropriate”) given their central importance.

(Response 280) Under the framework established by FSMA, and implemented in this rule, each facility determines through its hazard analysis when sanitation controls are necessary to control a hazard requiring a preventive control. The rule neither establishes circumstances (such as in distribution centers) where sanitation controls are not necessary nor prejudices whether sanitation controls are necessary in specific circumstances. Although we do not expect that facilities such as distribution centers would determine through their hazard analysis that sanitation controls are required, we do expect all animal food establishments that are subject to the CGMP requirements established in subpart B to fully comply with the applicable requirements for sanitation.

(Comment 281) One comment states that sanitation is discussed in two sections, as a CGMP and as a preventive control, and asks that all of the discussion related to sanitation is moved to one section.

(Response 281) The two sections discuss sanitation for different purposes. The requirements for general sanitation are located in the CGMP regulations, which may be considered prerequisites to the preventive controls. The requirements for sanitation as a preventive control are specific for controlling an identified hazard. Sanitation activities conducted at a

facility may be different depending on whether the sanitation activity is used as general facility sanitation or specifically to control a hazard. Also, sanitation as a preventive control is subject to the management components of § 507.39.

*E. Proposed § 507.36(c)(3)—Supplier Controls (Final § 507.34(c)(3))*

We proposed that supplier controls include the supplier program. See the discussion of comments on the supply-chain program, now in subpart E, in sections XL through XLVII.

*F. Proposed § 507.36(c)(4)—Recall Plan (Final § 507.34(c)(4))*

We proposed that preventive controls include, as appropriate, a recall plan as would be required by proposed § 507.38. See the discussion of comments on the recall plan in section XXVIII.

*G. Proposed § 507.36(c)(5)—Other Controls (Final § 507.34(c)(5))*

We proposed that preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

(Comment 282) Some comments ask us to specify that preventive controls include controls on raw materials and other ingredients.

(Response 282) The final rule specifies that preventive controls include supply-chain controls as appropriate to the facility and the animal food. The request of these comments is addressed by the requirements for the supply-chain program (see § 507.34(c)(3) and subpart E).

(Comment 283) One comment asks us to require compliance with the good manufacturing and feeding practices that apply to GRAS substances, found in § 582.1(b), as a preventive control.

(Response 283) Facilities required to register that manufacture, process, pack, or hold GRAS substances are subject to this final rule, including applicable preventive controls requirements. Preventive controls are intended to address certain known or reasonably foreseeable hazards, not an animal food facility’s compliance with the good manufacturing and feeding practices of § 582.1(b), although a facility may determine that a good manufacturing practice is a preventive control for a particular hazard.

**XXVII. Subpart C: Circumstances in Which the Owner, Operator or Agent in Charge of a Manufacturing/Processing Facility Is Not Required To Implement a Preventive Control (Final §§ 507.36 and 507.37)**

In the 2014 supplemental notice, we provided an opportunity for public comment on potential requirements for a supplier program as a preventive control, including comments on when a supplier program would not be required. As discussed in more detail in section XL, we have revised the phrase “supplier program” to “supply-chain program” throughout the regulatory text. As summarized in table 12 and discussed more fully in the following paragraphs, after considering comments on when a supplier program would not be required, we are establishing two new provisions. Although both sets of provisions have an effect on the required supply-chain program, they will be implemented outside the framework of a supply-chain program.

TABLE 12—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL

Final section designation	Proposed section designation	Description	Revision
507.36(a)(1) .....	N/A .....	A manufacturer/processor is not required to implement a preventive control if it determines and documents that the type of animal food could not be consumed without application of an appropriate control.	N/A.
507.36(a)(2) .....	507.37(a)(1)(ii)(C) .....	A manufacturer/processor is not required to implement a preventive control if it relies on its customer, who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C, to ensure that the identified hazard will be significantly minimized or prevented and both: (1) Discloses in documents accompanying the animal food that the animal food is “not processed to control [identified hazard]” and (2) annually obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard.	Includes a requirement for documentation that the animal food is “not processed to control [identified hazard].”

TABLE 12—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL—Continued

Final section designation	Proposed section designation	Description	Revision
507.36(a)(3) .....	.....	A manufacturer/processor is not required to implement a preventive control if it relies on its customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and it: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]” and (2) annually obtains from its customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements.	N/A.
507.36(a)(4) .....	507.37(a)(1)(ii)(C) .....	A manufacturer/processor is not required to implement a preventive control if it relies on its customer to ensure that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and both: (1) Discloses in documents accompanying the animal food that the animal food is “not processed to control [identified hazard]” and (2) annually obtains from its customer written assurance that the customer will both disclose the information that the animal food is “not processed to control [identified hazard]” and will only sell to another entity that agrees, in writing, it will either follow procedures that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or obtain a similar written assurance from the entity’s customer.	<ul style="list-style-type: none"> <li>• Addresses the circumstance where an entity (other than the facility’s customer) in the distribution chain controls the hazard</li> <li>• Includes a requirement for documentation that the animal food is “not processed to control [identified hazard].”</li> </ul>
507.36(a)(5) .....	N/A .....	A manufacturer/processor is not required to implement a preventive control if it has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food product it distributes and documents the implementation of that system.	N/A.
507.36(b) .....	507.37(g)(3) .....	Records documenting the applicable circumstances in § 507.36(a).	Includes a requirement for documentation of the additional circumstances in which a manufacturer/processor is not required to implement a preventive control.
507.36(c) .....	N/A .....	If a customer of the manufacturer/processor has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, the customer may provide this determination (including animal species and why the identified hazard is not a hazard) in its written assurance under § 507.36(a)(2)(ii) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.	N/A.
507.36(d) .....	N/A .....	If a customer of the customer of the manufacturer/processor (i.e., another entity in the distribution chain) has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, the entity may provide this determination (including animal species and why the identified hazard is not a hazard) in its written assurance under § 507.36(a)(4)(ii)(B) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.	N/A.

TABLE 12—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL—Continued

Final section designation	Proposed section designation	Description	Revision
507.37 .....	N/A .....	A facility that provides a written assurance under § 507.36(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.	N/A.

The first provision allows a manufacturer/processor to not implement a preventive control if the manufacturer/processor determines and documents that the type of animal food could not be consumed without application of the appropriate control by an entity in the supply or distribution chain other than that manufacturer/processor (see § 507.36(a)(1)). We describe comments leading to this provision, and our response to those comments, in Comment 284 and Response 284 respectively. Although we are establishing these provisions outside the framework of the supply-chain program, these provisions continue to play a role in the requirements for a supply-chain program, because they also provide an exception to the requirements for a manufacturer/processor to establish and implement a supply-chain program.

The second provision relates to comments we received on a proposed exception to the requirement for a manufacturer/processor to establish and implement a supplier program (proposed § 507.37(a)(1)(ii)(C)). (See Comment 285). Under proposed § 507.37(a)(1)(ii)(C), a receiving facility would not have been required to have a supplier program if it relied on its customer to control the hazard and annually obtained from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. As discussed in Response 285, we are replacing this provision with several provisions that apply when a manufacturer/processor identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, but can demonstrate and document that the identified hazard will be controlled by an entity in its distribution chain. A manufacturer/processor that satisfies the criteria in these provisions will not be required to implement a preventive control for the identified hazard. Under these provisions, the combination of three requirements will provide adequate assurance that the animal food will be processed to control the

identified hazard before it reaches consumers. These requirements are: (1) Documentation provided by the manufacturer/processor to its direct customer that the animal food is “not processed to control [identified hazard]”; (2) written assurances from customers regarding appropriate procedures to ensure that the animal food will receive further processing to control the identified hazards; and (3) provisions relating to accountability for written assurances. (In these provisions, “customer” means a commercial customer, not a consumer.)

(Comment 284) Some comments express concern about the ability for distributors/cooperatives identify the individual raw material or other ingredient supplier when the supplier that applied the control is more than one step back in the food chain. Some comments assert that receiving facilities should not be required to verify suppliers with which they do not have a direct commercial relationship. For example, in the case of the soybean supply chain, the U.S. processing facility likely has no direct relationship with the many farms involved in the growing and harvesting of the soybeans. Some comments ask for an exemption from supplier verification activities for animal foods such as soybeans because it is problematic to have a requirement that potentially could necessitate trace back to farms.

(Response 284) We are establishing a provision, applicable to both the supply chain and the distribution chain of a manufacturer/processor, for a circumstance when a manufacturer/processor does not need to implement a preventive control. We are providing that a manufacturer/processor does not need to implement a preventive control if it determines and documents that the type of animal food could not be consumed without application of the appropriate control (see § 507.36(a)(1)). However, depending on the facility, the raw material or other ingredient, and the type of animal food produced by the manufacturer/processor, there may be some circumstances where a manufacturer/processor could determine that a particular animal food

that passes through its facility satisfies the criterion “could not be consumed without application of the appropriate control.” In other cases, a facility may have determined through its hazard analysis that there are no hazards requiring a preventive control, and will not consider whether one of the circumstances in new § 507.36 apply.

As a consequential addition, new § 507.36(b) specifies the records that a manufacturer/processor would need to satisfy the documentation requirements established in new § 507.36(a)(1), and we have added new § 507.36(b) to the list of implementation records (§ 507.55) that are subject to the recordkeeping requirements of subpart F.

See also Comment 429, in which we discuss comments asking us to add flexibility to the requirements for a supply-chain program such that any entity other than the receiving facility can perform supplier verification activities. As discussed in Response 429, the rule provides additional flexibility in the supply-chain program with regard to who can perform certain activities (see § 507.115).

(Comment 285) Some comments ask us to delete the criterion for control of the hazard by the receiving facility’s customer, with annual written assurance that the customer had established and was following procedures (identified in the written assurance) that would significantly minimize or prevent the hazard. The stated reasons varied. For example, some comments state that a receiving facility may have so many customers that it is not possible to obtain written assurance annually from all customers. Other comments express concern that a customer may be unwilling to describe confidential trade secrets in order to identify in writing the procedures the customer has established and is following to control the hazard. Other comments express concern about “legal issues” when a receiving facility needs to assess the adequacy of the customers’ procedures for controlling a hazard because under current business practices a vendor can provide assurance to a buyer (its customer), but buyers do not typically provide such

assurance to vendors. Some comments express concern that written assurance does not guarantee that the customer is actually doing anything to significantly minimize or prevent the hazard.

Some comments ask us to provide an alternative that would allow the receiving facility to provide documentation to its customer about a hazard that needs a preventive control at a processing facility later in the distribution chain rather than obtain written assurance that its customer will control a hazard. If written assurance must be required, these comments ask us to allow the written assurance provided by the customer to state that the customer would evaluate the hazard and if necessary establish and follow procedures to significantly minimize or prevent the hazard.

Some comments state the receiving facility may not know the identity of all its ultimate customers, particularly if the receiving facility sells its products to a distributor who then sells to other entities. Some comments ask us to provide flexibility for facilities to determine whether annual updates of written assurance are necessary. Other comments ask us to specify that a receiving facility need not establish and implement a supplier program for raw materials and ingredients intended for further processing.

Some comments assert that the presence of low levels of pathogens on a raw product that will be subject to a lethal process further downstream does not pose a risk to the consumer, and should not be considered a significant hazard (*i.e.*, a hazard requiring a preventive control). These comments also assert that if we maintain that *Salmonella* contamination is a significant hazard for each member of the supply chain, then we should allow the preventive control to be applied in a subsequent step at another facility. Other comments ask us to clarify that a facility would not need to develop preventive controls where it produces raw materials or ingredients that are subject to subsequent processing that will address known or reasonably foreseeable hazards.

(Response 285) We are establishing several provisions, specifically applicable to the distribution chain of a manufacturer/processor, for circumstances when a manufacturer/processor does not need to implement a preventive control (§§ 507.36(a)(2), (3), (4), and (5); 507.36(b)(2), (3), (4) and (5); 507.36(c); 507.36(c) and (d), 507.37; and 507.215). See Response 284 for another new provision that applies to the supply chain in addition to the distribution chain (§ 507.36(a)(1)).

Under the first of these provisions (§ 507.36(a)(2)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer (who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) to ensure that the identified hazard will be significantly minimized or prevented and: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. The manufacturer/processor would include the specific hazard requiring a preventive control (*e.g.*, *Salmonella*) where the statement says “[identified hazard].” A facility that provides the written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance (see new § 507.37). The documents could be bills of lading or other papers that accompany the animal food or labels on the containers of the animal food.

Under the second of these provisions, (§ 507.36(a)(3)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer (who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C), to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and it: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements. By “customer who is not required to implement preventive controls under this part” we mean entities such as qualified facilities and retail food establishments.

Under the third of these provisions (§ 507.36(a)(4)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and: (1) Discloses in

documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and (2) annually obtains from its customer written assurance, subject to the requirements of § 507.37, that the customer will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”. The manufacturer/processor also must obtain written assurance that its customer will only sell to another entity that agrees, in writing, it will either: (1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C), or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or (2) obtain a similar written assurance from the entity’s customer.

Under the fourth of these provisions (§ 507.36(a)(5)), a manufacturer/processor is not required to implement a preventive control if it has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food product it distributes and documents the implementation of that system. Comments did not provide examples of such a system, but we do not want to preclude the development of such systems.

We have added several other requirements related to the four new provisions that we are specifically establishing as circumstances in which a manufacturer/processor need not implement a preventive control. As already noted in this response, new § 507.37 requires that a facility that provides a written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance. In addition, new § 507.36(b)(2), (3), (4), and (5) specify the records that a manufacturer/processor would need to satisfy the documentation requirements established in new § 507.36(a)(2), (3), (4) and (5), and new § 507.215 establishes requirements applicable to the written assurance between a manufacturer/processor and its customer. Taken together, the provisions of §§ 507.37 and 507.215 establish legal responsibilities for a facility that provides a written assurance under § 507.36(a)(2), (3) or

(4), even if that facility is not a manufacturer/processor.

The point of these provisions is to ensure that hazards that a manufacturer/processor has determined, through its hazard analysis, require a preventive control, but are not controlled in the supply chain before the manufacturer/processor or by the manufacturer/processor itself, are in fact controlled by a subsequent entity in the distribution chain. With the assurance from the manufacturer/processor's customer that the hazards will be controlled after the animal food product leaves the manufacturer/processor it is not necessary for the first manufacturer/processor to implement the applicable preventive control. We continue to believe that annual written assurance from a manufacturer/processor's direct customer is an appropriate mechanism to ensure that its customer is aware of the identified hazard and is taking steps to ensure that the animal food is processed to control the identified hazard. We do not believe that a manufacturer/processor will need all of the details of its customer's process to satisfy the requirement to state in writing the procedures the customer has established and is following to control the hazard. For example, the customer could merely state that its manufacturing processes include a lethality step for microbial pathogens of concern.

We agree that it is appropriate to require that the manufacturer/processor provide documentation to its customer indicating that the animal food must be processed to control an identified hazard. Such documentation will be a means of clear communication from the manufacturer/processor to its customer. When the hazard will not be controlled by the customer, the customer will still have documentation that can be passed on to the entity that is expected to process the animal food to control the identified hazard, so that it will be very clear to that entity that the identified hazard still needs to be controlled.

We understand that not all identified hazards in an animal food will be a hazard to all species of animals. For example, we consider all serotypes of *Salmonella* to be a hazard for dog and cat food. However, we would not consider *Salmonella* Heidelberg a hazard in food for cattle. Therefore, we have added provisions to allow this determination to be included in the customer's written assurance regarding an identified hazard so that the customer will not be required to assure it is controlling a hazard that it has determined does not need to be controlled for a specific animal species.

For the written assurance required by § 507.36(a)(2)(ii), new paragraph (c) of this section provides that if the customer has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, the customer's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.

For the written assurance required by § 507.36(a)(4)(ii)(B), new paragraph (d) of this section provides that if the entity in the distribution chain subsequent to the customer is subject to subpart C and has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, that entity's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) in its written assurance instead of providing assurance that the identified hazard will be significantly minimized or prevented.

(Comment 286) Some comments that ask us to delete the proposed requirement to maintain the written assurance as a record. Other comments ask us to revise the regulatory text of the documentation requirement to focus on documentation that (1) the receiving facility has notified its customers of the existence of actual or potential hazards in animal food provided to them by the receiving facility; or (2) the receiving facility has notified its customers of the existence of actual or potential hazards in animal food provided to them by the receiving facility and has received a written assurance that the customer will evaluate the hazard and, if necessary, will follow procedures to significantly minimize or prevent the hazard.

(Response 286) We decline this request. As already discussed in this section, it is the combination of requirements (*i.e.*, for documentation that the animal food is "not processed to control [identified hazard]"; assurance from customers regarding appropriate procedures to ensure that the animal food will receive further processing to control the identified hazards; and provisions relating to accountability for written assurances) that will provide adequate assurance that the animal food will be processed to control the identified hazard before it reaches consumers. Records documenting the written assurances are a key component of the provisions.

#### **XXVIII. Subpart C: Comments on Proposed § 507.38—Recall Plan**

We proposed that you must establish a written recall plan for animal food with a significant hazard and that the recall plan must include certain procedures. Some comments support the proposed requirements without change. For example, some comments express the view that a written recall plan is critical in the event of a system breakdown where adulterated animal foods have been distributed. Some comments that support the proposed requirements suggest alternative or additional regulatory text or other changes.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the requirements as proposed with the conforming revision to use the term "hazard requiring a preventive control" rather than "significant hazard." See Response 62 and table 31. As discussed in section XXVII, we are establishing a provision applying to certain assurances in § 507.37.

##### *A. Proposed § 507.38(a)—Requirement for a Written Recall Plan*

We proposed that you must establish a written recall plan for animal food with a significant hazard.

(Comment 287) Some comments ask us to require a written recall plan for all animal food (rather than just for animal food with a significant hazard) and to establish the requirements for a written recall plan as CGMP requirements in subpart B rather than as part of the requirements for hazard analysis and risk-based preventive controls in subpart C. These comments assert that all products can be subject to a recall. These comments contrast recall plans with other preventive controls in that recall plans are often specific to a firm or facility, but rarely are specific to particular animal foods. In addition, these comments note that a recall may be administered and managed at the corporate office rather than at the specific manufacturing facility that produced the animal food.

Some comments note the requirements for a written recall plan are sufficiently different from other provisions in subpart C that we proposed to specify that the recall plan would not be subject to the preventive control management requirements for monitoring, corrective actions, and verification (see § 507.39(c)). Other



comments assert that a recall plan is not a preventive control because it deals with products after they have been produced. Some comments note that facilities that are exempt from the requirements of subpart C, but remain subject to the CGMP requirements, would not be required to have a recall plan unless we establish the requirements in subpart B. Other comments note that the requirement for a recall plan is only if there is a hazard that requires a preventive control, but assert that a recall should only be initiated if a hazard has actually been identified to be present in the product.

Some comments note that our authority to require recall plans is not limited to section 418 of the FD&C Act and that we can use other legal authority to impose a requirement for recall plans in subpart B. Some comments note that FSMA specifically amended the FD&C Act to provide us with the authority to mandate a food recall (section 423 of the FD&C Act). These comments assert that it would be reasonable for us to conclude that in order to efficiently carry out section 423 of the FD&C Act we should issue requirements governing the conduct of recalls, because section 423 of the FD&C Act requires that we provide a firm with an opportunity to voluntarily recall a product before issuing an order to the firm to cease distribution and recall a product.

(Response 287) We decline the request to establish requirements for a written recall plan as a CGMP requirement in subpart B and are establishing the requirements as a preventive control in subpart C as proposed. We acknowledge that a recall plan would be useful to all animal food establishments, and we encourage all animal food establishments to have a recall plan. However, the report issued by the human food CGMP Modernization Working Group did not identify the lack of a written recall plan as something that needed to be changed (Ref. 41). (See 78 FR 3646 at 3651, the proposed rule for preventive controls for human food, for a discussion of the CGMP Modernization Working Group and the process leading to its report.) However, going forward we intend to monitor whether the lack of a broader requirement for a recall plan leads to problems when animal food establishments that are not subject to the requirements of subpart C are faced with recall situations. As we gain experience with the impact of the new requirement for a recall plan on those facilities subject to subpart C, we can reassess at a later date whether to conduct rulemaking to broaden the

requirement to apply to all animal food establishments subject to the CGMP requirements in subpart B. For now, animal food establishments that are not subject to subpart C can continue to follow our longstanding recall policy in part 7 (21 CFR part 7).

Consistent with the overall framework of FSMA, a recall plan (like other preventive controls) is only required when the facility has identified a hazard requiring a preventive control. A facility could establish a recall plan that applies to other animal foods it manufactures. We recognize that recalls may be managed by the corporate office of a firm rather than at the specific manufacturing facility that produced the animal food. Nothing in the rule precludes this approach. In such cases the corporate recall policy would be reflected in a facility's recall plan. (See also Response 239.) In addition, a facility that identifies one or more hazards requiring a preventive control in multiple animal food products could use the same recall plan for all applicable animal food products.

The rule specifies that the requirements for preventive control management components (*i.e.*, monitoring, corrective actions and corrections, and verification) apply as appropriate to ensure the effectiveness of the preventive control, taking into account the nature of the preventive control (§ 507.39(a)). As previously discussed, the preventive control management components are directed at animal food that remains at the facility, whereas the recall plan addresses animal food that has left the facility (78 FR 64736 at 64788). Our determination that the nature of the recall plan does not require these preventive control management components demonstrates the flexibility provided by FSMA and this rule, not that the recall plan must be considered a CGMP rather than a preventive control.

We have not yet made a determination of whether we should issue requirements governing the conduct of recalls, rather than rely on the guidelines in part 7, in order to fully implement section 423 of the FD&C Act. However, we have issued a draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls" which, when finalized, would address topics such as the criteria for a mandatory recall and the process that FDA must follow for a mandatory recall (Ref. 42).

(Comment 288) Some comments ask us to cross-reference the provisions of part 7 (21 CFR part 7) rather than establish requirements that these

comments assert would be duplicative with the provisions of part 7. These comments ask us to address any more substantive requirements than are already in part 7 as part of a review of part 7. These comments assert that part 507 should require a written recall plan, but not require a written recall plan for the animal food, to be consistent with the approach of part 7.

(Response 288) We decline these requests. Part 7 addresses enforcement policy and the provisions for recalls in subpart C of part 7 are "Guidance on Policy, Procedures, and Industry Responsibilities." These recall provisions do not establish requirements and are not binding on industry. They also are broadly directed to recalls for all FDA-regulated products, not just food. As already discussed in Response 284, nothing in this rule would prevent a facility that establishes a recall plan for a particular animal food from using that recall plan for any animal food product that the facility decides to recall.

(Comment 289) Some comments request that we have separate recall program requirements for human food by-products so that by-products produced during the manufacture of food and sold, or otherwise provided, for use in animal food would not be recalled if the product for people is recalled. Other comments assert we will need to define the criteria for an animal food recall in guidance.

(Response 289) We decline the request to have separate recall program requirements for human food by-products for use as animal food. Whether or not the by-product of a human food that is recalled should itself be recalled may depend on assessment of several factors such as what the hazard is, whether the hazard for which the human food is recalled is also a hazard for the animal(s) that consume the by-product, and where the hazard occurred in the manufacturing process. We have previously addressed the request for guidance. (See Response 1.)

*B. Proposed § 507.38(b)—Procedures That Describe the Steps To Be Taken, and Assign Responsibility for Taking Those Steps*

We proposed that the recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: (1) Directly notify the direct consignees of the animal food being recalled, including how to return or dispose of the affected animal food; (2) notify the public about any hazard presented by the animal

food when appropriate to protect human or animal health; (3) conduct effectiveness checks to verify that the recall is carried out; and (4) appropriately dispose of recalled animal food (e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying). We requested comment on whether: (1) The proposed procedures are appropriate for all types of facilities; (2) we should require a recall plan to include procedures and assignment of responsibility for notifying FDA of recalls subject to the plan; and (3) we should include a requirement for a mock recall as a verification activity.

(Comment 290) Some comments ask us to delete the proposed requirement that the recall plan include procedures for a facility to notify the public about any hazard presented by the animal food when appropriate to protect public health. These comments assert that such a requirement would be highly subjective and create a nebulous regulatory burden that could subject facilities to unnecessary regulatory oversight and enforcement actions. Other comments indicate that the requirement for notifying the public should specifically prevent silent recalls when manufacturers pull products from store shelves without consumer notification.

(Response 290) We decline this request. Our guidance for a recall strategy has long recommended issuing a public warning to alert the public that a product being recalled presents a serious hazard to health in urgent situations where other means for preventing use of the recalled product appear inadequate (§ 7.42(b)(2)). Operationally, such notification to the public is so common that our current home page on our Internet site (Ref. 43) gives prominence to recall information and we have established a free email subscription service for updates on recalls (Ref. 44). Consistent with the longstanding recall policy in part 7, subpart C, the proposed requirement qualifies that the notification to the public is “when appropriate to protect public health.” A market withdrawal of a product (see § 7.3(j)) is not a recall that would be subject to public notification.

(Comment 291) Some comments ask us to specify that the procedures require facilities to notify us about a recall to ensure that all suppliers, retailers, and consumers will have adequate notification of the recall action. Other comments agree that it is important for facilities to involve us in a recall situation as soon as possible, but assert that the best way to address such a notification is through the existing RFR

system. These comments assert that additional procedures or means to notify us would involve unnecessary additional steps and be duplicative, with no improvement to the public health. Some comments assert that if the recall is issued by a foreign facility, the responsibility should be with the importer of the product for notifying FDA. Some comments ask us to specify that the appropriate State regulatory Agency with inspection jurisdiction be notified in the event of a recall.

(Response 291) We agree with comments that it is important to notify us about a recall and that doing so can help to ensure that suppliers, retailers, and consumers will have adequate notification of the recall action. We also agree that the existing procedures to notify us through the RFR system can accomplish this goal when an animal food presents a risk of serious adverse health consequences or death and that it therefore is not necessary to duplicate the notification procedures already established in the RFR system in part 507. However, we encourage facilities to include in their recall plan any procedures they have to comply with the RFR or to include a cross-reference to those procedures. Doing so may save time, which is critical during a recall. When the recalled animal food does not present a risk of serious adverse health consequences or death (and, thus, there is not a report to the RFR), our guidance entitled “Guidance for Industry: Product Recalls, Including Removals and Corrections” recommends that recalling firms notify the local FDA District Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press or written notification to customers (Ref. 45). Including this guidance with the facility’s recall procedures may also save time.

We decline the request to designate that it is solely the importer of a food manufactured by a foreign facility who must notify FDA if the food is recalled by the foreign facility. We are not requiring that a recall plan include procedures and assignments of responsibility for notifying FDA of recalls subject to the recall plan. Facilities should refer to our guidance in part 7 entitled “Guidance for Industry: Product Recalls, Including Removals and Corrections” for recommendations on conducting recalls of food that does not present a risk of serious adverse health consequences or death, including notification to FDA (Ref. 45). If the recalled food is a reportable food (i.e., it does present a reasonable probability that use will cause serious adverse health

consequences or death to humans or animals), then section 417 of the FD&C Act requires that the responsible party, as defined in section 417, submit a report to FDA.

We agree with comments that it is important to notify appropriate State regulatory Agencies about a recall. We generally request that FDA District Offices notify State control officials of recalls issued by animal food manufacturers. Also, State officials with responsibilities for regulating animal food can access our Web site for “Animal and Veterinary Recalls and Withdrawals” where we post the current and most recent recalls of animal products, including animal food (Ref. 46). We note that whatever methods are used to dispose of adulterated animal food, the methods should comply with State and local requirements.

(Comment 292) Some comments ask us to add a requirement for mock recalls on a regular basis, such as biannually. Some of these comments state that mock recalls would familiarize the staff and communications network(s) with the recall process and would improve the facility’s capacity to conduct effective and efficient recalls in the event of a contamination event. Other comments assert that mock recalls would be the only way to determine the effectiveness of a recall program. Some comments note that mock recalls would be particularly critical for manufacturers that have limited experience in actual recalls.

Some comments acknowledge that a mock recall could be an important element of a recall plan but recommend that mock recalls remain voluntary, such as by including mock recalls as an example of how verification may be accomplished. Other comments note that the current recall procedures in part 7 do not recommend mock recalls. Some comments assert that a requirement to include a mock recall as a verification activity would be an excessive and inappropriate burden; that any gain in the protection of public health will not offset the resource requirements to accomplish a mock recall; that resources are better dedicated to developing a robust plan; and, use of a mock recall should be addressed in FDA guidance.

Some comments ask us to clarify the “metrics” for a mock recall, particularly with respect to the consequences of failing to meet an appropriate metric if a mock recall is conducted as a verification activity.

(Response 292) We agree that a mock recall would familiarize the facility with the recall process, could improve the facility’s capacity to conduct effective

and efficient recalls during a contamination event, may be particularly helpful for manufacturers that have limited experience in actual recalls, and could support the development of guidance on best practices for recalls, and we encourage facilities to conduct one or more mock recalls to accomplish these goals. However, as previously discussed, a recall plan would address food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at food while it remains at the facility. Comments are mixed regarding whether the rule should require a mock recall as a verification activity for the recall plan, and we have decided to not require a facility to conduct a mock

recall as a verification activity for its recall plan so that the focus of the monitoring, corrective actions, and verification in the rule remains focused on food being produced rather than on food that is distributed in commerce. We acknowledge that requiring mock recalls would go beyond our longstanding policies established in part 7. A facility that voluntarily conducts a mock recall would establish metrics appropriate to its plan and take action (such as modifications to its procedures, or additional training for its employees) if it is not satisfied with the results of the mock recall.

We note that retail companies are not subject to this rule and, thus, are not subject to the requirement to have a written recall plan.

**XXIX. Comments on Proposed § 507.39—Preventive Control Management Components**

We proposed preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control. Most of the comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following sections, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 13 with editorial and conforming changes as shown in table 31.

**TABLE 13—REVISIONS TO THE PROPOSED REQUIREMENTS FOR PREVENTIVE CONTROL MANAGEMENT COMPONENTS**

Section	Description	Revision
507.39 .....	Flexible requirements for preventive control management components.	Provide that preventive control management components take into account both the nature of the preventive control and its role in the facility's food safety system.

**A. Proposed § 507.39(a)—Flexible Requirements for Monitoring, Corrective Actions and Corrections, and Verification**

We proposed that, with some exceptions, the preventive controls would be subject to three preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control: Monitoring, corrective actions and corrections, and verification.

(Comment 293) Some comments support our proposal to provide flexibility in the oversight and management of preventive controls, including the explicit provision that preventive control management components take into account the nature of the preventive control. Some of these comments state that the provisions for the preventive control management components will allow facilities to tailor their food safety plans to their specific facility, product, and process and ensure that the regulatory requirements are risk-based. Other comments state that the proposed approach acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provides for a framework whereby appropriate decisions may be reached regarding hazards that require management controls that may include monitoring, corrections or corrective

actions, verification, and records. Other comments state that the provisions will allow businesses to allocate resources to spend the most time and resources controlling and monitoring those hazards that pose the greatest risk to public health.

However, many of these comments also ask us to convey not only that the application of a particular management component be appropriate (*i.e.*, capable of being applied), but also that it be necessary for food safety (*i.e.*, to meet the overall FSMA food safety goals or to ensure a particular control is effective) by specifying that the preventive control management components take into account both the nature of the preventive control and its role within the facility's overall food safety system. Some of these comments ask us to make companion changes reflecting that the preventive control management components take into account both the nature of the preventive control and its role within the facility's overall food safety system throughout applicable provisions of the rule, such as the definition of "significant hazard" (which we now refer to as "hazard requiring a preventive control") and in the requirements for preventive controls, monitoring, corrective actions and corrections, and verification. Some comments ask us to consistently refer to "the nature of the preventive control" (rather than simply to "the preventive control") when communicating the

flexibility that a facility has in identifying preventive controls and associated preventive control management components.

(Response 293) We agree that preventive control management components should take into account both the nature of the preventive control and its role in the facility's food safety system and have modified the regulatory text of § 507.39 to incorporate this suggestion. We reviewed the full regulatory text of proposed subpart C and made similar modifications to the regulatory text for the definition of "hazard requiring a preventive control" (§ 507.3); process controls (§ 507.34(c)(1)); monitoring (§ 507.40); verification (§ 507.45); validation (§ 507.47); and verification of implementation and effectiveness (§ 507.49).

(Comment 294) Some comments assert that the flexibility explicitly provided in the regulatory text could result in some facilities taking a broad approach to significant hazards and other facilities taking a more detailed approach. These comments express concern that inspectors will view the detailed approach (*e.g.*, with more preventive controls), as the standard to judge compliance with the rule. Other comments express concern that identifying a large number of preventive controls could also undermine the value of HACCP programs because treating too many controls as CCPs will pull

resources from those controls that are truly critical.

(Response 294) We agree that facilities are likely to take different approaches to complying with the rule. A facility-specific approach is consistent with FSMA, which places responsibility for hazard analysis and risk-based preventive controls on the owner, operator, or agent in charge of the facility (section 418(a) of the FD&C Act). We agree that having too many CCPs could dilute their significance, but not every hazard will require a CCP to be controlled. See table 6 in the 2014 supplemental notice for examples of preventive controls that would not be CCPs (79 FR 58476 at 58493).

During the initial stages of implementation, we expect that our investigators will ask subject matter experts in CVM to review the outcome of the facility's hazard analysis, the preventive controls established by the facility, and the associated preventive control management components that the facility has established and implemented. Over time, as our investigators gain experience, we expect that there will be fewer circumstances in which our investigators would consult CVM about such an outcome. (See also Response 2 and section LIV regarding our approach to compliance.)

(Comment 295) Some comments state that USDA's regulations (in 7 CFR 205.201(a)(3)) for the National Organic Program include regulatory text to "ensure the effectiveness" of measures in that program and that this regulatory text is similar to regulatory text in the requirements for preventive control management components. These comments assert that this type of regulatory text has created compliance challenges and ask us to consult with USDA about its experience with implementing effectiveness language associated with monitoring practices and procedures and ensure that the final rule uses regulatory text that will be clearly understood and readily implementable by those subject to its provisions.

(Response 295) Under the USDA regulation cited by these comments, an organic production or handling system plan must include a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to "verify that the plan is effectively implemented." We have not consulted with USDA regarding its experience in evaluating compliance with this requirement because we addressed the issue likely to cause these compliance challenges for monitoring

practices and procedures in an organic production or handling system plan when we established our requirements for monitoring preventive controls. Specifically, we require that a facility monitor the preventive controls with adequate frequency to "provide assurance that they are consistently performed," not to "verify that the plan is effectively implemented." Our requirements more clearly distinguish the purpose of monitoring and verification activities. See our previous discussion of the relationship between monitoring and verification, and our tentative conclusion to require monitoring of the performance of the preventive controls (78 FR 64736 at 64790). We are affirming that conclusion in this rule. (See Response 297.)

*B. Proposed § 507.39(b)—Applicability of Preventive Control Management Components to the Supply-Chain Program*

We proposed that the supplier program (which we now refer to as "supply-chain program") would be subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program, taking into account the nature of the hazard controlled before receipt of the raw material or ingredient: (1) Corrective actions and corrections, taking into account the nature of any supplier non-conformance; (2) review of records; and (3) reanalysis. We address comments on the supply-chain program in sections XL through XLVII. We are finalizing the applicability of preventive control management components to the supply-chain program as proposed.

*C. Proposed § 507.39(c)—Recall Plan Is Not Subject to Preventive Control Management Components*

We proposed that the recall plan that would be established in § 507.38 would not be subject to the preventive control management components.

(Comment 296) As discussed in Comment 287, some comments ask us to establish requirements for a written recall plan as a CGMP requirement in subpart B rather than as a preventive control in subpart C. As a companion change, some of these comments ask us to delete our proposed provision that the recall plan would not be subject to the preventive control management components.

(Response 296) As discussed in Response 287, we are establishing the requirements as a preventive control in subpart C as proposed. Therefore, we

are finalizing the provision that the recall plan not be subject to the preventive control management components.

For further discussion on comments on preventive control management components, see section XXIX in the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

**XXX. Subpart C: Comments on Proposed § 507.40—Monitoring**

We proposed to establish requirements for monitoring the preventive controls. We also discussed our tentative conclusion that the language of section 418 of the FD&C Act regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the "performance" of preventive controls.

Some comments agree with our tentative conclusion regarding the ambiguous nature of section 418. For example, some comments state that our interpretation seems appropriate because requiring monitoring of the "effectiveness" of the preventive controls would be redundant with required verification activities. In addition, requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Some comments agree that facilities must be required to maintain records; but disagree regarding the scope of monitoring. One comment agrees that monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately. Some comments support the proposed provisions without change. Some comments ask us to clarify how we will interpret the provision.

In the following paragraphs, we discuss comments that disagree with our tentative conclusion or with the proposed requirements, or ask us to clarify the proposed requirements or suggest one or more changes to the proposed requirements. After considering these comments, we are affirming our tentative conclusion that the language of section 418 of the FD&C Act regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the "performance" of preventive controls. We also have revised the proposed requirements as shown in table 14, with editorial and conforming changes as shown in table 31.

TABLE 14—REVISIONS TO THE PROPOSED REQUIREMENTS FOR MONITORING

Section	Description	Revision
507.40	Flexibility in requirements for monitoring.	Provide that monitoring take into account both the nature of the preventive control and its role in the facility's food safety system.
507.40(c)(2)(i)	Records of monitoring	Provide that records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.
507.40(c)(2)(ii)	Records of monitoring	Provide for exception records for monitoring of preventive controls other than refrigeration.

*A. Our Tentative Conclusion To Require Monitoring of the Performance of Preventive Controls*

(Comment 297) Some comments disagree with our tentative conclusion that it would be appropriate to require monitoring of the “performance” of preventive controls and assert that the concept of “performance evaluation” is too complex to be included in the rule.

(Response 297) These comments may have misinterpreted what we meant by “monitoring performance of preventive controls.” We used the term “performance” to mean “the execution or accomplishment of an action, operation, or process undertaken or ordered” (78 FR 64736 at 64790). We acknowledge that the definition of “monitoring” that we are establishing in this rule includes that the purpose of observations or measurements conducted as part of monitoring is to “assess” whether control measures are operating as intended. However, we provided examples showing that this assessment is a straightforward determination of whether a process is operating as intended and is not a complex evaluation as asserted by the comments. (See, e.g., the discussion of monitoring oven temperature to ensure pathogen elimination during baking of a pet treat 78 FR 64736 at 64789 through 64790.)

(Comment 298) Some comments that support monitoring the performance of preventive controls assert that our proposed definition of “monitoring” (proposed § 507.3), and our preamble discussions of “monitoring,” have the potential to confuse “monitoring the performance of preventive controls” with verification activities that address ongoing implementation of control measures.

(Response 298) See Response 47 in which we discuss comments on the definition of monitoring and describe the changes we have made to that definition to address concerns about the potential to confuse “monitoring the performance of preventive controls”

with verification activities that address ongoing implementation of control measures.

(Comment 299) Some comments assert that authority should be explicitly granted to the States to conduct food safety monitoring and that we should maintain our responsibilities for product tracing.

(Response 299) These comments misinterpret the provisions of section 418 of the FD&C Act and this rule. Section 418 places the responsibility for establishing and implementing a food safety system (including hazard analysis, risk-based preventive controls, preventive control management components (including monitoring, corrective action procedures, and verification), and recordkeeping) on the owner, operator, or agent in charge of a facility, not on FDA or any other regulatory authority. This requirement for monitoring within the framework of hazard analysis and risk-based preventive controls is distinct from regulatory oversight of animal food safety, such as during inspections and investigations of outbreaks of foodborne illness, which generally involve product tracing. We agree that it is important to coordinate regulatory oversight of animal food safety with the States and other food safety partners. As discussed in Response 2, we are working through the PFP to develop and implement a national Integrated Food Safety System consistent with FSMA’s emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA).

(Comment 300) One comment requests that routine monitoring not be required for feed mills unless they manufacture pet food.

(Response 300) We decline this request. We assume this comment is based on a presumption that pet food is a higher risk product than livestock or poultry food. The exemptions from preventive control requirements that we are establishing are specifically provided by section 103 of FSMA and

we decline to apply the rule only to animal foods deemed to be of higher risk. Instead, several provisions of the rule expressly qualify that the requirements apply as appropriate to the facility, the animal food, the nature of the preventive control, and its role in the facility’s food safety system, the nature of the hazard, or a combination of these factors (e.g., monitoring procedures must be established as appropriate to the nature of the preventive control and its role in the facility’s food safety system). For example, the hazards in a facility and historical information on the consistency of the control measure can be factors in determining the frequency of monitoring.

*B. Proposed § 507.40(a) and (b)—Flexibility in Requirements for Monitoring*

We proposed that, as appropriate to the preventive control, you must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls, and monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(Comment 301) Some comments agree that frequency and areas to be tested and monitored need to be determined based on each product and facility and ask us to allow each individual facility to determine the frequency and areas to be monitored based on a completed risk assessment. Some comments ask us to specify that the frequency of monitoring preventive controls must have a scientific basis.

(Response 301) It is unclear whether the comment agreeing that monitoring frequency and areas to be tested need to be determined based on each product and facility was directed to the monitoring provision or to environmental monitoring. Regardless, by requiring written procedures for monitoring, and specifying that the

procedures include the frequency with which the procedures are to be performed, the rule provides that each facility must determine the frequency of monitoring, as well as details such as the areas to be monitored. However, we decline the request to specify that these procedures be based on a completed “risk assessment.” The rule requires the facility to conduct a hazard analysis, which determines whether there are any hazards requiring a preventive control, and the facility would establish preventive controls for such hazards as appropriate to the facility and the animal food. The facility must consider factors associated with risk (*i.e.*, the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls) in evaluating whether any potential hazard is a hazard requiring a preventive control (§ 507.33(c)). Risk could be relevant to a facility’s identification of appropriate preventive controls for a particular hazard requiring a preventive control. However, it is the nature of the preventive control, rather than the risk associated with the hazard, that is more relevant to the frequency of monitoring and the areas to be monitored. Accordingly, the rule specifies that the facility establish written procedures, and conduct monitoring, as appropriate to the preventive control rather than based on risk associated with the hazard. (See, *e.g.*, the discussion of monitoring oven temperature to ensure pathogen elimination during baking of a pet treat 78 FR 64736 at 64789 through 64790.)

We decline the request to specify that the frequency of monitoring preventive controls must have a scientific basis. Monitoring should take place with sufficient frequency to detect a problem in the performance of a preventive control. The importance of the preventive control to the safety of the animal food can be one factor in setting a frequency. We acknowledge that scientific information may be appropriate in determining the frequency of monitoring in some cases. For example, the frequency may be statistically based, such as with statistical process control. However, in some cases, factors other than scientific information may be appropriate in determining the frequency of monitoring. For example, historical information on the consistency of the control measure can be a factor in determining frequency. When variability of the process is low, the frequency may be less than with a process that has more variability. As

another example, a process that is operated at a point close to a food safety parameter limit may be monitored more frequently than one where there is a large safety margin built into the process.

#### C. Proposed § 507.40(c)—Records

We proposed that all monitoring of preventive controls must be documented in records that are subject to verification and records review.

(Comment 302) Some comments point out that table 6 in the 2014 supplemental notice includes an example of a monitoring activity that generally would not require monitoring records (*i.e.*, monitoring for pieces of ferrous material with magnets) (see 79 FR 585476 at 58493). These comments assert that this example is in conflict with the proposed regulatory text and ask us to modify the regulatory text to provide the flexibility we acknowledged in the 2014 supplemental notice. One comment states the examples provided by FDA for monitoring performance of preventive controls pertain to preventive controls that have specific parameters. The comment states in the absence of specific parameters for a preventive control, monitoring is neither necessary nor appropriate. Other comments ask us to specify that monitoring must be documented as appropriate to the nature of the preventive control.

Some comments ask us to recognize the acceptability of monitoring systems that exclusively provide exception reports. These comments describe exception reporting as a structure where automated systems are designed to alert operators and management on an exception basis, *i.e.*, only when a deviation from food safety parameter limits are observed by the system. These comments assert that, in many cases, monitoring of preventive controls can be done by automated systems that provide exception reporting in a much more efficient manner than if performed by operators and that automated monitoring allows for increased sampling frequency (often continuous) and reduction of human error. The comments provide an example of a refrigeration temperature control that notifies on exception (*e.g.*, high temperature alarm) and may only record temperatures that exceed the specified temperature (without recording temperatures that meet control requirements). These comments acknowledge that such systems must be validated and periodically verified to ensure they are working properly. These comments ask us to clarify in the preamble to the final rule that

monitoring systems can work affirmatively or by exception and that both types of systems and their related documentation are acceptable.

(Response 302) We have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary. We agree that the exception reporting described in these comments, including validation and periodic verification to ensure that the system is working properly, would be an acceptable monitoring system in the circumstances provided in the comments, *i.e.*, for monitoring refrigeration temperature. Therefore, we have revised the regulatory text to provide that records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control. Although the comments specifically requested that we clarify our view on exception records in the preamble, we believe that clarifying the regulatory text will be more useful, both to facilities and to regulatory agencies that conduct inspections for compliance with the rule. If a facility uses “exception records,” the facility must have evidence that the system is working as intended, such as a record that the system has been challenged by increasing the temperature to a point at which an “exception record” is generated.

We also have revised the regulatory text to provide that exception records may be adequate in circumstances other than monitoring of refrigeration temperature. For example, in table 6 of the 2014 supplemental notice the example we provided of a monitoring activity that generally would not require monitoring records is monitoring for pieces of ferrous material with magnets. We believe that a magnet system that monitors for ferrous material would result in a record only when the system detects ferrous material.

#### XXXI. Subpart C: Comments on Proposed § 507.42—Corrective Actions and Corrections

We proposed to establish requirements for corrective actions and corrections. Some comments support the proposed requirements without change. For example, some comments assert that there is virtually no reason to have a food safety plan unless there are proper corrective actions in place so the product can be properly disposed of. Some comments agree that there should

be written procedures for corrective actions and note the importance of identifying and evaluating the problem, correcting it, and documenting the corrective action. Some comments express the view that the proposed requirement for clear corrective action in the event of an unanticipated

problem, and documenting all corrective actions, contributes to a comprehensive safety plan. Some comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following paragraphs, we discuss comments that disagree with, or

suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 15 with editorial and conforming changes as shown in table 31.

TABLE 15—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CORRECTIVE ACTIONS AND CORRECTIONS

Section	Description	Revision
507.42(a)	Corrective action procedures	Clarify that corrective action procedures depend on the nature of the hazard, as well as the nature of the preventive control.
507.42(a)(1)	Corrective action procedures	Clarify that the specified list of corrective action procedures is not intended to be finite.
507.42(b)	Corrective action in the event of an unanticipated food safety problem.	Specify that the requirement applies when “a corrective action procedure” (rather than “a specific corrective action procedure”) has not been established.
507.42(b)(1)(ii)	Corrective action in the event of an unanticipated food safety problem.	Specify that the requirement applies when a preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective (rather than just when a single preventive control has been found to be ineffective).
507.42(c)(2)	Corrections	Provide for additional circumstances when corrections, rather than corrective actions, are warranted.

*A. Proposed § 507.42(a)(1)— Requirement To Establish and Implement Corrective Action Procedures*

We proposed that, with some exceptions, as appropriate to the preventive control you must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. The corrective action procedures must include procedures to address, as appropriate, the presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing, as well as the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring.

(Comment 303) Some comments note that we proposed to list two circumstances that require written corrective active procedures (*i.e.*, product testing and environmental monitoring) and that it is not clear whether this list is intended to be exhaustive or not (*i.e.*, whether written corrective action procedures are required in only these two circumstances, or whether there may be other circumstances that require written corrective action procedures). These comments ask us to insert “but are not limited to” after “must include,” if we intend that the list is not exhaustive. Likewise, other comments state our proposal to specifically require corrective action procedures may result in a misunderstanding by some facilities about the need to take corrective actions in circumstances other than in response

to testing results, other non-conformances, or other types of verification activities. These comments assert that it would be better for food safety if the regulatory requirements took a more principled approach and generally required corrective action procedures, with the importance of corrective action procedures for testing programs addressed through guidance. If, however, we conclude that specific requirements for corrective action procedures for testing programs are necessary, these comments ask us to clarify that the nature and extent of any corrective actions should be proportional to the nature of the test findings.

(Response 303) We have revised the regulatory text, with associated editorial revisions and redesignations, to clarify that the specified list of corrective action procedures is not intended to be exhaustive (*i.e.*, not limited to the two corrective action procedures that we specified in the 2014 supplemental notice). The approach we used in the modified regulatory text (*i.e.*, “You must establish and implement written corrective action procedures . . . , including procedures to address, as appropriate . . .”) is similar to the approach used in several other provisions of the rule. (See, *e.g.*, sanitation controls (§ 507.34(c)(2)); and monitoring (§ 507.40(a)). We decline the suggestion to modify the regulatory text by adding “but is not limited to” after “includes”. The word “includes” means to have (someone or something) as part of a group or total; to contain (someone or something) in a group or as a part of

something (Ref. 47). The word “includes” does not need to be followed by “but is not limited to” to clearly communicate that a following list is not complete. We agree that the nature and extent of any corrective actions in response to the findings of testing programs should be proportional to the nature of the test findings. (See Response 304.)

(Comment 304) Some comments state that the nature and extent of the corrective actions should be proportional to the nature of the testing results. These comments ask us to require that a facility establish and implement corrective action procedures that must be taken if preventive controls are not properly implemented as appropriate to the nature of the hazard, the nature of the control measure, and the extent of the deviation.

(Response 304) We have revised the regulatory text to specify that the corrective action procedures are established and implemented based on the nature of the hazard in addition to the nature of the preventive control. We agree that the nature of the hazard plays a key role in the corrective actions that a facility would take. Although a facility’s corrective action procedures likely would specify actions to take based on the extent of the deviation, we consider this a detail that does not need to be specified in the rule.

(Comment 305) Some comments ask us to revise the provisions to clarify that corrective action procedures are not always necessary when testing detects the presence of a pathogen or indicator organism. These comments assert that

the extent of the corrective actions should be proportional to the nature of the testing results themselves because the level of contamination matters for those microorganisms with thresholds that need to be taken into account and because the location of contamination in the food processing environment matters (e.g., the zone in the facility where the contamination is detected). (For information about zones associated with environmental monitoring, see 78 FR 3646 at 3816.)

(Response 305) We decline this request. These comments appear to be confusing the requirement to establish and implement corrective action procedures with the content of the corrective action procedures. These comments also appear to assume that a requirement to have corrective action procedures (which describe the steps to be taken to ensure that appropriate action is taken to identify and correct a problem and, when necessary, to reduce the likelihood that the problem will recur; that all affected animal food is evaluated for safety; and that all affected animal food is prevented from entering into commerce when appropriate) pre-determines the outcome of following the corrective action procedures. This is not the case. If, as the comments assert, a facility concludes, for example, that the nature of some test results do not warrant steps to reduce the likelihood that a problem will recur and that affected animal food is safe and lawful (or, in the case of finding a pathogen in some zones in the facility, that no animal food is affected), then that is what its corrective action procedures would say. The reason to have corrective action procedures is to consider the likely scenarios in advance, with appropriate input from the facility's food safety team and preventive controls qualified individual, rather than react to these scenarios on an ad hoc basis.

(Comment 306) Some comments ask us to require that corrective actions include an analysis to determine the root cause of a problem, not only identify it. These comments also ask us to require follow-up actions to ensure the corrective action was effective and assert that although the requirements address the need to reanalyze the food safety plan they do not appear to specifically address a review of the corrective action.

(Response 306) The requests of these comments do not require any revisions to the regulatory text. The rule does not use the term "root cause" but it does require the facility to take appropriate action, when necessary, to reduce the likelihood that the problem will recur

(see § 507.42(a)(2)(ii)). Root cause analysis is simply part of a common approach to complying with this requirement. (Knowing the root cause is key to reducing the likelihood that a problem will happen again.) The rule also requires a review of records of corrective actions, but does so as a verification activity rather than as part of the corrective action procedures (see § 507.49(a)(4)).

(Comment 307) Some comments ask us to revise the proposed rule to address corrective actions in a more general way and then outline areas where specific corrective action procedures would be helpful, such as for testing programs, in guidance.

(Response 307) The proposed provisions do not prescribe the outcome of the corrective action procedures, but merely direct the facility to the types of actions that the procedures must address. In essence, the proposed provisions already do, as the comments request, address corrective actions in a general way.

(Comment 308) Some comments ask us to specify that the requirements to establish and implement written corrective action procedures also apply when a preventive control is found to be ineffective.

(Response 308) We have not revised the regulatory text as requested by these comments. The appropriate action when a preventive control is found to be ineffective is to reanalyze the food safety plan and to establish and implement a preventive control that is effective, not follow a corrective action procedure. A corrective action procedure is intended to address a problem that happens when following the procedures in a food safety plan that previously was verified to be valid, not to fix problems on an ongoing basis when a preventive control is ineffective (and, thus, the food safety plan is not valid). We agree that some of the steps that apply to corrective actions may need to be taken, such as evaluating affected animal food for safety and ensuring that adulterated animal food does not enter commerce. This is addressed by the provisions for corrective actions in the event of an unanticipated problem (§ 507.42(b)(1)), which require specific corrective actions to be taken (§ 507.42(b)(2)).

(Comment 309) Some comments requests flexibility as every facility is different from the next so prescriptive corrective actions required by rules may not be applicable or possible in all cases. Some commenters requested that documentation be maintained for corrective actions only if the corrective action was made to address an animal

food safety issue. Other comments say that the animal food safety plan should outline when a corrective action is required, as well as the procedure to be followed and the requirement should only focus on animal food safety issues and not quality issues.

(Response 309) As stated in Response 304, we have revised the regulatory text to specify that the corrective action procedures are established and implemented based on the nature of the hazard in addition to the nature of the preventive control. We agree that the nature of the hazard plays a key role in the corrective actions that a facility would take. The requirement is intended to address hazards and therefore would not address animal food quality issues unless they would present a hazard (e.g., if insufficient mixing would present the potential for nutrient deficiencies or toxicities). All corrective actions must be documented in records (see § 507.42(d)).

#### *B. Proposed § 507.42(a)(2)—Content of Corrective Action Procedures*

We proposed that corrective action procedures must describe the steps to be taken to ensure that: (1) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (2) appropriate action is taken to reduce the likelihood that the problem will recur; (3) all affected animal food is evaluated for safety; and (4) all affected animal food is prevented from entering into commerce, if you cannot ensure that the affected animal food is not adulterated under section 402 of the FD&C Act.

(Comment 310) Some comments assert that the corrective action procedures should not consider food to be "affected" if it is immediately subjected to an additional (or repeat) preventive control after determining that the initial preventive control was not properly implemented. These comments discuss an example in which there is a temperature deviation below accepted parameter limits for a given process, and the incorrectly processed product is re-processed correctly, and assert that it would be illogical to consider the food to be "affected" in the circumstance. Other comments ask us to modify the requirements to specify that they apply to all affected food "if any." One comment states the use of the term "all" with "affected" is redundant and may contribute to unwarranted and unnecessary regulatory emphasis and requests that the word "all" be removed.

(Response 310) We decline the requests to modify the regulatory text to remove the word "all" or specify that



the requirements apply to all affected animal food “if any.” Animal food is “affected” if a preventive control is not properly implemented during its production. However, the rule does not pre-determine the consequences when animal food is “affected.” Instead, the rule provides for the facility to evaluate the affected animal food for safety. If, as in the example described by the comments, the facility reapplies the preventive control such that the animal food is safe and is not adulterated under section 402 of the FD&C Act, there would be no need to take steps to prevent that animal food from entering commerce.

(Comment 311) Some comments ask us to provide that requirements for corrective actions be principle-based (e.g., affected product containment, control restored to operation before commencing production) rather than prescriptive.

(Response 311) The requirements for corrective actions established by this rule are principle-based in that they require the facility to describe the steps it will take rather than prescribe the steps it will take.

(Comment 312) Some comments ask us to revise the provision to make resampling and/or retesting one of the first steps in a corrective action procedure to take into account human error. These comments assert that mishandling during sampling, transport, and testing can contribute to a false positive result and that if the results of a followup test are negative, then the previous test could be considered an anomaly that could be ignored.

(Response 312) We decline this request. We disagree that an appropriate approach to positive findings of a test for contamination is to resample and retest and to consider positive findings to be an anomaly if subsequent test results are negative. Many animal food products are not homogeneous and contamination is localized. Even for homogeneous animal food products (such as liquids), the problem could be the sensitivity of the method if the level of contamination is low. For further discussion on our current thinking on presumptive positive results and additional testing, see our guidance entitled “Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods” (Ref. 48).

### *C. Proposed § 507.42(b)—Corrective Action in the Event of an Unanticipated Problem*

With some exceptions, we proposed that you must take corrective action to identify and correct a problem, reduce

the likelihood that the problem will recur, evaluate all affected animal food for safety, and, as necessary, prevent affected animal food from entering commerce as would be done following a corrective action procedure if any of the following circumstances apply: (1) A preventive control is not properly implemented and a specific corrective action has not been established; (2) a preventive control is found to be ineffective; or (3) a review of records finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions. We also proposed that if any of these circumstances apply, when appropriate you must reanalyze the food safety plan to determine whether modification of the food safety plan is required.

(Comment 313) Some comments ask us to delete the proposed requirement that a facility must reanalyze the food safety plan in the event of an unanticipated problem. These comments argue that FSMA does not specify reanalysis in the event of an unanticipated problem. In addition, these comments assert that the proposed requirement for reanalysis in the event of an unanticipated problem would be redundant with the proposed requirements for reanalysis as a verification activity (proposed § 507.50) and would not add value for food safety. These comments also assert that the term “problem” is ambiguous and ask us to replace “problem” with “food safety issue” if we retain the provision in the final rule.

(Response 313) We acknowledge that section 418 of the FD&C Act does not explicitly specify that a facility must reanalyze its food safety plan in the event of an unanticipated problem. In the 2014 supplemental notice, we clarified that reanalysis would be conducted “when appropriate.” For example, if a problem occurs because personnel did not understand the procedures or carry out the procedures correctly, additional training for applicable personnel may be warranted, but there likely would be no need to reanalyze the food safety plan.

We disagree that the term “problem” is ambiguous. The term “problem” signifies that something is wrong, whereas the term suggested by the comments (i.e., “issue”) may or may not signify that something is wrong. We agree that the requirements are directed to problems related to animal food safety.

We agree that there is a relationship between the requirements for corrective actions in the event of an unanticipated

food safety problem and the requirements for reanalysis. To reduce redundant regulatory text, in the 2014 supplemental notice we proposed to modify the regulatory text of the requirements for reanalysis to specify that reanalysis is required when appropriate after an unanticipated food safety problem, and we are establishing that modified provision in this final rule. Importantly, the provisions for reanalysis continue to require reanalysis when a preventive control is found to be ineffective. We are not aware of any circumstances in which it would not be appropriate to reanalyze the food safety plan if a preventive control is found to be ineffective.

(Comment 314) Some comments assert that the word “specific” is not appropriate as a modifier for “corrective action procedure” because many preventive controls will have corrective action procedures that allow flexibility based upon the nature of the hazard and control. These comments also state that the term “specific” in this context is more appropriate for a CCP control in a HACCP system.

(Response 314) We have revised the regulatory text to delete the word “specific.”

(Comment 315) Some comments ask us to emphasize that reanalysis is required only when a combination of two events occurs (i.e., a preventive control is not properly implemented and the facility has not established a corrective action procedure).

(Response 315) In the 2014 supplemental notice, we proposed revisions to the regulatory text to clearly specify the circumstances requiring reanalysis. One such circumstance is when a preventive control is not properly implemented and a corrective action procedure has not been established, as stated in § 507.42(b)(1)(i). The final provision includes the revisions included in the 2014 supplemental notice and is consistent with the request of these comments.

(Comment 316) Some comments ask us to add that corrective actions in the event of an unanticipated problem also apply when a preventive control is “missing.”

(Response 316) We have revised the regulatory text to require corrective actions whenever a preventive control, combination of preventive controls, or the food safety plan as a whole, is ineffective. (See § 507.42(b)(1)(ii).) In assessing what the comment might mean by a preventive control that is “missing,” we concluded that an unanticipated problem could, in some cases, mean that a combination of

preventive controls, or the facility's food safety plan as a whole (rather than a single preventive control), simply was not effective. If this is the case, reanalysis would be appropriate, and we also have modified the requirements for reanalysis to specify that a facility must reanalyze its food safety plan whenever it finds that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(Comment 317) Some comments ask us to replace the term "reanalyze" with the term "reassess."

(Response 317) We decline this request. Reanalysis goes beyond assessing the validity of a preventive control or food safety plan to control a hazard. Reanalysis can also include assessing whether all hazards have been identified, whether established procedures are practical and effective, and other factors.

**D. Proposed § 507.42(c)—Corrections**

We proposed that you do not need to comply with the requirements for corrective actions and corrections for conditions and practices that are not consistent with specified sanitation if you take action, in a timely manner, to correct such conditions and practices.

(Comment 318) Some comments support our proposal to provide for corrections, rather than corrective actions, for sanitation controls in some circumstances. Other comments assert that situations in which "corrections" can be applied are not limited to sanitation controls and could include actions to address other preventive controls such as preventive maintenance controls or CGMPs. As discussed in Comment 82, some comments emphasize the importance of distinguishing between the terms "correction" and "corrective action."

(Response 318) We have revised the regulatory text, with associated editorial revisions and redesignations, to provide for corrections, rather than corrective

actions and corrective action procedures, for minor and isolated problems that do not directly impact product safety. As discussed in Response 82, we also have defined the term "correction" to mean an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

**E. Proposed § 507.42(d)—Records**

We proposed that all corrective actions (and, when appropriate, corrections) must be documented in records and that these records are subject to the verification requirements in §§ 507.45(a)(3) and 507.49(a)(4)(i). We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

**XXXII. Subpart C: Comments on Proposed § 507.45—Verification**

In the 2013 proposed preventive controls rule for animal food, we proposed verification activities that would include validation, verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, written procedures, reanalysis, and documentation of all verification activities. We also requested comment on whether we should specify the verification activities that must be conducted for verification of monitoring (78 FR 64736 at 64796) and for verification of corrective actions (78 FR 64736 at 64796), and if so, what verification activities should be required.

To improve clarity and readability, in the 2014 supplemental notice we proposed to move the more extensive verification requirements for validation, implementation and effectiveness, and

reanalysis from the single proposed section (proposed § 507.45) to separate sections (proposed §§ 507.47, 507.49, and 507.50, respectively). In addition, to address comments that asked us to provide more flexibility to facilities, including flexibility in determining whether and how to conduct verification activities, in the 2014 supplemental notice we proposed that the verification activities be performed "as appropriate to the preventive control."

In this section, we discuss the proposed requirements for verification of monitoring, verification of corrective actions, and documentation of verification activities. See sections XXXIII through XXXV for comments on the proposed requirements for validation, verification of implementation and effectiveness, written procedures, and reanalysis. See tables 17, 18, and 19 for a summary of the revisions to those proposed requirements.

Some comments support the proposed requirements for verification of monitoring, verification of corrective actions, and documentation of verification activities without change. For example, comments support the documentation of verification activities (see section XXXI.C). In the following paragraphs, we discuss comments on the flexibility provided for a facility to conduct verification activities as appropriate to the nature of the preventive control. We also discuss comments that address our request for comment on whether we should revise the regulatory text to specify the verification activities that must be conducted for verification of monitoring and for verification of corrective actions, or express concern that the requirements as proposed are too prescriptive. After considering these comments, we have revised the verification requirements described in § 507.45 as shown in table 16.

TABLE 16—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VERIFICATION

Section	Description	Revision
507.45(a) .....	Flexibility to conduct verification activities.	Provide that verification activities take into account both the nature of the preventive control and its role in the facility's food safety system.

**A. Flexibility in Requirements for Verification**

(Comment 319) Some comments support the flexibility provided by use of the phrase "as appropriate to the preventive control" in the requirement that verification activities must include,

as appropriate to the preventive control, specified verification activities (*i.e.*, validation, verification that monitoring is being conducted, verification that appropriate decisions about corrective actions are being made, verification of implementation and effectiveness, and

reanalysis). These comments emphasize that verification activities must be tailored to the preventive control and assert that the use of the word "must" is potentially confusing in light of this flexibility, *e.g.*, because not all preventive controls must be validated

for food safety, and those preventive controls that do not need monitoring would not need verification of monitoring. Other comments ask us to allow facilities flexibility to verify that preventive controls are effective in the manner prescribed by FSMA, *i.e.*, such controls should be deemed to be effective by an appropriate means as determined and supported by the facility within its food safety plan.

(Response 319) The provisions for preventive control management components make clear that all preventive control management components, including verification, are required as appropriate to ensure the effectiveness of the preventive control, taking into account the nature of the preventive control and its role in the facility's food safety system (see § 507.39). Likewise, the provisions for each of the preventive control management components (*i.e.*, monitoring, corrective actions and corrections, and verification) individually provide flexibility, either by specifying that the provisions apply as appropriate to the nature of the preventive control and its role in the facility's food safety system (*i.e.*, for monitoring and verification) or both the nature of the preventive control and the nature of the hazard (*i.e.*, for corrective actions and corrections). The word "must" specifies the type of activities that a facility can use to satisfy the requirements for a particular preventive control management component.

We are retaining the term "must." However, we agree that the rule should provide flexibility for additional verification of implementation and effectiveness. To provide that additional flexibility, we have revised the specific requirements for verification of implementation and effectiveness to provide for other activities appropriate for verification of implementation and effectiveness (see § 507.49(a)(5)). As a conforming revision, we have revised the requirement for review of records to include a review of records of other verification activities within a reasonable time after the records are created (see § 507.49(a)(4)(ii)).

#### *B. Proposed § 507.45(a)—Verification Activities*

##### 1. Proposed § 507.45(a)(1)—Validation

We proposed that verification activities must include, as appropriate to the preventive control, validation in accordance with § 507.47. See section XXXIII for comments on validation as a verification activity.

##### 2. Proposed § 507.45(a)(2)—Verification of Monitoring

We proposed that verification activities must include, as appropriate to the preventive control, verification that monitoring is being conducted in accordance with § 507.40. We requested comment on whether we should specify the verification activities that must be conducted for monitoring, and if so, what verification activities should be required.

(Comment 320) Comments that address our request for comment on whether we should specify the verification activities that must be conducted for monitoring ask us to not do so because this prescriptive approach would be too limiting. These comments ask us to instead provide flexibility for the facility to determine the appropriate verification activities.

(Response 320) We agree that we should provide flexibility for the facility to determine these verification activities, and are not specifying the verification activities that must be conducted for monitoring.

##### 3. Proposed § 507.45(a)(3)—Verification of Corrective Actions

We proposed that verification activities must include, as appropriate to the preventive control, verification that appropriate decisions about corrective actions are being made in accordance with § 507.42. We requested comment on whether this section should specify the verification activities that must be conducted for corrective actions, and if so, what verification activities should be required.

(Comment 321) Some comments ask us not to specify the verification activities that must be conducted for corrective actions because this approach would be too limiting. These comments ask us to instead provide flexibility for the facility to determine the appropriate verification activities.

(Response 321) We agree that we should provide flexibility for the facility to determine the appropriate verification activities for corrective actions, and are not specifying the verification activities that must be conducted for corrective actions.

##### 4. Proposed § 507.45(a)(4)—Verification of Implementation and Effectiveness

We proposed that verification activities must include, as appropriate to the preventive control, verification of implementation and effectiveness in accordance with § 507.49. See section XXXIV for comments on verification of implementation and effectiveness.

(Comment 322) One comment contends that animal food facilities

should not be required to conduct product testing or environmental monitoring to verify implementation and effectiveness of preventive controls. The comment states that product testing and environmental monitoring at a facility that is not using appropriate controls will not normally discover potential hazards. The comment also states that all of the safety requirements necessary to protect the health of animals are already being met because this is necessary as a good business practice and is required by customers.

(Response 322) When a food safety plan is completed by a preventive controls qualified individual, they must ensure that the preventive controls in place are adequate to provide assurance that any hazards requiring a preventive control will be significantly minimized or prevented. We have provided adequate flexibility for a preventive controls qualified individual in an animal food facility to determine if product testing or environmental monitoring is necessary considering the facility, the animal food, the nature of the preventive control, and its role in the facility's food safety system (for further discussion see section XXXIV.C and XXXIV.E).

We disagree that all food safety measures necessary to protect the health of animals are always being followed. Each year, animal food is recalled, often due to a hazard that could cause serious health consequences or death. Animal food from a facility that is required to register and for which there is a reasonable probability that use of or exposure to the food would cause serious adverse health consequences or death to humans or animals is subject to reporting to FDA under section 417 of the FD&C Act (Reportable Food Registry).

##### 5. Proposed § 507.45(a)(5)—Reanalysis

We proposed that verification activities must include, as appropriate to the preventive control, reanalysis in accordance with § 507.50. See section XXXV for comments on reanalysis as a verification activity.

#### *C. Proposed § 507.45(b)—Documentation of Verification Activities*

We proposed that all verification activities must be documented in records. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

#### *D. Comments on Potential Requirements Regarding Complaints*

We requested comment on whether and how a facility's review of

complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards (78 FR 64736 at 64809).

(Comment 323) Some comments ask us to require review of consumer complaints as a verification activity and note that our HACCP regulations for seafood and juice require that verification activities include a review of consumer complaints to determine whether they relate to the performance of the HACCP plan or reveal the existence of unidentified CCPs. Some comments note circumstances in which consumer complaints have identified food safety problems that resulted in a company report to the RFR. Other comments assert that review of customer complaint data should not be required in the rule to verify that a facility's preventive controls are effectively minimizing the occurrence of hazards.

Some comments state that the frequency and type of complaints a facility receives is a very good indicator of the underlying issues associated with food production, reviewing these records would provide valuable insight into the type of issues that should be investigated, and this type of verification activity could therefore be extremely effective with little to no cost because the facility would already be performing this type of activity. Some comments state that many foodborne outbreaks have been identified through complaints and a review of complaints is a critical component of a food safety system. One comment says that many times customer complaints may be the first and only clue that problems exist in animal food because animal illnesses are not subject to the same reporting requirements as human illnesses, resulting in a much weaker basis for identifying, tracing, and correcting foodborne problems.

Other comments state that a food safety review of complaints is a prudent part of a food safety program but that

the value of such a review is in providing information and feedback for continuous improvement of the food safety management system rather than as a verification of preventive controls. These comments caution against use of consumer complaints as a regulatory requirement for verification of the food safety plan because most complaints relate to product quality. If such a requirement is nonetheless established in the final rule, these comments recommend that the rule only require followup and documentation for the rare occurrences where consumer complaints relate to food safety issues.

Other comments ask us not to require review of complaints as a verification activity. Some of these comments assert that complaints rarely relate to food safety or yield information that leads to discovery of a food safety issue. Some comments assert that requiring review of consumer complaints could result in unnecessary time and effort being spent on an activity with a limited correlation to food safety. Some comments assert that the provision would provide FDA access unnecessarily to all complaint files and lead to unproductive and subjective evaluations as to whether a given complaint pertains to the performance of the food safety plan. Other comments assert that complaints would be acted upon immediately for business reasons, and that waiting to react to complaints until conducting a review of records as a verification activity would be too late. Other comments assert that complaints are sensitive business information. Other comments assert that some consumer complaints are false or emotional (rather than factual) and have no place in development of preventive controls. Some comments assert that FSMA does not expressly direct us to require review of complaints. Some comments assert that review of complaints is not a precise scientific process, and that consumer comments are often open to different interpretations.

Some comments discuss the feasibility of consumer complaint

review. Comments state that consumer complaint records are often kept at a corporate level rather than at the individual facility. One comment requests mandatory complaint monitoring for animal food manufacturers. One comment points out FDA already has access to records, including complaint files, associated with animal food, which the Agency reasonably believes to be adulterated and presenting a threat of serious adverse health consequences.

(Response 323) We are not establishing a requirement for a review of complaints as a verification activity. We agree that review of complaints is more likely to be useful in providing information and feedback for continuous improvement of the food safety system rather than as a verification of preventive controls. However, we encourage facilities to do such a review, as they occasionally do uncover animal food safety issues.

**XXXIII. Subpart C: Comments on Proposed § 507.47—Validation**

We proposed to establish requirements for validation of preventive controls. Some comments support the proposed requirements without change. For example, some comments agree that validation must be performed by (or overseen by) a preventive controls qualified individual and that some preventive controls (e.g., sanitation controls and recall plans) do not require validation. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 17, with editorial and conforming changes as shown in table 31.

TABLE 17—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VALIDATION

Section	Description	Revision
507.47(a) .....	Flexibility for validating preventive controls.	Provide that validation be conducted as appropriate to both the nature of the preventive control and its role in the facility's food safety system.
507.47(b)(1) .....	Circumstances requiring validation	Provide that, when necessary to demonstrate the control measures can be implemented as designed, validation may be performed (1) Within 90 calendar days after production of the applicable animal food first begins or (2) within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification.

TABLE 17—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VALIDATION—Continued

Section	Description	Revision
507.47(b)(1) .....	Circumstances requiring validation	Add an additional circumstance requiring validation, <i>i.e.</i> , whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards requiring a preventive control.
507.47(c) .....	Preventive controls that do not require validation.	Clarify that a list of preventive controls that do not require validation is not an exhaustive list.

*A. Flexibility in the Requirements To Validate Preventive Controls*

With some exceptions (see discussion of proposed § 507.47(b)(3) in section XXXIII.D), we proposed that you must validate that the preventive controls identified and implemented in accordance with proposed § 507.36 to control the significant hazards are adequate to do (proposed § 507.47(a)).

(Comment 324) Some comments assert that the regulatory text is in conflict with the preamble discussion in the 2014 supplemental notice because the regulatory text (*i.e.*, “(e)xcept as provided by . . .”) narrowly provides exceptions only for validation of sanitation controls, supplier controls, and the recall plan, whereas the preamble discussion provides other examples of preventive controls that would not require validation (*i.e.*, zoning, training, preventive maintenance, and refrigerated storage). These comments also assert that although the regulatory text specifies that validation requirements apply “as appropriate to the nature of the preventive control,” that phrase could be interpreted to mean that only the validation act itself can be tailored and that the facility does not have the flexibility to conclude that validation isn’t necessary.

Some comments assert that the proposed regulatory text would prevent us from requiring validation of specific sanitation controls where it may be prudent to do so, either now or in the future as a result of a newly identified hazard, or the development of a tool, such as a test method, that would enable validation of the control for the specific hazard.

(Response 324) We have deleted “except as provided by paragraph (b)(3) of this section” from proposed § 507.47(a) to remove the limitation seen by the comments on the exceptions to the requirement for validation of preventive controls. We also have revised the regulatory text of § 507.47(c) to provide that a facility does not need to validate other preventive controls, if the preventive controls qualified individual prepares (or oversees the

preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility’s food safety system. We specified that the determination that validation is not required must be made by the preventive controls qualified individual to emphasize that specialized experience is necessary to evaluate whether validation is required. We made a conforming revision to the list of responsibilities of the preventive controls qualified individual (see § 507.53(a)).

(Comment 325) Some comments ask us to separate requirements for validation from requirements for verification because verification and validation are two different concepts and combining them is confusing. One comment said that we reversed the definitions of validation and verification, compared to the common use of the terms in HACCP activities. Some comments point out that while section 418(f)(1) of the FD&C Act explicitly requires verification, it does not require validation. Some of these comments assert that our proposed requirements for validation exceed the mandate of FSMA while others argue that the lack of explicit language in section 418 of the FD&C Act gives us legal flexibility in determining whether and how to require validation.

(Response 325) Our approach is consistent with section 418 of the FD&C Act. Section 418(f)(1) of the FD&C Act requires verification of the preventive controls, and validation is an element of verification (see both the NACMCF HACCP guidelines (Ref. 49) and our HACCP regulation for juice (§ 120.3(p))). We agree that the purpose of validation is different from the purpose of other verification activities, and we have revised the definitions of both terms to make this clearer. Although we are establishing a separate regulatory section for the validation requirements, we did so to improve clarity and readability rather than as a substantive change relevant to the issues discussed in these comments. (See Response 75.)

(Comment 326) Some comments assert that validation is more appropriate for a HACCP regulation and that requiring the validation of all preventive controls does not reflect the flexibility mandated by section 418(n)(3)(A) of FSMA. Other comments assert that effective preventive measures may be identified in the future that are not amenable to validation and it would be counterproductive for them not to be employed in food safety plans because they cannot meet the validation requirements. These comments explain that certain control measures are not suitable for validation activities due to the nature of the activity or previous validation by another entity (*e.g.*, a supplier).

(Response 326) The 2013 proposed preventive controls rule for animal food would not have required the validation of all preventive controls. For example, we specifically proposed that the validation of preventive controls need not address sanitation controls and the recall plan. To emphasize that a facility has flexibility in determining which other preventive controls require validation, in the 2014 supplemental notice we revised the proposed regulatory text to require validation “as appropriate to the nature of the preventive control.” See Response 324 for additional revisions we have made to the regulatory text to provide flexibility for a facility to determine that validation is not necessary.

(Comment 327) Some comments ask us to allow validation of the whole system instead of individual controls.

(Response 327) See the discussion of the definition of validation in Response 75. Under the definition, validation can be directed to a control measure, combination of control measures, or the food safety plan as a whole.

(Comment 328) Some comments ask us to align validation requirements with the relative risk of operations.

(Response 328) Validation requirements apply only to preventive controls that are established and implemented based on the outcome of a hazard analysis, which requires consideration of risk. We also require

validation as appropriate to the nature of the preventive control and its role in the facility's food safety system. This provides flexibility with respect to validation and allows consideration of risk.

(Comment 329) Some comments ask us to provide guidance and clarification on topics relevant to validation, especially for small facilities that may lack the resources needed to generate studies and scientific data to validate processes. Some comments ask us to clarify our expectations for a validated process and on conducting studies for validation purposes. Some comments ask us to provide resources for validation, noting that some preventive controls will be difficult to validate and that no scientific research or data are available for certain controls. Some comments indicate that validation information provided by FDA should be in the form of non-binding guidance documents. Some comments ask us to delay enforcement for the validation requirements until a readily accessible repository of validated processes, and scientific and technical information, can be created to assist stakeholders in complying with the validation requirements.

(Response 329) We intend that the guidance we are developing will address topics such as those recommended in the comments. (See Response 1). In addition, the FSPCA is developing information for training, which may be useful to animal food facilities. We are not requiring facilities to comply with the requirements of subparts C and E of this rule, including the validation requirements, for 2, 3, or 4 years depending on the size of the facility. We expect that segments of the animal food industry will work together and with the FSPCA to develop scientific and technical information that can be used as evidence to validate a variety of preventive controls, and will be helpful to facilities.

(Comment 330) Some comments indicate that the rule lacked specifications for, and was unclear on, the process that FDA would utilize to approve or accept validation data and/or studies. Some comments ask us to develop a mechanism for industry to make sure their approach and studies meet the requirements of the rule, such as certification of process authorities or the establishment of a liaison between FDA and industry to ensure validation protocols are in compliance.

(Response 330) As discussed in Response 1, we are developing several guidance documents within FDA, including guidance on validation. In addition, as part of a collaborative effort

with the FSPCA we are obtaining technical information useful for developing guidelines for preventive controls and outreach to industry, and we intend that effort to include guidance on approaches to satisfy the validation requirements of the rule. We do not intend to develop a mechanism for certification of process authorities or establish a liaison between FDA and industry to ensure validation protocols are in compliance. The guidance we are developing on validation should help industry determine whether their validation approaches are likely to be acceptable to us.

*B. Proposed § 507.47(b)(1)—When Validation Must Be Performed and Role of Preventive Controls Qualified Individual in Validation*

We proposed that validation of the preventive controls must be performed by (or overseen by) a preventive controls qualified individual prior to implementation of the food safety plan (or, when necessary, during the first 6 weeks of production) and whenever a reanalysis of the food safety plan reveals the need to do so.

(Comment 331) Some comments ask us to clarify whether an individual attending food safety training by an entity such as a cooperative extension or a State department of agriculture could be a "preventive controls qualified individual" for the purpose of performing or overseeing the validation of preventive controls.

(Response 331) See the discussion in section XXXVII.B for additional information about training applicable to a preventive controls qualified individual. We have not specified additional requirements for a preventive controls qualified individual with respect to validation. A person may be a preventive controls qualified individual through job experience, as well as training. Food safety training provided by an entity such as a cooperative extension specialist or a State department of agriculture could be appropriate training for many of the functions of the preventive controls qualified individual if the training is consistent with the standardized curriculum being developed by the FSPCA.

(Comment 332) Some comments question whether 6 weeks is enough time to perform all applicable validation studies that would address the execution element of validation. Some comments ask us to explain the basis for the proposed 6-week timeframe. Some comments ask us to align with the 90-day timeframe in the FSIS Validation Guidelines (Ref. 50). Some comments

note that the seasonal nature of production of some food products may make it impractical to perform all required validations within 6 weeks. Some comments suggest that validation be performed within a specified number of production batches, such as 10 production batches. Some comments emphasize the need for flexibility and ask us to both adopt a 90-day timeframe and provide for a longer timeframe with a written justification, or provide for ongoing evidence of process validation. One comment recommends removing a required timeframe for validation or providing a compliance extension until such time as we could better support the requirements, such as in guidance. One comment asserts that the timeframe should be prior to implementation of the food safety plan. Some comments ask us to specify that validation be performed within a reasonable time as justified by the preventive controls qualified individual. Some comments ask for more time for small businesses to perform validation studies.

(Response 332) We note that the 90-day timeframe for validation is established in FSIS' regulations at 9 CFR 304.3(b) and (c) and 9 CFR 381.22(b) and (c) (Conditions for receiving inspection for meat and meat products and poultry and poultry products, respectively). The FSIS Validation Guidelines are a companion to those regulations. We have revised the regulatory text, with associated editorial changes, to make two changes to the proposed 6-week timeframe for validation of preventive controls. First, we have adopted the 90-day timeframe already established in the FSIS' regulations by specifying that when necessary to demonstrate the control measures can be implemented as designed, validation may be performed within 90 days after production of the applicable animal food first begins. Although we had proposed a 6-week timeframe based on the 3 to 6 week timeframe suggested in the Codex Guidelines for the Validation of Food Safety Control Measures (Ref. 22), we agree that practical limitations associated with the production of some animal food products may make it difficult to perform validation within 6 weeks. The 90-day timeframe in FSIS' regulations, and incorporated into the FSIS Validation Guidelines, reflects more than 15 years of experience with validating HACCP systems for meat and poultry. Although we have provided for validation to be performed within 90 days after production of the applicable food first begins, we do not believe it would take a full 90-days of production

to determine whether the facility can provide assurances that a control measure is working as intended to control the hazard.

Second, we have provided for validation within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable animal food first begins. We acknowledge that practical limitations such as those described in the comments could prevent a facility from performing the validation within 90 days after production of the applicable animal food first begins. A timeframe that exceeds 90 days after production of the applicable animal food first begins will be the exception rather than the norm and we are requiring that the preventive controls qualified individual provide (or oversee the preparation of) a written justification for such a timeframe. We made a conforming revision to the list of responsibilities of the preventive controls qualified individual (see § 507.53(a)).

(Comment 333) Some comments ask us to add another circumstance when validation would be required, *i.e.*, whenever a change is made to the control being applied.

(Response 333) We have revised the regulatory text to require validation whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards requiring a preventive control. Under this provision, a facility would revalidate a preventive control if, for example, a different type of equipment is used to deliver a heat process, because it would be necessary to determine that the new equipment can consistently achieve the required temperature and time of the process. However, a facility would not need to revalidate a preventive control if, for example, a thermal process is changed by increasing the time or temperature, because a less stringent thermal process would already have been validated.

(Comment 334) Some comments ask us to require validation both before production and 6 weeks after production begins.

(Response 334) We decline this request. A facility has flexibility to perform validation as appropriate to the nature of the preventive controls, whether before production (*e.g.*, by obtaining and evaluating generally available scientific and technical information or by conducting studies),

after production begins (to demonstrate the control measures can be implemented as designed during full-scale production), or both.

#### *C. Proposed § 507.47(b)(2)—What Validation Must Include*

We proposed that the validation of preventive controls must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards.

(Comment 335) Some comments assert that our discussion of validation refers to “scientific proof” for the validation of a processing step and ask us to define what is and is not considered scientific proof for validation.

(Response 335) We used terms such as “scientific and technical information” and “scientific and technical basis” rather than “scientific proof” when discussing validation. For information about what we mean by “scientific and technical information,” (see 78 FR 64736 at 64794 through 64795).

(Comment 336) Some comments ask us to clarify expectations of validations for basic sanitary processes. Another comment asks us to exempt the validation of CGMPs.

(Response 336) The requirements for validation only apply to preventive controls. Any practice governed by CGMPs only requires validation if a facility identifies that practice as a preventive control for a hazard. To the extent that the comment is referring to sanitary practices governed by CGMPs (such as in § 507.19), the validation requirements would not apply. To the extent that the comment is referring to sanitation controls established as a preventive control, those sanitation controls are excluded from the validation requirements (see § 507.47(c)).

(Comment 337) Some comments ask that we not require further validation of well-accepted preventive controls, such as refrigeration temperature.

(Response 337) A facility may rely on generally available scientific and technical information to demonstrate the adequacy of controls such as refrigeration but must obtain that information and establish it as a record (see § 507.45(b)).

(Comment 338) Some comments express concern that specific methods are not available to enable validation. Some comments express concern that the requirement to “conduct studies”

might be intended, or could be interpreted, to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices). These comments assert that any such requirement would incur extreme costs and burdens without delivering commensurate public health benefits.

(Response 338) We do not intend the requirement to “conduct studies” to mean that firms are required to develop or validate analytical methods.

(Comment 339) Some comments recommend validation via indirect methods such as scientific publications, government documents, predictive modeling and other technical information from equipment manufacturers and other sources. Other comments assert that there are a variety of circumstances in which the collection and evaluation of scientific and technical information is not necessary (*e.g.*, the use of sieving or metal detectors to control physical hazards).

(Response 339) See Responses 324 and 326. We agree that not all preventive controls require validation, and the facility has flexibility to take into account the nature of the preventive control when determining whether to perform validation. The regulatory text, which provides for scientific and technical evidence that a control measure is capable of effectively controlling the identified hazards, provides for the use of “indirect methods” as recommended by the comments. However, even when sources such as scientific publications are the basis for validation, studies may be needed to demonstrate that the process used can be implemented in the facility to control the hazard.

#### *D. Proposed § 507.47(c)(3)—Preventive Controls for Which Validation Is Not Required*

We proposed that validation need not address sanitation controls, the recall plan, and the supplier program (which we now refer to as the “supply-chain” program).

(Comment 340) Some comments ask us to eliminate the specific list of controls that are excluded from the validation requirement and instead revise the regulatory text to provide the facility with flexibility to determine when validation is appropriate.

(Response 340) As discussed in Response 324, we have deleted “except as provided by paragraph (b)(3) of this section” from proposed § 507.47(a) to remove the limitation seen by the comments on the exceptions to the requirement for validation of preventive controls. We also have revised the

regulatory text of § 507.47(c) to provide that a facility does not need to validate other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. We see no reason to also eliminate the list of those controls for which we have already determined that validation is not necessary, and require each facility to develop its own rationale for concluding that validation is not necessary based on the nature of these preventive controls. The rule would not

prevent a facility from validating one of these preventive controls, such as a sanitation control, if it chooses to do so.

**XXXIV. Subpart C: Comments on Proposed § 507.49—Verification of Implementation and Effectiveness**

We proposed that you must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. We proposed that to do so you must conduct specified activities (*i.e.*, calibration, product testing, environmental monitoring, and review of records) as appropriate to the facility, the animal food, and the nature of the preventive control. We also proposed that you must establish and

implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments, product testing, and environmental monitoring.

Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision. In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 18.

TABLE 18—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VERIFICATION OF IMPLEMENTATION AND EFFECTIVENESS

Section	Description	Revision
507.49(a) .....	Flexibility in the requirement to conduct activities to verify implementation and effectiveness.	Provide that activities for verification of implementation and effectiveness take into account both the nature of the preventive control and its role in the facility's food safety system.
507.49(a)(1) .....	Verification of implementation and effectiveness for process monitoring instruments and verification instruments.	Provide for accuracy checks in addition to calibration.
507.49(a)(4)(i) .....	Timeframe for review of records of monitoring and corrective action records.	Provide for records review within 7 working days after the records are created, or within or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification.
507.49(a)(5) .....	Other activities appropriate for verification of implementation and effectiveness.	Clarify that there could be alternative verification activities of implementation and effectiveness other than those that we specify in the rule.
507.49(b) .....	Written procedures for verification of implementation and effectiveness.	Clarify that written procedures for verification of implementation and effectiveness are established and implemented as appropriate to the role of the preventive control in the facility's food safety system, as well as appropriate to the facility, the animal food, and the nature of the preventive control.
507.49(b)(1) .....	Written procedures for verification of implementation and effectiveness for process monitoring instruments and verification instruments.	Require written procedures for accuracy checks in addition to calibration.

*A. Flexibility in the Requirement To Conduct Activities To Verify Implementation and Effectiveness*

We proposed that you must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards by conducting specified activities as appropriate to the facility, the animal food, and the nature of the preventive control. We proposed to specify the following verification activities: (1) Calibration; (2) product testing; (3) environmental monitoring; and (4) review of records.

In the following paragraphs, we discuss comments generally directed to the need for a facility to have flexibility to apply these requirements (particularly the requirements for product testing and environmental

monitoring) in a manner that works best for the facility in light of its animal food products and the nature of the preventive controls that would be verified. In sections XXXIV.B through XXXIV.F, we discuss the requirements for calibration, product testing, environmental monitoring, and review of records more specifically.

(Comment 341) Some comments express support for the flexibility provided by specifying that verification activities must be conducted “as appropriate to the facility, the animal food, and the nature of the preventive control.” Some comments state that the proposed provision means that, based on risk, an animal food manufacturer could decide whether or not to do product testing and, when applicable, the type of test and the testing

frequency. One comment says the provision will have limited value where the presence of some levels of pathogens is expected and is not necessarily an animal food safety problem. Some comments agree with the proposed provisions because they address product testing through flexible written procedures that consider both testing and corrective action plans rather than through mandatory or prescribed requirements. Other comments agree with the proposed provisions because they require facilities to develop and use testing programs that are tailored to their facility, equipment, processes, products, and other specific circumstances, and do not prescribe specific requirements for testing, such as finished product testing. Some comments state that product testing may



not be effective in identifying the acceptability of a specific ingredient or finished product lot on any given day, but it can help assess and verify the effectiveness of a food safety plan as a whole and the facility's capability to consistently deliver against it.

Some comments assert that the preamble discussion in the 2014 supplemental notice is in conflict with the proposed regulatory text and ask us to modify the regulatory text to provide the flexibility we signaled in that supplemental notice. These comments express concern that the term "must" (*i.e.*, "you must conduct activities that include the following") could be interpreted to mean that activities listed in the regulatory text (in particular, product testing and environmental monitoring) are always required in some form. Some comments ask us to clarify whether product testing and environmental monitoring are required or optional. Other comments assert that facilities should have the flexibility to determine whether to conduct product testing and environmental monitoring based on a risk assessment. Some comments assert that there are circumstances (such as unpackaged animal food; ingredients for animal food stored in vented or open areas, in oilseed production; and rendering) where these tests would not be necessary. Some comments assert that a determination to conduct environmental monitoring should be on a case-by-case basis and that other verification activities may be used (such as process verifications or testing of intermediates) to verify implementation and effectiveness. Other comments ask us to exempt operations when their hazard analysis appropriately concludes that there is no foreseeable risk. One comment says FDA should not require routine monitoring for feed mills unless they manufacture pet food.

One comment says environmental monitoring should not be required as a verification activity for significant hazards as other controls can be used and environmental monitoring will impose undue burdens and costs to industry. Many comments state that environmental monitoring requirements should only be applied to "significant hazards," if any, that are present within the firm's operation, and as with product testing, animal food facilities must be provided the flexibility to tailor their environmental monitoring programs based on risk. Comments note that in cases where the animal food is likely to undergo further processing that would minimize or eliminate any microbiological hazards, environmental pathogens would not be a significant

hazard and such facilities could focus their resources on other controls. One comment says it does not agree that the potential for later processing mitigates the need for environmental monitoring because processes such as pelleting reduce but do not entirely eliminate pathogens.

(Response 341) The provisions for verification provide flexibility by specifying that they apply as appropriate to the nature of the preventive control and its role in the facility's food safety system. As noted by some comments, the provisions address testing through flexible written procedures that allow facilities to develop and use testing programs that are tailored to their facility, equipment, processes, products, and other specific circumstances. We agree that an appropriate outcome of the hazard analysis for some facilities will be that product testing and environmental monitoring are not required; it is not necessary to grant an "exemption" to allow a facility to achieve this outcome. For example, environmental monitoring would be required to verify effectiveness of sanitation controls when an animal food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen because such environmental monitoring is appropriate to the facility (one manufacturing animal food), the food (such as a dry (extruded) pet food exposed to the environment), and the nature of the preventive control (sanitation controls). Animal food such as dry and raw pet food and pet treats are among the products for which manufacturing operations might need to have an environmental monitoring program when such animal food is exposed to the environment.

We discuss product testing for microbial pathogens in another FDA memorandum, including the use of pathogens and indicator organisms and microbial testing of foods for process control and for problem solving (Ref. 52). The circumstances in which product testing would be required are dependent on a variety of factors as described in the Appendix to the 2013 proposed preventive controls rule for animal food (78 FR 64736 at 64836). As with environmental monitoring, product testing must be conducted as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system. For example, a raw material or other ingredient added to an

animal food after a pathogen "kill step" must be tested before use when the raw material or other ingredient has been associated with a pathogen and has not been treated to significantly minimize or prevent that pathogen (*e.g.*, poultry based flavoring spray applied on dry pet food). Product testing would be required because it is appropriate to the facility (one making an animal food), the food (pet food), and the nature of the preventive control (there is no control applied to the poultry based flavoring spray).

When process control testing for an indicator organism, or environmental monitoring for an indicator organism, indicates an animal food (*e.g.*, dry pet food) is reasonably likely to be contaminated with a pathogen, that animal food must be tested for the pathogen. For example, if environmental monitoring reveals animal food-contact surfaces contaminated with *Salmonella* and additional environmental monitoring following corrective actions indicates animal food-contact surfaces are still contaminated with *Salmonella*, product testing would be required because it is appropriate to the facility (one making that animal food), the animal food (pet food, which supports the growth of *Salmonella*), test results from environmental monitoring (which show the presence of an indicator organism for *Salmonella* on animal food-contact surfaces in the animal food processing environment), and the nature of the preventive control (sanitation controls to prevent contamination by environmental pathogens, which appear to be inadequate).

The word "must" specifies the type of activities that a facility can use to satisfy the requirements for a particular preventive control management component, and we are retaining the term "must." However, we agree that the rule should provide flexibility for additional verification of implementation and effectiveness. To provide that additional flexibility, we have revised the specific requirements for verification of implementation and effectiveness to provide for other activities appropriate for verification of implementation and effectiveness (see § 507.49(a)(5)).

We believe that the performance of environmental monitoring, for an appropriate microorganism of public (human and animal) health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (*i.e.*, sanitation controls) when contamination of animal food with an environmental pathogen is a hazard

requiring a preventive control. We anticipate that facilities producing animal food that enters into the home and is frequently handled in the home will include biologic hazards of human health concerns associated with that animal food, as well as those of animal health concerns in their hazards requiring a preventive control. (See, for example, our discussion of *Salmonella* in pet food in the 2013 proposed preventive controls rule for animal food (78 FR 64736 at 64747).)

(Comment 342) Many comments ask us to issue guidance, rather than requirements, for product testing and environmental monitoring based on concerns such as the following: The value of environmental monitoring will be reduced if it becomes a minimum regulatory requirement; there are well-known limitations to product testing and negative results from product testing can create a false sense of security; negative results are likely to occur unless intensive sampling is conducted dependent upon quality sampling criteria; product testing is not preventive, would put industry into a reactive mode, and would pull valuable resources from activities focused on preventing contamination; there is limited technology available to test contaminants in some animal food matrices and limited time available for perishable commodities; any regulatory requirement will soon be outdated as products change and science improves; and product testing would vastly increase the cost of the rule and will drive many businesses out of business without necessarily improving animal food safety; and requirements for product testing would require the States to direct resources to respond to non-compliant product testing results, and such resources would be better directed to environmental monitoring.

Some of these comments emphasize the need for flexibility so that product testing and environmental monitoring are options that are available to the facility rather than requirements for all facilities. Other comments assert that guidance provides greater opportunity for industry innovation and stakeholder participation to determine the appropriate use of verification measures, and avoids a “one-size-fits-all” approach to regulations. Some of these comments state that we should encourage environmental monitoring to be conducted “through facility specific food safety plans,” which would provide the flexibility necessary to monitor risks associated with exposures of animal foods. Other comments state that operators should be given the necessary flexibility to implement any

requirements in the most effective and efficient manner using a risk-based approach and taking into account the specific conditions of their facilities and operations. Some comments express concern that including a requirement makes it difficult for businesses to justify a conclusion that testing is not necessary.

Some comments ask us to solicit drafts of proposed guidance documents from the sustainable agriculture and local/regional food system community; publish a list of possible topics for future guidance each year; seek input in advance from the sustainable agriculture and local/regional food system community before preparing draft guidance (including public meetings, workshops, and formation of an advisory committee); hold public meetings on draft guidance after publication; and present draft guidance to an advisory committee including representatives from the sustainable agriculture and local/regional food system community.

Some comments suggest that an ingredient manufacturer may identify an environmental pathogen but the facility would not implement a preventive control to significantly minimize or prevent the environmental pathogen because the ingredient would be subsequently processed to control the hazard by another facility.

(Response 342) We are retaining the requirements for product testing and environmental monitoring in the rule, with the revisions, already discussed, to provide that verification activities depend on the role of the preventive control in the facility’s food safety system (see Response 293); corrective action procedures depend on the nature of the hazard (see Response 304); and written procedures for product testing and environmental monitoring are established and implemented as appropriate to the role of the preventive control in the facility’s food safety system. These revisions clarify in the regulatory text the flexibility that we discussed in the 2014 supplemental notice (79 FR 58476 at 58493 through 58495). Some of the comments that ask us to issue guidance rather than requirements appear to believe that only guidance can provide sufficient flexibility for product testing and environmental monitoring. This is not the case. (See Response 341.)

We disagree that environmental monitoring will become a minimum regulatory requirement in all cases; the decision to conduct environmental monitoring is made by the facility and some comments discuss specific examples of when environmental

monitoring or product testing would not be warranted. If a facility relies on its customer to control an environmental pathogen then the facility must follow the requirements in subpart E for supply-chain program. Moreover, the fact that further manufacturing might be capable of eliminating an environmental pathogen that has contaminated an animal food is not a reason to not take reasonable measures to prevent contamination from the environment and to verify that such measures are effective through environmental monitoring.

We have acknowledged limitations of product testing (79 FR 58476 at 58493 through 58494) and agree that a facility should consider such limitations when determining whether to conduct product testing and keep such limitations in mind when obtaining negative results from product testing. We also agree that product testing is not preventive. However, the mere facts that there are limitations, and that product testing is itself not a preventive measure, do not eliminate all benefits of product testing; we agree with comments that although product testing may not be effective in identifying the acceptability of a specific ingredient or finished product lot on any given day, it can help assess and verify the effectiveness of a food safety plan as a whole and the facility’s capability to consistently deliver against it. We agree that there is limited technology available to test for some hazards in animal food but expect that testing of animal food by a facility as the sole verification of the effectiveness its food safety plan as a whole would be the exception rather than the norm.

We disagree that regulatory requirements for product testing and environmental monitoring will soon be outdated as products change and science improves; the rule requires reanalysis of the food safety plan as a whole at least every 3 years, and requires reanalysis of the food safety plan as a whole, or the applicable preventive control, in light of new information (see § 507.50(a) and (b)). We agree that there are some costs to product testing, but the rule provides flexibility for the facility to determine when product testing is appropriate. We acknowledge that the States will be required, in many cases, to follow up on positive findings obtained during product testing but disagree that this is a reason to eliminate the proposed requirements. The States would only be directing resources when the findings indicate contamination of animal food, and doing so will protect public (human and animal) health.

We will follow the procedures in § 10.115 for issuing guidance documents. Under § 10.115(f), members of the public can suggest areas for guidance document development and submit drafts of proposed guidance documents for FDA to consider. Under § 10.115(g), after we prepare a draft guidance we may hold public meetings or workshops, or present the draft guidance document to an advisory committee for review; doing so is not common and is determined on a case-by-case basis.

(Comment 343) One comment requests that we add the additional factor of the “intended use of the animal food” to help further clarify that these activities should be conducted based upon the appropriate end use of the animal food as it was intended by the manufacturer, and not upon any potential use of the product not originally intended.

(Response 343) We believe the requirement as written allows the manufacturer’s intended use to be taken into consideration when conducting the hazard analysis. However, to the extent that these comments are asserting that a facility can ignore consumer behavior that the facility considers contrary to principles of food safety, we disagree. For example, a facility could not conclude that it need not identify and evaluate a known or reasonably foreseeable hazard because the facility intends to provide safe handling instructions on the label of a packaged pet food. We do recognize that if a manufacturer/processor has adequately controlled a hazard and has properly packaged, held, and labeled their product, they are not responsible for unforeseeable misuse by a consumer, such as a person who intentionally feeds swine food to sheep even though the product is accurately labeled as containing copper which can be toxic for sheep. For manufacturers/processors that rely on their customer or another entity in the distribution chain to the control a hazard, they must follow the requirements in § 507.36(a)(2), (3), (4) or (5). (See Response 285 for additional information.)

#### *B. Proposed § 507.49(a)(1)—Calibration*

We proposed to require calibration of process monitoring instruments and verification instruments.

(Comment 344) Some comments distinguish “calibration” from an accuracy check, which the comments describe as a test to confirm that a particular equipment or measurement device is accurate. These comments assert that calibration may not be possible for certain equipment or

measurement devices, and the appropriate corrective action may be replacement or application of corrective values. These comments ask us to specify that an accuracy check may be used as a verification activity in lieu of calibration.

(Response 344) We have revised the proposed requirements to require calibration of process monitoring instruments and verification instruments, or checking them for accuracy. However, if the outcome of an accuracy check is that a process monitoring instrument or verification instrument is not accurate, the facility must follow up by calibrating the device, rather than by applying corrective values, when it is practical to do so and replace the device when it is not practical to calibrate it.

#### *C. Comments Directed to Proposed Requirements for Both Product Testing (Proposed § 507.49(a)(2) and (b)(2)) and Environmental Monitoring (Proposed § 507.49(a)(3) and (b)(3))*

We proposed that to verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards you must conduct activities that include product testing and environmental monitoring, as appropriate to the facility, the animal food, and the nature of the preventive control (§ 507.49(a)(2) and (a)(3)). We also proposed that you must establish and implement written procedures for product testing and for environmental monitoring (§ 507.49(b)(2) and (b)(3)).

(Comment 345) Some comments ask us to revise the regulatory text to be explicit that there are circumstances when product testing and environmental monitoring would not be necessary. One comment supports a requirement that incoming raw materials and feed ingredients must be tested for harmful pathogens. Another comment opposes mandatory product testing for every lot of raw material received. Some comments discuss topics for us to include in guidance on procedures for product testing and environmental monitoring, such as which pathogens to test for; the range of products that should be tested; circumstances that warrant testing; what a facility would document and what factors the facility would consider before determining that product testing is not appropriate for its animal food product; frequency of sampling and number of samples to be collected; actions to take after a positive result; available test methods; reporting requirements for results; compliance

strategies; and criteria for laboratories conducting the testing.

(Response 345) We decline to revise the regulatory text. The decision as to whether product testing and environmental monitoring are warranted depends on the facility and its animal food product, as well as the nature of the preventive control and its role in the facility’s food safety system, and a slight variation on circumstances that would lead one facility to conclude that such testing programs were not required could lead a different facility to the opposite conclusion. Memoranda placed in the docket for the 2014 preventive controls supplemental notice for human food provide additional information on these topics requested in the comment (Refs. 51 and 52). Although directed to product testing and environmental monitoring for human food production, some of the information is relevant to animal food, as well.

(Comment 346) Some comments ask us to clarify that tests can be performed by third-party facilities or laboratories, as well as by the facility itself. Some comments ask us to clarify that we will accept test results in the same format as the format used for other purposes, such as third-party certification services.

(Response 346) The rule places no restrictions on who conducts testing. However, facilities have a responsibility to choose testing labs that will produce reliable and accurate test results. (See Response 348.) The rule does not specify the format of test results, provided that the record documenting testing satisfies the recordkeeping requirements of subpart F.

(Comment 347) Some comments express concern about requirements for product testing and environmental monitoring in light of section 202 of FSMA (section 422 of the FD&C Act (21 U.S.C. 350k)). (Section 422 of the FD&C Act addresses laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances and including requirements for accredited laboratories to report the results of laboratory testing to FDA in certain circumstances.) These comments express concern that requirements for facilities to submit results of environmental monitoring to us will create an additional disincentive to looking for pathogens established in the facility. These comments assert that the results of environmental monitoring tests should be available to us for inspection but not submitted to us if product has not been distributed and that submitting the results of routine tests would be burdensome without benefit. These comments ask us to

clarify whether facilities or laboratories would be required to submit the results of environmental monitoring tests to us. Likewise, some comments ask us to clarify whether product testing (including testing of raw materials or other ingredients as part of supplier controls) is subject to the requirements of section 422 of the FD&C Act for using accredited laboratories and for reporting test results to us. Other comments ask us to establish standards and procedures for certifying laboratories that would perform the tests. These comments assert that these standards and procedures are needed to ensure the credibility of the testing and to provide direction for facilities that establish in-house testing facilities. Other comments urge us to establish regulations implementing section 422 of the FD&C Act because they would complement the requirements of the animal food preventive controls rule and because model laboratory standards that address quality controls, proficiency testing, training and education of laboratory personnel offer the protections necessary for ensuring reliable, accurate test results. Other comments assert that if laboratories are not accredited or samples are not collected in a sanitary manner, there is no guarantee the results will be scientifically valid.

(Response 347) Section 422 of the FD&C Act would require, in relevant part, that food testing be conducted by an accredited laboratory (and the results of such testing be sent directly to FDA) whenever such testing is conducted in response to a specific testing requirement under the FD&C Act or its implementing regulations when applied to address an identified or suspected animal food safety problem or to support admission of an animal food under an Import Alert that requires food testing. Although another rulemaking will address the requirements of section 422 of the FD&C Act, our current thinking is that routine product testing and environmental monitoring conducted as a verification activity is not being applied to address an identified or suspected animal food safety problem that requires food testing and would not be subject to requirements to use an accredited laboratory that would submit the results to FDA. We will review the results of environmental monitoring and product testing, if any, during inspections.

The primary concern expressed in these comments was with respect to laboratories reporting results to FDA and not with use of accredited laboratories. The rule requires a facility to establish and implement written procedures for product testing and

environmental monitoring and that the procedures for such testing be scientifically valid. One way to comply with the requirement that testing procedures be scientifically valid is to use an accredited laboratory.

(Comment 348) Some comments ask us to expand the proposed requirement to identify the laboratory conducting the testing to also specify whether that laboratory is accredited and uses the appropriate standards (such as quality control, proficiency testing, and trained laboratory staff). These comments assert that such information would be useful to facilities.

(Response 348) We decline this request. These comments appear to be asking us to establish in the preventive controls for animal food rule requirements related to section 422 of the FD&C Act. Doing so in advance of regulations implementing section 422 of the FD&C Act is premature. However, facilities have a responsibility to choose testing labs that will produce reliable and accurate test results even if the rule does not require the facility to specify whether the laboratory is accredited.

(Comment 349) One comment requested the FSMA regulations regarding ISO methods for *Listeria* and *Salmonella* be changed to using BAM (Bacteriological Analytical Manual) methodology.

(Response 349) While we require scientifically valid procedures for testing, the rule does not specify a particular method be used. A laboratory could use an FDA BAM method, an ISO method, or another method that is validated in the relevant animal food matrix.

(Comment 350) Some comments say that there is little scientific data to show environmentally exposed animal food, such as raw liquid ingredients and finished liquid animal food products, as well as food for livestock creates a potential for harmful biological hazards and an evaluation of environmental pathogens should not be required as part of the hazard analysis. Other comments point out it is common practice to store ingredients with some exposure to the environment during a portion of their storage, complete outdoor storage is standard practice both at the production facility, as well as where it will be consumed without resulting in harm. Some comments say that mere exposure to the environment does not inherently increase the risk of contamination of animal food.

Some comments say environmental testing should only be required for packaged animal foods and recommend that environmental testing be required whenever animal food ingredients or

finished animal foods are exposed to the environment after undergoing a process aimed at reducing pathogens (e.g., a heat kill step such as rendering or the extrusion process) or other hazards that could be transmitted through the environment. These comments say processing aimed at reducing hazards will be ineffective if pathogen loads or hazard levels going into the processing are too high and are concerned that the proposed rule would not require renderers, who often handle sick and dead animals, to make sure that the plant environment is not a pathway for the recycling of pathogens into the animal food system through contaminated animal products. Many comments state that all finished animal food is ready to eat whether or not it is packaged, so it is not reasonable to limit environmental monitoring only to animal foods that may be packaged.

(Response 350) We do not expect either product testing or environmental monitoring to be common in facilities that process, pack, or hold RACs for animal consumption. We agree that there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold RACs that are rarely consumed unprocessed, such as soybeans, or for a manufacturer/processor that will rely on its customer or another entity in the distribution chain to control a hazard as specified in § 507.36(a)(2), (3), and (4). We expect that many facilities that conduct operations such as drying grain are likely to conclude, as a result of their hazard analysis, that neither product testing nor environmental monitoring are warranted and would direct their resources to food safety practices and verification measures other than environmental monitoring or product testing. While a hazard analysis must include an evaluation of environmental pathogens when animal food is exposed to the environment prior to packaging and the animal food does not include a control measure that would significantly minimize the pathogens (see § 507.33(c)(2)), we agree that holding animal food in areas exposed to the environment in some instances will present a low risk of contamination from environmental pathogens. Facilities in these instances will likely conclude there is not a hazard requiring a preventive control. However, facilities that identify an environmental pathogen requiring a preventive control would conduct environmental monitoring as appropriate to the facility, the animal food, and the nature of the preventive control.

(Comment 351) Some comments express concern about the cost of testing and suggest creation of a one-time grant program for very small businesses that would assist them in developing their initial food safety plans and testing programs. One comment says that segments of the animal food production industry currently not performing these types of activities will be challenged to interpret the requirements and develop effective programs. The comment states that inconsistent interpretations of these requirements by an industry fearful of being found in violation of the rule may lead to unnecessary testing and supplier activities and needlessly drive up the cost of compliance.

(Response 351) Very small businesses are qualified facilities that are subject to modified requirements, which do not require testing or development of a food safety plan. We intend that the guidance we are developing will be helpful to all sizes of businesses, and particularly those not currently conducting these activities, that are subject to the requirements for product testing and environmental monitoring. (See Response 1.)

#### *D. Proposed § 507.49(a)(2)—Product Testing*

(Comment 352) Some comments ask us to require finished product testing for food products designated as high-risk, particularly when the product supports pathogen growth during its shelf life. Other comments suggest that finished product or ingredient testing should be implemented as appropriate in situations where a risk has been identified and an effective preventive control cannot be implemented. Other comments ask us to require product testing if an environmental pathogen is identified as a significant hazard.

(Response 352) We decline these requests. A facility's decision to conduct product testing, and to establish the frequency of such testing, will reflect a risk-based approach consistent with its hazard analysis. Consequently, we expect that facilities that produce animal foods that have frequently been associated with outbreaks of foodborne illness (in humans or animals), or produce animal food for which an effective preventive control cannot be implemented, would establish product testing programs more often than facilities that do not produce such animal foods.

A facility that identifies an environmental pathogen as a hazard requiring a preventive control such as sanitation controls would conduct environmental monitoring. Such a facility would decide what, if any, role

product testing would play as a verification activity, or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the animal food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system.

(Comment 353) Some comments ask us to clarify (or specify) when product testing would be directed at raw materials and other ingredients and when product testing would be directed at finished product. Some comments favor testing raw materials and other ingredients as part of "product testing," whereas other comments state that testing raw materials and other ingredients should be considered part of a supplier program rather than verification of implementation and effectiveness. Other comments state that it is unclear what preventive control step would be verified by product testing and what types of facilities would be required to perform product testing. One comment states product testing for animal food should solely focus on finished products that are consumed by animals in accordance with their intended use as described in the facility's animal food safety plan.

(Response 353) We use the term "product testing" to mean testing any animal food product, whether raw materials or other ingredients, in-process animal foods, or finished products and, thus, product testing can be directed to any of these animal food products. For example, testing raw materials and other ingredients could be verification of a supplier; testing in-process material after a kill step could be verification of process control; testing finished product could be verification of the food safety plan as a whole, and capture a problem introduced during manufacture, including from contaminated raw materials and other ingredients, if raw materials and other ingredients had been tested before use. Product testing generally is not the most effective means of measuring the adequacy of cleaning and sanitation programs, but such testing is common to track a facility's overall hygienic production measures.

(Comment 354) Some comments assert that a facility that implements supplier verification and environmental monitoring (or other measures) should not be required to perform product testing in addition to the other controls and verification measures.

(Response 354) The facility determines whether product testing is necessary as appropriate to the facility, the animal food, and the nature of the

preventive control and its role in the facility's food safety system. The factors mentioned by the comment are examples of factors that a facility would consider in making its determination.

(Comment 355) Some comments ask us to revise the requirement for product testing to clarify that product testing applies to significant hazards.

(Response 355) We decline this request. Product testing is a verification activity for a preventive control, and a preventive control is established for a "significant hazard" (which we now refer to as "hazard requiring a preventive control"). It is not necessary to repeat, for each type of verification activity, that the activity applies to hazards requiring a preventive control.

(Comment 356) Some comments assert that the real point of product testing is to test all lots or batches. These comments explain that they would be required to retest every lot of product in order to pass an analysis of the product on to its customers, even if testing had already been performed by their vendors (*i.e.*, suppliers), because each of their customers receives a proprietary blend. These comments further explain that it is not economically or physically possible to retest small lots of product already tested by their vendors, and that the risk has already been mitigated by its vendors.

(Response 356) The situation described by these comments appears to be a supplier-customer relationship in that the customer, not this rule, has established a requirement for a certificate of analysis for every lot of received product. The product testing that this rule requires as a verification activity is to help assess and verify the effectiveness of a food safety plan and the facility's capability to consistently deliver against it, not to establish the acceptability of every lot or batch.

(Comment 357) Some comments assert product testing should primarily be used as a measure of process control, not for acceptance testing; that product testing should normally be viewed as a monitoring and review tool, not as a product conformance verification tool. The comment states testing programs for product conformance verification should be the exception rather than the rule.

(Response 357) These comments appear to have misunderstood the proposed requirements for product testing. Consistent with the views expressed by these comments, we proposed requirements for product testing as a verification measure of the food safety plan as a whole, not for product conformance.

(Comment 358) One comment says test results, whether via voluntary company programs to verify process controls or mandated by regulation, should not be required to be submitted to FDA unless they indicate serious human or animal health consequences (*i.e.*, necessitate a Class I recall) as is required under the existing requirements for the RFR. Comments state that FDA inspectors should not penalize facilities for finding potential problems through verification if appropriate corrective actions are taken.

(Response 358) This comment appears to have misunderstood the requirements for product testing, which do not include reporting product testing results to FDA. However, during an inspection, if product testing was used as a verification measure, the inspector may review the documentation for that testing and the records documenting any corrective action procedures taken as a result of that testing.

*E. Proposed § 507.49(a)(3)—Environmental Monitoring*

We proposed to require environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples.

(Comment 359) Some comments ask us to specify that environmental monitoring of pathogens be executed according to a risk analysis. Many comments say environmental monitoring should be a verification tool based on a risk assessment as different animals show different susceptibility to pathogens, pathogen growth is dependent upon the animal food, and pathogens grow differently in different environments and seasons. Some comments state that the corrective actions for environmental monitoring should be risk based and take into account information such as organism threshold, sampling, and analytical methodology. One comment says the requirement should be applied only to “significant hazards” if any, that are present within the operation. One comment states that it is not clear who would be responsible for environmental monitoring at various points in the supply chain. The comment requests more clarification on the “boundaries” of responsibility for proposed measures like environmental monitoring. One comment says prior to including environmental monitoring in the regulation, methodologies and minimum standards that establish the

threshold industry must meet should be developed and vetted.

(Response 359) We decline these requests. See the discussion in Response 301, which explains how risk applies to the facility’s hazard analysis and the determination by the facility to establish preventive controls for hazards requiring a preventive control as appropriate to the facility and the animal food. In contrast, the requirements for environmental monitoring are a verification activity that a facility would conduct to verify that one or more preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards requiring a preventive control and would be established as appropriate to the facility, the animal food, and the nature of the preventive control rather than according to a risk analysis. The rule provides flexibility for the facility to determine appropriate test methodologies and the threshold appropriate for the environmental pathogen being monitored to verify the effectiveness of the facility’s preventive control. For requirements that apply to hazards that a customer of the facility, “or another entity in the distribution chain,” will control. See the requirements in § 507.36 and the discussion in section XXVII.

(Comment 360) Numerous comments request that we distinguish between production of pet food and other animal food. Many comments state that FDA has publically stated that it intends environmental monitoring to apply mainly to facilities that manufacture pet food and pet treats; however, the language extends the requirement to any facility that packages animal food that does not receive a treatment to minimize pathogens. Comments say it must be made clear, through outreach, education, and compliance policy guides, that the requirement to conduct environmental monitoring is intended for a limited range of facilities, products and processes, and does not apply to livestock feed or animal food for which environmental pathogens do not pose a significant hazard in the finished animal food. Another comment expressed concern because *Salmonella* has been found in finished poultry feed. One comment says we should require *Salmonella* testing as part of an environmental program. One comment asks us to explicitly recognize in the preamble to the final rule that contamination of animal food with an environmental pathogen may be a significant hazard in many dry pet food manufacturing facilities.

(Response 360) We agree that environmental monitoring may be particularly relevant to pet food manufacturing and the majority of environmental monitoring may occur in dry or raw pet food manufacturing facilities. However, its usefulness is not limited exclusively to pet food production. Therefore, the requirement for environmental monitoring is flexible to allow a facility to determine whether environmental monitoring is needed based on the facility, the type of animal food produced, the nature of the preventive control for the environmental hazard and its role in a facility’s food safety system.

We decline the request to require *Salmonella* testing as part of environmental monitoring. We believe that most facilities producing pet foods (other than those subject to part 113 that are exempt from subpart C with respect to microbiological hazards regulated under part 113) will identify *Salmonella* spp. as a known or reasonably foreseeable hazard that requires a preventive control verified by environmental monitoring. We decline the request to exempt livestock food or animal food other than pet food from the provisions for environmental monitoring. However, we believe use of environmental monitoring by a livestock or poultry food facility as a verification of a preventive control would be the exception rather than the norm.

*F. Proposed § 507.49(a)(4)—Review of Records*

We proposed to require review of specified records by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. We proposed to require review of records of monitoring and corrective action records within a week after the records are made, and review of records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made.

(Comment 361) Some comments assert that it is not necessary for a preventive controls qualified individual to conduct or oversee review of records as a verification activity, noting that review of records in another food safety regulation (*i.e.*, the LACF requirements in part 113) can be done by persons adequately trained in recordkeeping and review of records.

(Response 361) The rule does not preclude review of records by persons other than the preventive controls qualified individual, provided that the preventive controls qualified individual provides oversight for that review. Oversight by a preventive controls qualified individual is necessary because the review of records is critical to assessing the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation (78 FR 64736 at 64796 through 64797). Oversight by a preventive controls qualified individual is consistent with requirements of Federal HACCP regulations for seafood, juice, and meat and poultry (Ref. 49) (78 FR 64736 at 64796 through 64797).

(Comment 362) Some comments ask us to provide for a timeframe longer than 1 week (such as 7 working days) for review of records of monitoring and corrective actions. Some comments ask us to provide the same flexibility for review of records of monitoring and corrective actions as we proposed for review of records of calibration, product testing, environmental monitoring, and supplier verification activities ("within a reasonable time" after the records are made), e.g., because some preventive controls may be monitored less frequently than is typical in a traditional HACCP plan dominated with CCPs. Some comments note that corrective actions may not be fully implemented within 7 days and ask us to provide for review of these records within a week or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce. Some comments ask us to retain the 1 week timeframe for review of records associated with perishable foods, but to extend the timeframe to 1 month for nonperishable foods.

Some comments state that some food processors that operate on a batch production basis (rather than a continuous production basis) review all records related to a particular batch all at once just before release of the batch for distribution. These comments assert that it would be inefficient, unnecessary, and needlessly complicated to require management to review a few production records in advance of the normal complete records review, particularly when laboratory testing conducted on the batch by an outside laboratory takes several weeks to complete.

(Response 362) We have revised the proposed requirement to require review of records of monitoring and corrective actions within 7 working days after the records are made or within a reasonable timeframe, provided that the preventive

controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days. A timeframe that exceeds 7 working days will be the exception rather than the norm. For example, reviewing records before release of product may be considered adequate by a facility, although this may be later than one week after the records were created. A facility may determine that all records for a lot of product will be reviewed after product testing or environmental monitoring records relevant to that lot of product are available, which may be more than a week after monitoring records were created. We made a conforming change to the list of responsibilities of the preventive controls qualified individual to address the requirement for the preventive controls qualified individual to provide (or oversee the preparation of) a written justification for such a timeframe (see § 507.53(a)).

We are not requiring that a facility review records of monitoring and corrective actions before release of product or that the timeframe for the review depends on the shelf life of the animal food. The purpose of reviewing records is not to determine whether to release product. Instead, the purpose of reviewing records is to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. However, a facility will have flexibility to review records of monitoring and corrective actions within a timeframe that exceeds 7 working days, such as before product release, provided that the facility provides a written justification for doing so. Depending on the nature of the record, a facility that reviews these types of records in a timeframe that exceeds 7 working days, and finds a problem, may be faced with recall decisions for a relatively large number of affected lots of product.

(Comment 363) Some comments ask us to revise the provisions for review of records by more generally referring to records of "verification testing (e.g., product testing and/or environmental monitoring as applicable)."

(Response 363) We have revised the regulatory text to refer to records of "testing (e.g., product testing, environmental monitoring)."

(Comment 364) Some comments refer to our request for comment on whether the regulatory text should specify the verification activities that must be conducted for corrective actions. These comments assert that if we do not

further specify verification activities for corrective actions then we should eliminate the proposed requirement to review records of corrective actions.

(Response 364) Records are necessary to document all verification activities (see § 507.45(b)). The fact that the rule provides flexibility for the facility to determine the verification activities for corrective actions, rather than prescribes these verification activities, has no bearing on the requirement to document the verification activities.

(Comment 365) Some comments emphasize the importance of calibrating those instruments and monitoring devices that are critical to the preventive control, and reviewing the associated records, before validation of a lethality step and as frequently as necessary thereafter. These comments question whether requiring review of calibration records "within a reasonable time" will be adequate.

(Response 365) We agree that instruments and monitoring devices that are critical to a preventive control should be calibrated, and calibration records should be reviewed, before conducting studies to validate a lethality step. However, the provision is directed at verification of implementation and effectiveness of preventive controls on an ongoing basis. This rule does not prescribe specific steps that a facility must take before conducting validation studies.

A facility has flexibility to appropriately determine the frequency of reviewing calibration records based on the facility, the animal food, and the nature of the preventive control. We agree that it would be prudent to review calibration records of those instruments and monitoring devices that are critical to the preventive control more frequently than of those instruments and monitoring devices that are not critical to the preventive control. Depending on the nature of the control being calibrated, a facility that reviews calibration records infrequently, and finds a problem with calibration of process monitoring instruments and verification instruments, may be faced with recall decisions for a relatively large number of affected lots of product.

#### *G. Proposed § 507.49(b)—Written Procedures*

##### 1. Proposed § 507.49(b)(1)—Frequency of Calibration

We proposed that you must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

(Comment 366) Some comments ask us to specify that an accuracy check may be used as a verification activity in lieu of calibration. These comments also ask us to specify that written procedures address the frequency of accuracy checks, as well as calibration.

(Response 366) We have revised the proposed requirement to specify that written procedures address the frequency of accuracy checks, as well as calibration.

## 2. Proposed § 507.49(b)(2) and (b)(3)—Product Testing and Environmental Monitoring

We proposed that you must establish and implement written procedures for product testing. We proposed that procedures for product testing must: (1) Be scientifically valid; (2) identify the test microorganism(s); (3) specify the procedures for identifying samples, including their relationship to specific lots of product; (4) include the procedures for sampling, including the number of samples and the sampling frequency; (5) identify the test(s) conducted, including the analytical method(s) used; (6) identify the laboratory conducting the testing; and (7) include the corrective action procedures required by § 507.42(a)(1).

Likewise, we proposed that you must establish and implement written procedures for environmental monitoring. Procedures for environmental monitoring must: (1) Be scientifically valid; (2) identify the test microorganism(s); (3) identify the locations from which the samples will be collected and the number of sites to be tested during routine environmental monitoring; (4) identify the timing and frequency for collecting and testing samples; (5) identify the test(s) conducted, including the analytical method(s) used; (6) identify the laboratory conducting the testing; and (7) include the corrective action procedures required by § 507.42(a)(1)(ii).

(Comment 367) Some comments express concern that the word “valid” in the phrase “scientifically valid” could be construed to mean “validated” because not all testing protocols can be validated within the traditional meaning of the term. These comments state their belief that what we intend is for these testing programs to be “technically sound.” Other comments express concern that “scientifically valid” may be interpreted to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices).

(Response 367) We are retaining the term “scientifically valid” in these

provisions. We disagree that we would interpret “scientifically valid” to mean that facilities are required to develop or validate analytical methods. We discussed our interpretation of the term “scientifically valid” in the Appendix to the 2013 proposed preventive controls rule (78 FR 64736 at 64834 through 64835), and noted that this interpretation was consistent with our previous discussion of the term “scientifically valid” (in place of “validated”) in the rulemaking to establish CGMP requirements for dietary supplements (68 FR 12158 at 12198, March 13, 2003). While validated methods are considered “scientifically valid,” methods that have not gone through formal validation processes but have been published in scientific journals, for example, may also be “scientifically valid.” We do expect methods used for testing to be adequate for their intended use.

Although we agree that methods that are “scientifically valid” would also be “technically sound,” we disagree that the hypothetical concern that we would construe “scientifically valid” to mean “validated” warrants changing “scientifically valid” to a new term (such as “technically sound”) in light of our previous statements regarding this term and experience in the context of CGMP requirements. See the final rule establishing the dietary supplement CGMPs for additional discussion on the terms “validated” and “scientifically valid” (72 FR 34752 at 34853).

(Comment 368) Some comments support the proposed requirements for written procedures for environmental monitoring, including providing flexibility to use indicator organisms and to design the timing, location, and frequency of environmental monitoring programs in a risk-based manner, and in not prescribing specific locations (e.g., food-contact surfaces or “zone 1”) or sample quantities for testing. Other comments ask us to add details to the written procedures for product testing and environmental monitoring regarding when and where sampling is required and the number of samples to take. Some comments ask us to make sure the most current “sampling planning science” is used for environmental monitoring by specifying that procedures for environmental monitoring must employ sample quality criteria objectives. Other comments assert that the product testing procedure requirements are inadequate and ask us to require that procedures for product testing specify the procedures for identifying samples (including their relationship to specific lots of product); describe how sampling was conducted

(to establish that the sample obtained adequately represents the lot of product the sample is intended to represent); and include the procedures for sample quality control from field to lab.

(Response 368) We decline the request to prescribe additional details, such as those described in these comments, in the requirements for written procedures for product testing and environmental monitoring. As with other procedures required by the rule, those relating to environmental monitoring and product testing must be adequate for their intended purpose. Further, procedures will not be identical in all circumstances. For example, a facility that produces products with a short shelf life may choose a different frequency of swabbing and testing than a facility that produces products with a long shelf life.

(Comment 369) Some comments ask us to provide more flexibility in product testing by not requiring establishments to provide written procedures for product testing and corrective action procedures.

(Response 369) These comments are unclear. By requiring that a facility establish its own procedures, the rule provides facilities with flexibility to develop a product testing program that works best for its facility and its products. We are retaining the requirements for written procedures for product testing, as well as for corrective action procedures.

(Comment 370) Some comments ask us to add a provision requiring that all positive results must result in corrective action being taken.

(Response 370) We decline this request. The rule requires that a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate, the presence of a pathogen or appropriate indicator organism in an animal food product detected as a result of product testing and the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring (see § 507.42(a)(1)). However, the rule does not predetermine what corrective actions a facility must take when presented with positive results from product testing or environmental monitoring. The corrective action procedures that a facility would develop, and the actual corrective actions that the facility would take, will depend on the nature of the hazard and the nature of the preventive control, as well as information relevant to the positive result (e.g., pathogen or



indicator organism, product or environment, animal food-contact surface or non-animal food-contact surface).

For additional discussion of comments on verification of implementation and effectiveness, see section XXXIV of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

**XXXV. Subpart C: Comments on Proposed § 507.50—Reanalysis**

We proposed to establish requirements for reanalysis of the food safety plan. Some comments support the proposed requirements without change. For example, comments agree that a preventive controls qualified individual must perform (or oversee) the reanalysis (see section XXXV.D). Some comments that support the proposed provisions

suggest alternative or additional regulatory text.

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 19, with editorial and conforming changes as shown in table 31.

TABLE 19—REVISIONS TO THE PROPOSED REQUIREMENTS FOR REANALYSIS

Section	Description	Revision
507.50(b) .....	Circumstances that require reanalysis .....	Provide for reanalysis of an applicable portion of the food safety plan (rather than the complete food safety plan) in specified circumstances.
507.50(b)(4) .....	Circumstances that require reanalysis .....	Require reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, whenever a preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective.
507.507(c) .....	Timeframe to complete the reanalysis .....	Clarify that the requirement applies to completing the reanalysis and <i>validating</i> any additional preventive controls (as appropriate to the nature of the preventive control and its role in the facility's food safety system), rather than to completing the reanalysis and <i>implementing</i> any additional preventive controls (emphasis added).

**A. Proposed § 507.50(a)—Circumstances Requiring Reanalysis**

We proposed that you must conduct a reanalysis of the food safety plan: (1) At least once every 3 years; (2) whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard; (3) whenever you become aware of new information about potential hazards associated with the animal food; (4) whenever appropriate after an unanticipated animal food safety problem; and (5) whenever you find that a preventive control is ineffective.

(Comment 371) Some comments assert that the need to reanalyze the food safety plan will depend on the nature of the preventive control and its role in the food safety system. These comments also assert that if a specific preventive control is found to be ineffective, only the applicable portion of the food safety plan would need to be reanalyzed.

(Response 371) We agree and have revised the regulatory text, with associated editorial changes and redesignation, to separate the requirement to reanalyze the food safety plan as a whole every 3 years from all other circumstances when reanalysis is required “for cause.” When reanalysis is “for cause,” the regulatory text provides that reanalysis is of the food safety plan as a whole, or the applicable portion of the food safety plan.

(Comment 372) Some comments ask us to define “reanalysis” to mean “a reassessment of the validity of a preventive control or food safety plan to control a hazard. Reanalysis may include a system review and, where necessary, activities to revalidate a control measure or combination of control measures.”

(Response 372) We decline this request. Reanalysis goes beyond assessing the validity of a preventive control or food safety plan to control a hazard. Reanalysis can also include assessing whether all hazards have been identified, whether established procedures are practical and effective, and other factors.

(Comment 373) Some comments ask us to require reanalysis on an annual basis, noting that annual reanalysis is required by Federal HACCP regulations for seafood, juice, and meat and poultry.

(Response 373) We decline this request. We proposed to require reanalysis at least once every 3 years as a minimum requirement in the event that there is no other circumstance warranting reanalysis (see § 507.50(b)(2) through (4)). That 3-year minimum is consistent with the statute (see section 418(i) of the FD&C Act). As a practical matter, we expect that reanalysis will occur more frequently as a result of changes in the activities conducted at a facility (§ 507.50(b)(1) through (4)).

(Comment 374) Some comments suggest editorial changes to improve the readability of the requirement to

conduct reanalysis when there is a change in a preventive control.

(Response 374) We are including these editorial changes in the regulatory text, which now reads whenever “a significant change in the activities conducted at your facility creates a reasonable potential . . .”

(Comment 375) Some comments assert that the proposed requirement to conduct reanalysis whenever you become aware of new information about potential hazards associated with the food does not align with FSMA statutory language, is ambiguous, and would establish vague compliance obligations.

(Response 375) We disagree that the proposed requirement is ambiguous and would establish vague compliance obligations. See our previous discussion regarding the emergence of the first outbreak of foodborne illness in the United States, in 2006–2007, caused by consumption of peanut butter contaminated with *Salmonella* (78 FR 64736 at 64798). Although we acknowledge that the proposed requirement is not explicit in section 418(i) of the FD&C Act, we disagree it is not in alignment with FSMA as a whole. FSMA directs the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility and identify and implement preventive controls to significantly minimize or prevent the occurrence of those hazards (see section

418(a) of the FD&C Act). In other words, FSMA focuses on a system to prevent food safety problems rather than a system to react to problems after they occur. Requiring that a facility reanalyze its food safety plan, or the applicable portion of the food safety plan, in response to information such as the emergence of a new foodborne pathogen, or an outbreak of foodborne illness from consumption of an animal food product (or handling by consumers of a pet food product) not previously associated with foodborne illness from a well-known pathogen, aligns very well with the statutory direction in FSMA.

(Comment 376) Some comments ask us to add a requirement to conduct reanalysis whenever a preventive control is found to be “missing” in addition to whenever a preventive control is found to be “ineffective.”

(Response 376) We have revised the regulatory text to require reanalysis whenever a preventive control, a combination of preventive controls, or the food safety plan as a whole, is ineffective. (See § 507.50(b)(4).) A “missing” preventive control could be discovered during verification to establish the validity of the food safety plan as a whole or as a result of an unanticipated problem. If circumstances lead a facility to conclude that an additional (or different) preventive control is necessary, the facility would include that preventive control in its food safety plan along with associated preventive control management components, including verification to establish the validity of the food safety plan.

#### *B. Proposed § 507.50(b)—Timeframe To Complete Reanalysis*

We proposed that you must complete the reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. We have clarified that the requirement is to complete the reanalysis and validate (rather than implement) any additional preventive controls as appropriate to the nature of the preventive control and its role in the facility’s food safety system.

(Comment 377) As discussed in Comment 332, some comments question whether 6 weeks is enough time to perform all applicable validation studies that would address the execution element of validation. Likewise, some comments question whether 6 weeks is enough time to complete reanalysis.

(Response 377) Consistent with revisions we have made to the

timeframe to complete validation (see Response 332), we have revised the timeframe to complete the reanalysis and validate, as appropriate to the nature of the preventive control and its role in the facility’s food safety system, any additional preventive controls to be within 90 days after production of the applicable animal food first begins or within a reasonable timeframe, provided that the preventive controls qualified individual provides (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable animal food first begins. We made a conforming change to the list of responsibilities of the preventive controls qualified individual (see § 507.53(a)).

(Comment 378) Some comments state that the phrase “before the change in activities at the facility is operative” is ambiguous in that it is unclear if the phrase is referencing the initial change in activities that triggered the reanalysis or a change in activities subsequent to the reanalysis. These comments ask us to clarify the requirement by substituting the phrase “before the relevant process is operative.”

(Response 378) We agree that there was ambiguity in this phrase, because changes in activities could result in the need for reanalysis and reanalysis could result in the need for changes in activities, both of which can result in a new preventive control. We have made several revisions to the regulatory text, with associated editorial changes, to clarify the requirements for reanalysis. First, we have clarified that reanalysis can be routine (at least every 3 years) or “for cause” (*i.e.*, a significant change that creates the potential for a new hazard or an increase in a previously identified hazard; when you become aware of new information about potential hazards associated with the animal food; when there is an unanticipated animal food safety problem; or whenever a preventive control, combination of preventive controls or the food safety plan as a whole is ineffective). Second, we have specified that the reanalysis “for cause” may be for the entire food safety plan or only for an applicable portion.

In addition, we have clarified that the reanalysis and the validation, as appropriate to the nature of the preventive control and its role in the facility’s food safety system, of any additional preventive controls needed to address an identified hazard, would need to be completed before any change in activities (including any change in preventive controls) is operative. When additional time is necessary, we have provided for a timeframe within 90 days

after production of the applicable animal food first begins or within a reasonable timeframe, provided that the preventive controls qualified individual provides (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable animal food first begins. In other words, if you decide to make a change, you should conduct a reanalysis before you make that change if there is potential for that change to create or increase a hazard; a reanalysis that results in changes to preventive controls should be completed and the preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility’s food safety system, before changes in activities to produce animal food using a new preventive control are put into operation. However, we acknowledge that it may be necessary to produce product to demonstrate a revised preventive control can be implemented appropriately, and provide for an extended timeframe to make this assessment.

#### *C. Proposed § 507.50(c)—Requirement To Revise the Written Food Safety Plan or Document Why Revisions Are Not Needed*

We proposed that you must revise the written food safety plan if a significant change is made or document the basis for the conclusion that no revisions are needed. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

#### *D. Proposed § 507.50(d)—Requirement for Oversight of Reanalysis by a Preventive Controls Qualified Individual*

We proposed that a preventive controls qualified individual must perform (or oversee) the reanalysis. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed. See section XXXVII.B for comments on the qualifications for a preventive controls qualified individual who would perform or oversee the reanalysis.

#### *E. Proposed § 507.50(e)—Reanalysis on the Initiative of FDA*

We proposed that you must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

(Comment 379) Some comments ask us to issue formal, written communications about new hazards and developments in scientific understanding. These comments express

concern that communications of this type could be inconsistent if they are communicated by individual investigators. Other comments ask us to specify in the regulatory text that it is the Commissioner of Food and Drugs who makes the determination that it is necessary to conduct a reanalysis of the food safety plan.

(Response 379) We agree that a communication from FDA about the need to reanalyze the food safety plan should be issued in a formal written manner but disagree that it is necessary to specify that it is the Commissioner of Food and Drugs who makes the determination that it is necessary to conduct a reanalysis of the food safety plan. The comment provides no basis for precluding such a determination by

an organizational component (such as CVM or a component of FDA’s Office of Regulatory Affairs) that has operational responsibility for animal food safety and subject matter experts to advise the managers in those organizational components.

**XXXVI. Subpart C: Comments on Proposed § 507.51—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food**

We proposed that if your facility is solely engaged in the storage of packaged animal food that is not exposed to the environment, you must conduct certain activities for any such refrigerated packaged animal food that requires time/temperature controls for

safety (TCS animal food) to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance. We requested comment on the proposed list of modified requirements. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In this section, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 20.

TABLE 20—REVISIONS TO THE PROPOSED MODIFIED REQUIREMENTS FOR UNEXPOSED, REFRIGERATED, PACKAGED ANIMAL FOOD

Section	Description	Revision
507.51(a)	Circumstances that make a facility subject to the modified requirements for unexposed, refrigerated packaged animal food.	Clarify that the requirements apply to a temperature control area in a facility that holds TCS animal food rather than to each product in the holding facility.
507.51(a)(2)	Modified requirements for monitoring the temperature controls.	Specify that it is the temperature controls that are consistently performed.
507.51(a)(3)	Modified requirements for corrective actions.	Clarify that corrective actions need only be taken when a loss of temperature control may impact the safety of the TCS animal food.
507.51(a)(4)(i)	Modified requirements for verification of temperature controls.	Provide additional flexibility for accuracy checks, in addition to calibration, to verify that temperature controls are consistently implemented.
507.51(a)(4)(iii)	Modified requirements for verification of temperature controls.	Provide additional flexibility for reviewing records of monitoring and corrective actions either within 7-working days after the records are made or within a reasonable timeframe.
507.51(a)(5)(i)	Records documenting the monitoring of temperature controls.	Provide additional flexibility for records documenting the monitoring of temperature controls to be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control.
507.51(a)(5)(ii)	Records documenting corrective actions.	Conforming change associated with the modified requirements for corrective actions to clarify that records of corrective actions are required when there is a loss of temperature control that may impact the safety of the TCS animal food.

*A. Proposed § 507.51(a)—Modified Requirements for Unexposed Refrigerated Packaged Animal Food That Requires Time/Temperature Controls*

1. Proposed § 507.51(a)(1)—Establish and Implement Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance.

We also tentatively concluded that it would be rare for a facility solely engaged in the storage of unexposed packaged animal food to not have information regarding whether a

refrigerated packaged animal food is a TCS animal food and, if so, what specific temperature controls are necessary for safe storage of the food. We requested comment on this tentative conclusion.

(Comment 380) Some comments ask us to clarify that the requirement to establish and implement temperature controls applies to temperature control areas in a facility rather than to each product in a facility.

(Response 380) We agree that the requirement to establish and implement temperature controls applies to temperature control areas in a facility rather than to each product in a facility. To make this clearer, we have revised the proposed requirement to clarify that the facility must conduct activities as appropriate to ensure the effectiveness

of the temperature controls rather than conduct activities “for any such refrigerated packaged animal food.”

(Comment 381) Some comments disagree with our tentative conclusion that it would be rare for a facility solely engaged in the storage of unexposed packaged animal food to not have information regarding whether a refrigerated packaged food is a TCS animal food and, if so, what specific temperature controls are necessary for safe storage of the animal food. These comments ask us to specify that the responsibility for determining whether an animal food is a TCS animal food falls to the manufacturer of the animal food rather than the warehouse storing the animal food, because the warehouse merely provides a service. Other

comments note that the animal food product owners determine the optimal conditions for storage of their products based on their own hazard analysis and preventive controls, and that the animal food product owners can simply communicate those requirements to the warehouses that will store the products.

(Response 381) In this type of circumstance, it is appropriate for the manufacturer of the animal food to share the responsibility with the warehouse for proper storage of the animal food. The various provisions of section 418 of the FD&C Act explicitly place the responsibility for complying with the requirements for hazard analysis and risk-based preventive controls, including modified requirements, on the owner, operator, or agent in charge of a facility and, thus, a facility that is a warehouse is responsible for its own food safety plan. Regardless, the manufacturer also has responsibilities under section 418 of the FD&C Act to determine the storage conditions necessary for animal food safety and to take steps to ensure that the animal food is stored under conditions that will ensure its safety.

It is not necessary to specify this joint responsibility for determining storage conditions in the rule, because the rule already clearly specifies that its provisions apply to persons who manufacture/process animal food, as well as to persons who hold animal food. Both the warehouse and the manufacturer have flexibility in determining how to comply with the rule, including the specific mechanism whereby the warehouse would receive information about storage of an animal food product from the manufacturer or owner of the product. Moreover, a citizen petition submitted to FDA (Docket No. FDA-2011-P-056), in requesting an exemption or modified requirements for facilities solely engaged in the storage of packaged foods not exposed to the environment, asserts that such facilities work closely with food manufacturers to understand the conditions and controls needed to ensure the quality of the foods they store and distribute and that manufacturers appropriately instruct the warehouses to ensure packaged products are being properly stored (78 FR 64736 at 64768).

(Comment 382) Some comments ask us to clarify which facility, the shipping facility or the receiving facility, will be responsible for ensuring that temperature control is maintained during transportation of TCS animal foods.

(Response 382) We address specifics about the responsibilities of shipping

facilities and receiving facilities in the 2014 proposed sanitary transportation rule (79 FR 7006). We will address comments regarding the responsibilities of shippers and receivers in the final sanitary transportation rule.

#### 2. Proposed § 507.51(a)(2)—Monitor the Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed. We requested comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

(Comment 383) Some comments ask us to explain in the preamble of the final rule that we will accept monitoring systems that provide exception reports to satisfy the modified requirements. The comments describe exception reporting as a structure where automated systems are designed to alert operators and management when the monitoring system observes a deviation from an established limit. These comments assert that monitoring of preventive controls by automated systems can be more efficient than monitoring by personnel, and can eliminate human error.

(Response 383) We have revised the recordkeeping provisions of these modified requirements to provide that the temperature monitoring records for the modified requirements may be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control. Although the comments explicitly asked us to provide a clarification in the preamble of this rule, we decided the clarification within the regulatory text would be clearer to facilities that are subject to the requirements, as well as to investigators who will be inspecting facilities for compliance with the rule.

(Comment 384) Some comments state that written procedures for monitoring temperature are not necessary. One reason provided by the comments is that the required records (specified in proposed § 507.51(a)(5)) would provide sufficient information on the type and frequency of monitoring. Another reason is that the specific activities we proposed to ensure the effectiveness of the temperature controls already address activities that a facility would include in a written procedure.

(Response 384) We agree with the comments that we need not require that a facility develop written procedures for monitoring temperature.

#### 3. Proposed § 507.51(a)(3)—Requirement To Take Corrective Actions

We proposed that if your facility is subject to the modified requirements, you must take appropriate corrective actions if there is a problem with the temperature controls for a TCS animal food.

(Comment 385) Some comments ask us to narrow the term “temperature control” to more specifically focus it on temperature controls that are relevant to food safety because some problems with the controls may not impact the product temperature (and, thus, would not impact food safety).

(Response 385) We have revised the proposed requirement (and the applicable recordkeeping requirement) to specify that corrective actions are necessary only when there is a loss of temperature control that may impact the safety of a TCS animal food.

(Comment 386) Some comments assert that the responsibility for determining any corrective actions for a TCS animal food when there is a loss of temperature control falls to the manufacturer of the food rather than to the warehouse. These comments also assert that a warehouse is a third party who is not legally empowered to make independent decisions about when and where to ship the product, or not to ship it at all. These comments ask us to clarify that the responsibility of a warehouse for “preventing” affected food entering commerce ends when the product is returned to the manufacturer or processor.

(Response 386) Returning affected animal food to the manufacturer/processor or owner of the animal food is one way to satisfy the requirement to prevent animal food from entering commerce if the owner, operator, or agent in charge of a warehouse cannot ensure the affected animal food is not adulterated under section 402 of the FD&C Act, either on its own or after consultation with the manufacturer or processor of the animal food. It is not necessary to specify this specific action on the part of a warehouse in the regulatory text.

#### 4. Proposed § 507.51(a)(4)—Requirement To Verify Consistent Implementation of Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must verify that temperature controls are consistently implemented by: (1) Calibrating temperature monitoring and recording devices; (2) reviewing records of calibration within

a reasonable time after the records are made; and (3) reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made.

(Comment 387) Some comments assert that the proposed requirement to “calibrate” devices that monitor and record temperature is inconsistent with the requirement to test such devices for accuracy in the LACF regulations in part 113. These comments assert that “accuracy check” is a more appropriate term to use in the modified requirements because many instruments that monitor or record temperature have very low drift values and may seldom require calibration.

(Response 387) We have revised the proposed requirements to require verification that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices or checking them for accuracy. However, if the outcome of an accuracy check is that a temperature monitoring or recording device is not accurate, the facility must follow up by calibrating or replacing the device. See also Comment 344 and Response 344.

(Comment 4388) Some comments assert that reviewing records of calibration or accuracy checks is only needed if a designated tolerance is exceeded.

(Response 4388) Although we recognize that in most instances an out-of-calibration device will be identified and corrected at the time a calibration or accuracy check is performed, this is not always the case. The purpose of reviewing records of calibration or accuracy checks is to identify a problem that may have been missed or may not have been corrected rather than to react to a problem after the problem is identified. The records review is also a verification that the temperature controls were consistently implemented and that corrective actions were taken if needed.

(Comment 389) Some comments ask us to modify the frequency of checking monitoring records to specify that it be done with a frequency to demonstrate control rather than within a week after the records are made.

(Response 389) We have revised the proposed requirement to require review of records of monitoring (as well as records of corrective actions taken to correct a problem with the control of temperature) within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of)

a written justification for a timeframe that exceeds 7 working days.

(Comment 390) Some comments assert that the proposed verification and review activities are too prescriptive because they require reviews that are not necessary. However, these comments also assert that the proposed verification activities are too vague because they do not specify the reasons for reviewing the records. These comments ask us to focus the regulatory text on achieving the overall objective of the review (*i.e.*, ensuring the adequacy of the control) and to provide examples of meaningful review activities in guidance.

(Response 390) We disagree that the proposed verification activities would require reviews that are not necessary. The purpose of the records review is both to identify a problem with a temperature monitoring device that may not have been detected or corrected, and to verify that the temperature controls were consistently implemented and that corrective actions were taken if needed. The requirement is consistent with requirement for records review in subpart C (§ 507.49(a)(4)), which specifies records review as a verification activity to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.

#### 5. Proposed § 507.51(a)(5)—Establish and Maintain Records

We proposed that if your facility is subject to the modified requirements, you must establish and maintain records that document monitoring, corrective actions, and verification activities.

(Comment 391) Some comments state that temperature controls in refrigerated warehouses are extremely reliable and therefore extensive record keeping and record review are not value-added. These comments ask us to revise the proposed provision to require a record only if a deviation in the environmental temperature from the prescribed limits was noted.

(Response 391) We have revised the regulatory text to provide that temperature monitoring records may be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control. The revised provision is consistent with the more general requirement for monitoring records of refrigeration temperature during storage of TCS animal food (see § 507.40(c)(2)).

#### B. Proposed § 507.51(b)—Records

We proposed that the records that a facility must establish and maintain for the proposed modified requirements are subject to the requirements that would be established in proposed subpart F. We received no comments that disagreed with our proposal, and are finalizing proposed § 507.51(b) without change.

#### XXXVII. Subpart C: Comments on Proposed § 507.53—Requirements Applicable to a Preventive Controls Qualified Individual and a Qualified Auditor

We proposed to establish requirements for the qualifications of a preventive controls qualified individual and a qualified auditor. Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the provisions as proposed with conforming changes as shown in table 31.

#### A. Proposed § 507.53(a) and (b)—What a Preventive Controls Qualified Individual or Qualified Auditor Must Do or Oversee

We proposed to list the functions that must be performed by one or more preventive controls qualified individuals (*i.e.*, preparation of the food safety plan; validation of the preventive controls; review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions; and reanalysis of the food safety plan) or by a qualified auditor (*i.e.*, conduct an onsite audit). We proposed to list these functions for simplicity (*i.e.*, to make it easy to see all of the requirements in a single place). We specified that this list of functions already proposed to be established in applicable sections of the rule did not in itself impose any additional requirements.

(Comment 392) Some comments ask us to clarify whether the preventive controls qualified individual must be on the premises during operating hours. Other comments ask us to clarify that the preventive controls qualified individual is not responsible for performing laboratory testing, because the preventive controls qualified individual may not be appropriately educated and trained for laboratory testing.

(Response 392) The rule does not require that the preventive controls qualified individual be onsite during operating hours. The rule also does not require that the preventive controls qualified individual be responsible for performing laboratory testing, although review of testing records (e.g., records of product testing or environmental testing) must be conducted or overseen by a preventive controls qualified individual.

(Comment 393) Some comments ask us to consider the implication of having the preventive controls qualified individual serve as the process authority, serve as the auditor, and offer final sign off on a validation and corrective actions, and suggest that a third party may be necessary to ensure that uniform standards are applied.

(Response 393) To the extent that the comment suggests that the functions of the preventive controls qualified individual create a conflict of interest, we disagree. The rule focuses on the need for applicable training and experience to perform certain functions. The preventive controls qualified individual must develop (or oversee the development of) the food safety plan that controls the identified hazards and then ensures through review of records that the plan is being implemented as designed. The rule does not require that a facility engage a third party to provide oversight of any individual, including a preventive controls qualified individual, but does not preclude a facility from doing so if it chooses.

#### *B. Proposed § 507.53(c)—Qualification Requirements*

##### 1. Proposed § 507.53(c)(1)—Preventive Controls Qualified Individual

We proposed that to be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. We also proposed that this individual may be, but is not required to be, an employee of the facility.

(Comment 394) Some comments express concern that there is lack of specificity on what constitutes appropriate training and experience for a preventive controls qualified individual and ask us to clarify what FDA's standardized curriculum for preventive controls qualified individuals will consist of, what

experience will be recognized as meeting the requirement, how FDA will recognize the experience and whether and how FDA will recognize industry providers of training programs. Some comments state that currently industry members may choose from many private organizations and academia to obtain training under established HACCP based training programs and audit training programs. Some comments ask us to allow flexibility for industry to continue current training programs without receiving express approval from the FSPCA.

(Response 394) As discussed in Response 1, the FSPCA is establishing a standardized curriculum. The curriculum will focus on the specific requirements of the preventive controls rule. Training providers do not need approval from the FSPCA to use the curriculum.

(Comment 395) Some comments ask who will assess the qualifications of a particular preventive controls qualified individual or determine whether particular individuals are in fact "qualified." Some comments ask us to use an outcome-based demonstration of competency. Some comments ask us to specify that all work experience must be comparable or that a preventive controls qualified individual must pass a proficiency test. Some comments ask us to establish minimum standards for competency. Some comments ask us to clarify what job experiences would be sufficient. Some comments ask how we will verify that reported training and experience are true.

(Response 395) We are not establishing minimum standards for competency and do not intend routinely to directly assess the qualifications of persons who function as the preventive controls qualified individual, whether by their training or by their job experience. Instead, we intend to focus our inspections on the adequacy of the food safety plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate training or experience to carry out the assigned functions, including whether reported training and experience is accurately represented.

(Comment 396) Some comments ask us to provide for competency requirements to be met through on-the-job experience in lieu of traditional classroom training. Some comments ask us to clarify what we mean by training that is "at least equivalent" to that received under a standardized curriculum recognized as adequate by FDA. Some comments ask us to clarify

whether individuals who have successfully completed training in the development and application of risk-based preventive controls through programs delivered and recognized under the International HACCP Alliance would be considered to have completed training "equivalent" to that recognized by FDA for the development and application of risk-based preventive controls.

(Response 396) The requirements do provide for qualification through appropriate job experience, such as experience with successfully implementing HACCP systems or other preventive-based food safety systems. It is the responsibility of the owner, operator, or agent in charge of the facility to determine whether any individual who prepares (or oversees the preparation of) the food safety plan has appropriate qualifications to do so, whether by on-the-job experience or by training.

There are some differences in the requirements of the animal food preventive controls rule compared to the requirements of HACCP regulations for seafood, juice, and meat and poultry such that training provided by the International HACCP Alliance may not be equivalent. To avoid unnecessary duplication of training, such an individual may only need to attend partial, supplemental courses in order to meet the training requirements. Alternatively, a person who has received the International HACCP Alliance training and has implemented a HACCP plan may be qualified through job experience.

(Comment 397) Some comments ask us to emphasize that a standardized curriculum in the development and application of risk-based preventive controls may not provide a preventive controls qualified individual with sufficient expertise to design and conduct robust, scientific validation studies to support the adequacy of control measures.

(Response 397) We acknowledge that a single training course may not provide adequate training for every function of the preventive controls qualified individual for the animal foods produced by a facility. In some cases an individual may gain the full complement of knowledge and experience through multiple, specific training courses; in other cases an individual may gain the full complement of knowledge and experience through job experience or through a combination of training and job experience.

(Comment 398) Some comments ask us not to establish requirements that are

overly strict because there is a finite supply of food safety experts in the country and many facilities will need multiple preventive controls qualified individuals.

(Response 398) We disagree that the requirements applicable to the preventive controls qualified individual should be designed to match any current limitations in the number of individuals who have the knowledge and skill to prepare (or oversee the preparation of) a food safety plan. We expect that market forces will act to increase the number of preventive controls qualified individuals to match the demand generated by this rule. In addition, as discussed in section LIII.A, we are further staggering the compliance dates for subparts C and E of the rule, so that those businesses that are not small will need to comply with subparts C and E of the rule within 2 years, and small businesses will need to comply with subparts C and E of the rule within 3 years. Very small businesses are not required to develop a food safety plan or conduct other activities that require oversight by a preventive controls qualified individual.

## 2. Proposed § 507.53(c)(2)—Qualified Auditor

We proposed that to be a qualified auditor, a preventive controls qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(Comment 399) Some comments object to the proposed requirement that a qualified auditor must be a preventive controls qualified individual with certain technical auditing expertise. One comment asserts that a qualified auditor should not be required to have the broader skills of a preventive controls qualified individual.

(Response 399) We have revised the definition of “qualified auditor,” and the requirements applicable to a “qualified auditor,” such that a “qualified auditor” means a person who is a “qualified individual” as that term is defined in this final rule, rather than a “preventive controls qualified individual,” because some auditors may be auditing businesses (such as produce farms) that are not subject to the requirements for hazard analysis and risk-based preventive controls, and it would not be necessary for such an auditor to be a “preventive controls qualified individual.”

(Comment 400) Some comments ask us to consider specifying training for qualified auditors. These comments also ask us to consider certain industry

documents in any guidance we may issue regarding qualified auditors.

(Response 400) At this time, we are not planning to specify a training curriculum for qualified auditors. If we develop guidance related to qualified auditors, we will consider industry documents that are already available.

### C. Proposed § 507.53(d)—Records

We proposed that all applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained. For clarity, we have revised the requirement to specify the type of training that must be documented, *i.e.*, applicable training in the development and application of risk-based preventive controls (see 78 FR 64736 at 64804).

(Comment 401) Some comments ask us to explain how job experience should be documented in records to prove qualifications.

(Response 401) The rule does not require documentation of job experience. A facility has flexibility to determine whether and how to document a preventive controls qualified individual’s job experience. For example, a facility could ask a preventive controls qualified individual to provide a resume documenting applicable experience. As discussed in Response 395, we intend to focus our inspections on the adequacy of the food safety plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate experience to carry out the assigned functions.

For further discussion on comments received to the proposed rule for preventive controls rule for human food, see the final rule of the human food preventive controls rule published elsewhere in this issue of the **Federal Register**.

### XXXVIII. Subpart C: Comments on Proposed § 507.55—Implementation Records

We proposed to list all records documenting implementation of the food safety plan in § 507.55(a). We noted that proposed § 507.55(a) would not establish any new requirements but merely make it obvious at a glance what implementation records are required under proposed part 507, subpart C. We received no comments that disagreed with this proposed provision and are finalizing it as proposed.

We proposed that the records that you must establish and maintain are subject to the requirements of proposed subpart F (“Requirements Applying to Records

that Must be Established and Maintained”). (Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 507.) We received no comments that disagreed with this proposed provision and are finalizing it as proposed.

### XXXIX. Subpart D: Comments on Proposed New Provisions for Withdrawal of a Qualified Facility Exemption

In the 2013 proposed animal food preventive controls rule, we proposed to establish procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart D; the withdrawal provisions). In the 2014 supplemental notice, we discussed several comments we received on these withdrawal provisions and proposed modifications and additions to them. Some of the re-proposed provisions would modify the provisions that we included in the 2013 proposed preventive controls rule (such as the timeframe for compliance with an order withdrawing an exemption), whereas others would be new provisions (such as a procedure to reinstate an exemption that had been withdrawn). In this section of this document we discuss comments that we received on the withdrawal provisions in the 2013 proposed preventive controls rule, but did not address in the 2014 supplemental notice. We also discuss comments that we received on the re-proposed withdrawal provisions in the 2014 supplemental notice.

Most of the comments support the proposed provisions, suggest alternative or additional regulatory text, or ask us to clarify how we will interpret the provision.

For several provisions, we received no comments that disagreed with our proposal, and are finalizing the provisions without change. These provisions are § 507.75 (Presiding officer for an appeal and for an informal hearing); § 507.77 (Timeframe for issuing a decision on an appeal); § 507.80 (Revocation of an order to withdraw a qualified facility exemption); and § 507.83 (Final agency action).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with or suggest one or more changes to the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 21 with editorial and conforming changes as shown in table 31.

TABLE 21—REVISIONS TO THE PROPOSED PROVISIONS FOR WITHDRAWAL OF A QUALIFIED FACILITY EXEMPTION

Section	Description	Revision
507.60(b)(2) .....	Timeframe for a qualified facility to respond to a notification from FDA about circumstances that may lead FDA to withdraw the facility's exemption.	Allow 15 calendar days, rather than 10 calendar days, for the facility to respond.
507.65(c) .....	Contents of an order to withdraw a qualified facility exemption.	Editorial changes to clarify that the order will specify which of two circumstances that may lead FDA to withdraw a qualified facility exemption apply, or whether both of these two circumstances apply.
507.65(d)(1) .....	Contents of an order to withdraw a qualified facility exemption.	Specify that the timeframe for the qualified facility to comply with the order is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order.
507.65(d)(2) .....	Timeframe for a qualified facility to appeal an order withdrawing the facility's exemption.	Allow 15 calendar days, rather than 10 calendar days, for the facility to appeal the order.
507.65(e) .....	Contents of an order to withdraw a qualified facility exemption.	Include a statement informing the facility that it may ask us to reinstate an exemption that was withdrawn by following the procedures in §507.85.
507.67 .....	Compliance with, or appeal of, an order to withdraw a qualified facility exemption.	Specifies that a qualified facility that loses its exemption would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption.
507.67(a)(1) and (c)(1).	Compliance with, or appeal of, an order to withdraw a qualified facility exemption.	Specify that the timeframe for the qualified facility to comply with the order is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order.

*A. Proposed § 507.60—Circumstances That May Lead FDA To Withdraw a Qualified Facility Exemption*

We proposed that we may withdraw the exemption that would apply to a qualified facility in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility, or if we determine that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility. We also proposed that before we issue an order to withdraw an exemption, we: (1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak; (2) must notify you, in writing, of circumstances that may lead us to withdraw the exemption, and provide an opportunity for you to respond in writing, within 10 calendar days of the date of receipt of the notification, to our notification; and (3) must consider your actions to address the circumstances that may lead us to withdraw the exemption.

(Comment 402) Some comments agree with the proposed provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified facility exemption. For example, some comments agree that other regulatory

actions should be considered before withdrawing a qualified facility exemption, and some comments agree that it is appropriate to assess corrective actions taken by a qualified facility in response to an animal food safety problem when considering whether to withdraw its exemption. Other comments agree that these provisions are reasonable and will provide qualified facilities due process and greater clarity on the withdrawal process, but suggest that we could issue guidance rather than include these provisions in the rule to allow us greater flexibility should we have to act quickly to protect the public (human or animal) health.

Other comments disagree with these proposed provisions and ask us to delete them from the final rule. These comments assert that FSMA does not require us to describe the actions that we may take prior to withdrawing a qualified facility exemption and that it is not necessary to do so because it is customary for us to work with an animal food facility to address problems before taking enforcement actions. These comments also express concern that listing possible regulatory actions before we would issue an order to withdraw a qualified facility exemption could create an expectation that we will always exercise such regulatory actions before issuing the order. These comments also express concern that being bound by these provisions could prevent us from acting quickly to protect public health.

(Response 402) We are retaining the provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified facility exemption. We agree that it is customary for us to work with an animal food facility to address problems before taking enforcement actions, but disagree that specifying this customary practice in the rule would prevent us from acting quickly to protect public (human or animal) health. As previously discussed, we consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions such as those described in these provisions may provide a more expeditious approach to correcting a problem than withdrawing an exemption (79 FR 58524 at 58553). We also disagree that the rule binds us to take alternative regulatory action before issuing an order to withdraw a qualified facility exemption, other than to notify the facility in writing of circumstances that may lead us to withdraw the exemption, provide an opportunity for the facility to respond in writing, and consider the actions taken by the facility to address the circumstances we describe. The rule clearly specifies that regulatory actions such as a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction are actions that we “may” (not “must”) take before issuing an order to withdraw a qualified facility



exemption. Providing the facility with an opportunity to correct the problems before we take steps to withdraw an exemption has the potential to save Agency resources associated with preparing an order, responding to an appeal of the order and request for a hearing, and administering a hearing. Directing resources to help a facility correct problems, rather than to administer a withdrawal process that could be resolved by the time of a hearing, is appropriate public health policy.

(Comment 403) Some comments ask us to specify that the notification of circumstances that may lead FDA to withdraw the exemption must include facts specific to the situation and information about how the facility can remedy the situation.

(Response 403) By specifying that we must notify the facility of circumstances that may lead us to withdraw an exemption, we mean that we would include facts specific to the situation. It is the responsibility of the facility, not FDA, to remedy the situation.

(Comment 404) Some comments ask us to state affirmatively that we must not withdraw the exemption if the facility has satisfactorily addressed the problematic conditions or conduct at the facility. These comments assert that, without this affirmative statement, the requirement that we “consider the actions taken by the facility” remains unclear.

(Response 404) We decline this request. If the facility has satisfactorily addressed the problematic conditions or conduct, there would be no problematic circumstances for us to describe in the order withdrawing the qualified facility exemption.

(Comment 405) Some comments ask us to provide additional time for a qualified facility to respond, in writing, to a notification of circumstances that may lead us to withdraw its exemption. Comments suggest timeframes of 60, 90, and 120 days as a reasonable or appropriate period of time for a qualified facility to compile information and documentation of facts and to respond to a notification of circumstances that may cause us to withdraw its exemption. Some of these comments express concern that the proposed deadline is too short, and that the short timeframe violates the intent of the exemption. Some comments ask us to establish graduated response times, with less response time allowed for more serious animal food safety concerns.

(Response 405) We have revised the provision to provide for 15 calendar days, rather than 10 calendar days, for

a facility to respond in writing to our notification. The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 406) Some comments ask us to clarify how an exemption can be revoked (and restored) on diversified farms that produce both exempt and non-exempt products.

(Response 406) We assume that this comment is referring to a farm mixed-type facility that produces some products (such as forage products or plant protein meals) that are exempt from the requirements for hazard analysis and risk-based preventive controls, as well as some products that are not exempt from these requirements. Neither withdrawing nor reinstating a qualified facility exemption would have any impact on products that are not subject to the requirements for hazard analysis and risk-based preventive controls. In contrast, administrative procedures such as injunction and suspension of registration likely would apply to all animal food production by the facility.

(Comment 407) Some comments ask us to consistently use either “calendar days” or “working days” throughout the provisions directed to withdrawal of an exemption. Some comments ask us to use “business days” rather than “calendar days” or “working days.”

(Response 407) We have expressed the timeframes for all of the withdrawal provisions in calendar days.

(Comment 408) Some comments ask us to clarify that the decision to withdraw a qualified facility exemption is an individualized determination and will not be applied to a class of farmers by stating this clearly in the preamble.

(Response 408) The decision to withdraw a qualified facility exemption is an individualized determination and will not be applied to a class of facilities or farmers.

(Comment 409) Some comments assert that the timeframes for responding to a notification that an exemption may be withdrawn should be the same regardless of whether the notification is sent to a qualified facility subject to the human or animal food preventive controls rule or a farm subject to the produce safety rule. These comments state that many small farms do value-added processing and will be subject to both rules.

(Response 409) Although the produce safety rule is not yet final, we intend to

make the administrative procedures associated with withdrawal of an exemption consistent to the extent practicable, including the timeframe for responding to a notification.

(Comment 410) Some comments ask us to expand the scope of the withdrawal provisions to include facilities that would satisfy criteria for an exemption from the requirements for hazard analysis and risk-based preventive controls for low-risk activity/food combinations (*i.e.*, the exemptions in proposed §§ 507.5(e) and (f)).

(Response 410) We decline this request. Section 418 of the FD&C Act does not provide for withdrawal of the exemptions established in § 507.5(e) and (f). The withdrawal provision in section 418(l)(3) of the FD&C Act is limited to qualified facilities.

#### *B. Proposed § 507.62—Issuance of an Order To Withdraw a Qualified Facility Exemption*

We proposed procedures for the steps we would take to issue an order to withdraw an exemption applicable to a qualified facility, including procedures that would: (1) Emphasize that a senior FDA official (such as an FDA District Director, the Director of the Division of Compliance in CVM, or a more senior FDA official) must approve an order to withdraw the exemption before the order is issued; (2) provide that any officer or qualified employee of FDA may issue the order after it has been approved; (3) specify that we would issue the order to the owner, operator, or agent in charge of the facility; and (4) require that the order be in writing and be signed and dated by the officer or qualified employee of FDA who is issuing the order.

(Comment 411) Some comments ask us to include in the procedures timeframes for: (1) Submitting an order after an initial determination that criteria for withdrawing an exemption are met; (2) approval or denial by the FDA District Director; (3) issuing the withdrawal (with automatic revocation of order if FDA does not issue the order within the specified timeframe); and (4) delivery of the order to the owner, operator, or agent in charge of the facility. Other comments recommend that the procedures for issuing an order specify that we send the order in a way that ensures its receipt, such as through certified mail with confirmation of delivery to ensure the facility operator receives the order.

(Response 411) We are not establishing timeframes for the steps we take before a facility receives an order for withdrawal of an exemption. The timeframes surrounding our internal

process for developing an order have no bearing on the time that a facility will need to respond to the order or on the information it will need to do so. We agree that it is appropriate to specify timeframes for the procedural steps that follow a facility's receipt of an order, and the withdrawal procedures include such timeframes.

We are not specifying that we send an order in a way that ensures its receipt. Although certified mail with confirmation of delivery is one way to ensure receipt, other methods are available, including delivery through private carriers that provide mechanisms to document receipt. In light of the provision (which we included in the 2014 supplemental notice) linking the timeframes for a facility to comply with, or appeal, an order to the date of receipt of the order (rather than to the date of the order), it will be up to us to deliver the order in a way that provides us with evidence of receipt.

*C. Proposed § 507.65—Contents of an Order To Withdraw a Qualified Facility Exemption*

We proposed specific information that would be included in an order to withdraw an exemption, including (1) The date of the order and the name, address, and location of the qualified facility; (2) a brief, general statement of the reasons for the order, including information relevant to the circumstances that led us to issue the order; (3) a statement that the facility must either comply with subpart C within 120 calendar days of receipt, or appeal the order within 10 calendar days of receipt; (4) the text of section 418(l) of the FD&C Act and of the withdrawal provisions in part 507, subpart D; (5) information about an informal hearing on an appeal of the order; and (6) contact information for appropriate senior FDA officials, as well as the name and the title of the FDA representative who approved the order.

(Comment 412) Some comments recommend that the order specify which of the two circumstances that could lead us to issue the order apply.

(Response 412) We have made editorial changes to the regulatory text to make it more clear that the provision requires us to specify which circumstance applies. (*i.e.*, an active investigation of foodborne illness, or conduct or conditions associated with the qualified facility), or whether both of these two circumstances apply. See the revised regulatory text for § 507.65(c).

(Comment 413) Some comments ask us to add more specific requirements for

the content of an order to withdraw an exemption, including specific evidence about the circumstances leading to the order. The comments maintain that doing so would help the facility respond with particularity to the facts and issues contained in the order if the facility appeals the order. The comments also recommend that the order include the evidence on which the order is based including, as applicable, evidence linking the active investigation of a foodborne illness outbreak directly to the facility or measurable evidence (collected using generally accepted scientific standards) indicating the presence in the facility of pathogens that pose an imminent threat to public (human or animal) health, or conduct or conditions that are material to the safety of animal food. The comments also recommend that the order include, when applicable, a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

(Response 413) We agree that the order must provide sufficient information to enable a facility to respond with particularity to specific evidence about the circumstances leading to the order. However, we disagree that the order must do so by including the specific information recommended by the comments, and we have not revised the proposed withdrawal provisions to incorporate the suggestions of these comments. The comments appear to be more focused on whether the circumstances that lead us to issue an order meet an evidentiary standard than on explaining the problem so that a facility can both understand the problem and respond with particularity to the facts and issues contained in the order. The withdrawal provisions that we are establishing in this provision require the order to include a brief, general statement of the reasons for the order, including information relevant to: (1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or (2) conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at the facility. The requirements that we are establishing in this provision would enable a qualified facility to both understand the problem and respond to it. In addition, because other requirements in these withdrawal provisions specify that we must notify a qualified facility of circumstances that may lead us to withdraw its exemption before we issue the actual order, the order withdrawing the exemption

would be the second time that the facility hears about the problems (see § 507.60(b)(2)). We intend that the process of responding to the notification that we must send before issuing an order to withdraw an exemption, including discussing the problems with FDA as warranted, would provide additional information to the facility to enable the facility to both understand the problem and respond to it.

(Comment 414) Some comments ask us to provide 15 “business days” from date of receipt of the order, rather than the proposed 10 calendar days from date of receipt of the order, for the facility to appeal the order.

(Response 414) We have revised the provision to provide for 15 calendar days, rather than 15 business days, for a facility to appeal the order. We also have made conforming changes to establish the same 15 calendar day timeframe in all provisions that specify the timeframe to appeal the order (*i.e.*, §§ 507.67(a)(2), 507.69(a)(1), and 507.71(a)(2)). We also extended the timeframe for the hearing to be held to be within 15 calendar days, rather than the proposed 10 calendar days, after the date the appeal is filed to provide more time for the facility to prepare for the hearing (see § 507.73(a)). The timeframe for the hearing to be held continues to provide for an alternative timeframe agreed upon in writing by both the facility and FDA; a facility that would have preferred the proposed timeframe of 10 calendar days could request that the hearing be held more quickly than 15 calendar days.

The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 415) Some comments support the proposed timeframe of 120 calendar days for a qualified facility whose exemption has been withdrawn to comply with the animal food preventive controls rule, but ask us to make the timeframe for complying with a FSMA rule the same regardless of whether the exemption is withdrawn from a qualified facility subject to the animal food preventive controls rule or from a farm subject to the produce safety rule. Other comments ask us to extend the timeframe to come into compliance, *e.g.*, to 1 or 2 years. Some of these comments suggest that qualified facilities should have 120 days to develop a plan of action, but 2 years to fully comply. Some of the comments argue that large farms and

manufacturers are given a year to come into compliance, and that requiring small and very small businesses to comply in a shorter time period would effectively drive them out of business. Other comments ask us to consider provisions that would require compliance with only those portions of the rule that formed the basis for the revocation.

(Response 415) We continue to believe that the 120-day timeframe is adequate, but we have added flexibility such that a facility may request, with a justification in writing to FDA, a reasonable timeframe for compliance that exceeds 120 calendar days from the receipt of the order. FDA must grant the request for the facility to receive the extended timeframe. We are not generally extending the timeframe because circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility. A qualified facility that receives an order to withdraw its exemption would have received advance notification of the circumstances leading to the order and would have had an opportunity to correct the problems rather than have us proceed to issue the order (see § 570.60(b)). If the facility requests a hearing, more than 40 days could elapse between the date that the facility receives the order and the date that the presiding officer for the hearing confirms the order to withdraw the exemption. Given that the circumstances that would lead us to issue the order involve either: (1) An active investigation of a foodborne illness outbreak that is directly linked to the qualified facility or (2) a determination that withdrawal of the exemption is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at the facility, a delay of 1 to 2 years to comply with the rule is not warranted. We also do not believe that it would be appropriate to require a facility to come into compliance with only those provisions that formed the basis of the revocation. The provisions of subparts C and E are interrelated and operate as a system and therefore are not optimized through piecemeal implementation. However, FDA may consider staggered implementation as an option in granting a request for an extension of the timeframe to comply with an order to

withdraw the exemption for a qualified facility.

As already discussed, the new requirements for hazard analysis and risk-based preventive controls are not “one-size-fits-all.” Although each facility subject to the rule must prepare and implement a food safety plan, the preventive controls that the facility would establish and implement would depend on the facility, the animal food, and the outcome of the facility’s hazard analysis. In addition, the preventive control management components that a facility would establish and implement for its preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s animal food safety system.

Although the produce safety rule is not yet final, we intend to make the administrative procedures associated with withdrawal of an exemption consistent to the extent practicable, including the timeframe to comply with the applicable rule if an exemption is withdrawn.

(Comment 416) Some comments ask us to include in the order a statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85.

(Response 416) We have revised the requirements for the contents of an order as requested by these comments.

#### *D. Proposed § 507.67—Compliance With, or Appeal of, an Order To Withdraw a Qualified Facility Exemption*

We proposed that: (1) You must either comply with applicable requirements of part 507 within 120 calendar days of receipt, or appeal the order within 10 calendar days of receipt; (2) submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action unless the Commissioner of FDA, as a matter of discretion, determines that delay or a stay is in the public interest; and (3) if you appeal the order, and we confirm the order, you must comply with applicable requirements of part 507 within 120 calendar days of confirmation of receipt of the order.

(Comment 417) Some comments ask us to specify that a qualified facility that loses its exemption from the requirements for hazard analysis and risk-based preventive controls would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption.

(Response 417) A qualified facility that loses its exemption from the requirements for hazard analysis and risk-based preventive controls would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption. To make this clearer, the final withdrawal procedures now include this information (see the regulatory text for § 507.67(c)).

#### *E. Proposed § 507.69—Procedure for Submitting an Appeal*

We proposed that (1) To appeal an order, you must submit a written appeal to FDA within 15 calendar days of receipt and respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely; and (2) In your written appeal, you may include a written request for an informal hearing.

(Comment 418) Some comments ask us to rely on records kept in the normal course of business for documentation that will be sufficient to respond to an order to withdraw a qualified facility’s exemption, rather than requiring a facility to “respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.” These comments assert that we should not require a facility that submits a written appeal to provide documents and records that they are not required to keep.

(Response 418) We decline this request. In a withdrawal action, FDA is providing a qualified facility multiple opportunities to persuade FDA that withdrawal is not appropriate. If the facility relies on documentation as part of its response, it is reasonable to require that this documentation be provided to FDA.

#### *F. Proposed § 507.71—Procedure for Requesting an Informal Hearing*

We proposed that if you appeal the order: (1) You may request an informal hearing, and must do so together with your written appeal (within 15 calendar days of the date of receipt of the order and (2) a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted; you would receive written notice of the presiding officer’s determination, explaining the reason for the denial.

(Comment 419) Some comments ask us to guarantee a hearing so that a qualified facility can present its case in

person before having its exemption revoked.

(Response 419) We decline this request. We agree that a qualified facility has a right to appeal an order to withdraw an exemption, and we have provided for a right to appeal.

*G. Proposed § 507.73—Requirements Applicable to an Informal Hearing*

We proposed that if you request an informal hearing, and we grant the request: (1) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and by us; (2) the presiding officer may require that the hearing be completed within 1 calendar day; and (3) we must conduct the hearing in accordance with part 16 (21 CFR part 16), with some specified modifications, including that no party shall have the right, under § 16.119, to petition FDA for reconsideration or a stay of the presiding officer's final decision.

(Comment 420) Some comments object to our proposal that no party shall have the right, under § 16.119 to petition FDA for reconsideration or a stay of the presiding officer's final decision. These comments assert that our justification (*i.e.*, that the circumstances that would lead to a withdrawal merit prompt action and that a facility has the opportunity for judicial review in accordance with 21 CFR 10.45) is not a sufficient argument for justifying the removal of the option to file a motion for reconsideration or stay. These comments ask us to revise proposed § 507.73(c)(6) to specify that the qualified facility shall have the right to file a motion for reconsideration or stay.

(Response 420) We decline this request. In the 2014 supplemental controls notice, we proposed an additional mechanism for a qualified facility to present its view that its exemption should not be withdrawn, *i.e.*, by providing advance written notification to a qualified facility if we are considering withdrawing an exemption and providing an opportunity for the facility to respond before we issue an order to withdraw an exemption. We also proposed to provide an opportunity for reinstatement of an exemption that had been withdrawn. We believe the multiple opportunities now available to a facility provide adequate opportunities for a facility's views to be considered, and further mechanisms are not warranted.

*H. Proposed § 507.85—Reinstatement of a Qualified Facility Exemption That Was Withdrawn*

We proposed four provisions for reinstating a withdrawn qualified facility exemption. First, we proposed that if the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in CVM) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or in the case of a foreign facility, the Director of the Division of Compliance in CVM) will, on his own initiative or on the request of a facility, reinstate the exemption (proposed § 507.85(a)).

Second, we proposed that you may ask FDA to reinstate an exemption that has been withdrawn by following specific steps (§ 507.85(b)(1) and (2)). Third, we proposed that if your exemption was withdrawn in the event of an active investigation of a foodborne illness outbreak that is directly linked to your facility and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your qualified facility exemption and will notify you in writing that your exempt status has been reinstated.

We proposed that if your exemption was withdrawn both in the event of an active investigation of a foodborne illness outbreak that is directly linked to your facility and because FDA had determined that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with your facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility, and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified facility exemption.

(Comment 421) Some comments agree with our tentative conclusion that the absence of a specific provision in section 418 of the FD&C Act for the reinstatement of an exemption that is

withdrawn does not preclude us from providing for such a process (79 FR 58524 at 58553). Other comments disagree with that tentative conclusion and assert that Congress crafted the withdrawal provision as a “one strike, you're out” provision. These comments also assert that including the withdrawal provision as a “one strike, you're out” provision was an essential part of the legislative agreement that allowed for adoption of the qualified facility exemption. These comments also assert that reinstatement would undermine the intent of the withdrawal provision because it would reduce the incentive for small animal food processors to ensure that the products they sell are as safe as possible. These comments also assert that a recognized principle of statutory interpretation provides that exemptions to statutes should be strictly construed, particularly when the statute addresses public health and safety, and that we are giving the exemption an impermissibly broad construction.

Some comments ask why we believe that a business deserves a “second bite of the apple” in light of the understanding (under proposed § 507.60(b) and (c)) that we will first seek to correct problems before considering withdrawal. These comments also question at what point a facility would apply for reinstatement, and ask why we would allow a facility that has already come into compliance with FSMA's requirement to implement preventive controls to abandon those controls in favor of reinstating its exempt status. These comments ask us to eliminate the proposed provisions allowing for reinstatement.

Some comments do not support the proposed reinstatement provisions when an animal food facility has been directly linked to a foodborne illness outbreak. Some comments support the proposed reinstatement provisions only when we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility that had its exemption withdrawn.

(Response 421) We disagree that the proposed reinstatement provisions would give the exemption an impermissibly broad construction. The express statutory language of section 418(l) of the FD&C Act does not support the comments' assertion that the withdrawal provision is a “one strike, you're out” provision. We also disagree that reinstatement would undermine the intent of the withdrawal provision because it would reduce the incentive for small animal food processors to ensure that the products they sell are as

safe as possible. We expect that the withdrawal provision itself provides a big incentive for small animal food processors to ensure that the products they sell are as safe as possible because of the business disruption that would occur if they are subject to withdrawal of the exemption. We proposed that a facility would need to present data and information to demonstrate that it has adequately resolved the problems with the conditions or conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility, such that continued withdrawal of the exemption is not necessary to protect public (human or animal) health and prevent or mitigate a foodborne illness outbreak.

We disagree that we should categorically refuse to consider reinstating a qualified facility exemption if we had withdrawn the exemption because an animal food facility had been directly linked to a foodborne illness outbreak. First, if information later comes to light to raise considerable doubt that a qualified facility had, indeed, been directly linked to a foodborne illness outbreak, and conditions and conduct at the facility do not otherwise warrant withdrawing the facility's exemption, it would be appropriate for us to reinstate the facility's exemption. Second, we would only reinstate the exemption if we determined that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human or animal) health and prevent or mitigate a foodborne illness outbreak.

(Comment 422) Some comments that support the reinstatement of a withdrawn exemption ask us to establish a timeframe within which FDA will reinstate an exemption. Some comments ask us to specify in the regulatory text that the reinstatement would occur in a reasonable period of time, both in circumstances where FDA has decided on its own initiative to reinstate the exemption and in circumstances where a facility submits a request for reinstatement. Some comments suggest 10 days is a reasonable period of time within which FDA should reinstate an exemption.

(Response 422) We decline the requests to establish a timeframe for reinstatement in the regulatory text. If we determine on our own initiative to reinstate an exemption (e.g., because we later determine, after finishing the active investigation of a foodborne

illness outbreak, that the outbreak is not directly linked to the facility), our determination would be effective immediately. If we receive a request to reinstate a withdrawn exemption, we intend to respond in a reasonable timeframe consistent with available resources. In some cases, we may respond that we need more information in order to evaluate your request.

(Comment 423) Some comments ask that the process for reinstatement include at least one level of administrative appeal if we deny a facility's request for reinstatement.

(Response 423) We have not revised the regulatory text to provide for an administrative appeal if we deny a facility's request for reinstatement. Existing procedures allow a facility to ask for a meeting with applicable FDA officials (see § 10.65(c)) and appeal our decision if we deny the request (see § 10.75).

(Comment 424) Some comments ask us to establish a 1-year probationary period before the withdrawn qualified facility exemption could be fully reinstated.

(Response 424) We decline this request. We intend to act on a request for reinstatement based on the merits of the data and information presented in the request, not after a pre-determined timeframe.

#### *I. Conforming Amendment to 21 CFR Part 16*

We proposed to amend § 16.1(b)(2) to include part 507, subpart D, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available. We received no comments that disagreed with this proposed provision, and are finalizing it as proposed.

#### *J. Other Comments on the Withdrawal Provisions*

(Comment 425) Several comments ask us to provide clarification through guidance, issued for public comment, on a variety of topics associated with the withdrawal provisions.

(Response 425) We will consider the need for guidance in the future. At this time, we consider that withdrawing an exemption would be both rare and dependent upon the circumstances. We need to direct our resources to developing guidance on issues that would apply more broadly, and more generally, than the withdrawal provisions.

(Comment 426) Some comments ask detailed questions about how we would coordinate the withdrawal process with the States.

(Response 426) In general, we work with our State partners and other government counterparts in dealing with enforcement actions, including coordinating actions or deferring to each other when one department has authority to swiftly act to protect the consumer. In the specific case of this rule, we are working through the PFP to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see Response 2 and section 209(b) of FSMA).

(Comment 427) Some comments ask us to add provisions regarding notification of the appropriate State regulatory agency when a qualified facility exemption is withdrawn and reinstated.

(Response 427) We decline this request. As previously noted, we are sensitive to the time required for various inspection activities and intend to communicate with States regarding our expectations for how to verify whether a facility is a qualified facility. The status of a facility as a qualified facility principally affects the requirements that it is subject to, and will be most useful to FDA and our food safety partners when preparing for inspection. At this time we do not intend to establish a system notifying the applicable State authorities at a point in time when the status of a facility as a qualified facility changes, whether as a result of withdrawal or reinstatement of a qualified facility exemption or because the facility's business has grown to the point where it exceeds the financial for very small business.

#### **XL. Subpart E: General Comments on Proposed Requirements for a Supply-Chain Program**

In the 2014 supplemental notice, we provided an opportunity for public comment on potential requirements for a supplier program as a preventive control. The supplier program for a receiving facility would be limited to those raw materials and other ingredients for which the receiving facility has identified a significant hazard (which we now refer to as a "hazard requiring a preventive control"). Under the definitions established in this rule, "supplier" means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de

minimis nature; “receiving facility” means a facility that is subject to subparts C and E and that manufactures/ processes a raw material or other ingredient that it receives from a supplier (see § 507.3).

We previously explained our understanding that, particularly for RACs, there may be multiple establishments, including cooperatives, packing houses, and distributors, between a receiving facility and the establishment that would be considered the supplier, which would make supplier verification very challenging under certain circumstances (79 FR 58476 at 58497). We requested comment on what verification activities would be appropriate for receiving facilities to conduct when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/ processors. We discussed an example in which a receiving facility is a feed mill that receives oats from a distributor, who receives grains from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms, where the hazards are being controlled, and asked what supplier controls should be applied for the grains coming from the farms. We requested comment on whether and how the requirements for supplier verification should address such situations. We also requested comment regarding whether (and, if so,

how) the final preventive controls rule for animal food should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain, and Point B in the supply chain is a facility that only packs or holds animal food, but does not manufacture/process animal food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain.

In the remainder of this section, we discuss comments that address our request for comment on complex supply-chain scenarios such as those described in the 2014 supplemental notice. We also describe our reasons for revising the proposed requirements for a supplier program to provide additional flexibility for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities. When an entity other than the receiving facility determines, conducts, or both determines and conducts the appropriate supplier verification activities, the receiving facility must review and assess that entity’s applicable documentation, and document the receiving facility’s review and assessment. Providing this additional flexibility required a series of changes to multiple proposed provisions. To improve clarity and readability, we redesignated proposed § 507.36 into eight distinct sections of regulatory text in a newly established subpart E (Supply-Chain Program), with

editorial changes associated with the new structure of the redesignated regulations. See table 22 for the section numbers and titles in subpart E. See table 23 for an overview of the major revisions to the proposed requirements for a supply-chain program. See sections XLI through XLVII for a discussion of the specific provisions of the final requirements for a supply-chain program, and tables 24 to 29 for more detailed summaries of revisions to these specific provisions. Because table 23 is an overview, the changes identified in table 23 appear again in, tables 24 to 29. Because the editorial changes associated with the redesignation are extensive, we do not list them in table 31.

The title of subpart E is “Supply-Chain Program” rather than “Supplier Program.” As shown in table 23 and discussed in more detail in section XLI.D, we have added one requirement applicable to non-suppliers. “Supply-chain program” is a more appropriate term to reflect a subpart that includes a requirement applicable to nonsuppliers in addition to the requirements applicable to suppliers. In the remainder of this document, we use the phrase “supply-chain program” in section headings and when referring to the provisions of the final rule. We continue to use the term “supplier program” when describing the proposed provisions and the comments regarding the proposed provisions.

TABLE 22.4—REDESIGNATION OF THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM IN SUBPART E [Supply-chain program]

Section	Description
507.105 .....	Requirement to establish and implement a supply-chain program.
507.110 .....	General requirements applicable to a supply-chain program.
507.115 .....	Responsibilities of the receiving facility.
507.120 .....	Using approved suppliers.
507.125 .....	Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).
507.130 .....	Conducting supplier verification activities for raw materials and other ingredients.
507.135 .....	Onsite audit.
507.175 .....	Records documenting the supply-chain program.

TABLE 23.5—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
Throughout .....	Throughout .....	The type of preventive control applicable to the supply-chain program.	Refer to “supply-chain-applied control” rather than “preventive control” or variations such as “hazard requiring a preventive control when the hazard is controlled before receipt of the raw material or other ingredient.”
507.36(a)(2) (in subpart C).	507.37(a)(1)(ii) .....	A supply-chain program is not required when the hazard will be controlled by the receiving facility’s customer in the distribution chain.	Shifted to be in provisions outside the framework of the supply-chain program in subpart E.

TABLE 23.5—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Revision
507.105(a)(2) .....	N/A .....	Circumstances that do not require a supply-chain program.	The receiving facility does not need a supply-chain program when the receiving facility is an importer, is in compliance with the forthcoming FSVP requirements, and has documentation of verification activities conducted under the forthcoming FSVP program.
507.105(a)(3) .....	N/A .....	Exemption from the requirements for a supply-chain program.	Exemption for animal food supplied for research or evaluation.
507.105(c) .....	N/A .....	Requirements applicable to non-suppliers .....	When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a nonsupplier applies controls to certain produce (i.e., produce that will be subject to the forthcoming produce safety rule), because growing, harvesting, and packing activities are under different management), the receiving facility must (1) verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity in the supply chain, review and assess the entity's applicable documentation, and document that review and assessment.
507.110(c) .....	507.37(a)(3)(ii) .....	Purpose of the supply-chain program .....	Specify only that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.
507.110(d) .....	507.37(b) .....	Factors that must be considered in determining appropriate supplier verification activities.	<ul style="list-style-type: none"> <li>• Clarification that these factors must be considered in approving suppliers, as well as in determining appropriate supplier verification activities.</li> <li>• Flexibility in the factors that must be considered if a supplier is a qualified facility, a produce farm that will not be subject to the forthcoming produce safety rule on the basis of size and/or direct farm marketing, or a shell egg producer that is not subject to the requirements of 21 CFR part 118 (production, storage, and transportation of shell eggs) because it has less than 3,000 laying hens.</li> </ul>
507.115(a) .....	N/A .....	Responsibilities of the receiving facility .....	Provide flexibility for an entity other than the receiving facility to determine, conduct, and document supplier verification activities, provided that the receiving facility reviews and assesses applicable documentation from that entity and documents the receiving facility's review and assessment.
507.115(b) .....	N/A .....	Responsibilities of the receiving facility .....	Specify documentation that a receiving facility may not accept from a supplier to satisfy the receiving facility's responsibilities for its supply-chain program.
507.120(a) .....	507.37(a)(3)(i) .....	Approval of suppliers .....	Explicit requirement for a receiving facility to approve its suppliers.
507.120(b) .....	507.37(a)(3)(i) .....	Approval of suppliers .....	Explicit requirement for a receiving facility to establish and follow written procedures for receiving raw materials and other ingredients.
507.130(e) .....	N/A .....	Alternative supplier verification activity .....	Provide for an alternative supplier verification activity when the supplier is a shell egg producer with less than 3,000 laying hens.
507.130(f) .....	N/A .....	Independence of the supplier .....	Specify that there must not be any financial conflicts of interests that influence the results of the verification activities listed in §507.110(b) and payment must not be related to the results of the activity.

TABLE 23.5—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Revision
507.135(c)(1) .....	507.37(e) .....	Substitution of an inspection for an audit .....	Provide additional flexibility for domestic inspection by representatives of other Federal Agencies (such as USDA), or by representatives of State, local, tribal, or territorial agencies.
507.175 .....	507.37(g) .....	Records documenting the supply-chain program.	List additional records associated with the revised provisions.

(Comment 428) Several comments ask us to issue guidance rather than establish requirements for a supplier program in the rule. Some comments assert that the benefits of a supplier verification program do not outweigh the costs; that we did not consider the effects of such a requirement on farms and small businesses; and that FSMA does not actually contain a requirement for a supplier verification program. Conversely, other comments support including a mandatory supplier program in the rule for hazards that are controlled in raw materials and other ingredients before receipt by the receiving facility, although many comments assert that a supplier verification program should be viewed as a verification activity rather than a preventive control. Some comments assert that a mandatory domestic supplier program is necessary to provide parity with the requirements of the FSVP rule authorized by FSMA, while other comments assert that FSMA’s authorization of foreign supplier verification should not be used to justify a domestic supplier program. Some of these comments single out our request for comment, in the proposed FSVP rule, on whether to allow an entity that would be both an importer (under the FSVP rule) and a receiving facility (under the animal food preventive controls rule) to be deemed in compliance with the FSVP rule if it was in compliance with the supplier verification provisions of the animal food preventive controls rule, and agree with such an approach (78 FR 45730 at 45748).

(Response 428) We agree that it is necessary to include a mandatory supply-chain program in the rule to ensure the safety of animal food where hazards are controlled in raw materials and other ingredients before receipt by a receiving facility, and we are finalizing such a requirement in this rule. The statute specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act). Further, we believe a supply-chain program is a measure that

a person knowledgeable about food safety would establish and implement in order to significantly minimize or prevent hazards requiring a preventive control in an incoming raw material or other ingredient.

Supplier verification is sufficiently important for the control of hazards in both domestic and imported animal foods that FSMA contains provisions for both domestic and foreign supplier verification (sections 418(o)(3) and 805 of the FD&C Act). Because we have aligned the provisions for supplier verification in the FSVP rule with the provisions for a supply-chain program in this rule, we are allowing importers and receiving facilities to take advantage of that fact in considering compliance with both part 507 and our forthcoming FSVP regulations that we proposed to establish in part 1, subpart L, so that they do not have to duplicate verification activities (see § 507.105(a)(2)).

(Comment 429) Some comments that addressed questions we asked in the 2013 proposed preventive controls rule for animal food and the 2014 supplemental notice recommend that we add flexibility to the requirements for a supplier program such that any entity in the supply chain between the supplier and the receiving facility can perform supplier verification activities. Some comments ask us to allow a receiving facility to have a supplier program established for it by another entity. Other comments assert that it would be too burdensome for a receiving facility to consider any information related to the supplier’s supplier or to go further back in the supply chain beyond the entity that is one back from the receiving facility. Other comments assert that we should eliminate any requirements for a supplier program from the rule because a supplier program involving more entities than just the receiving facility and the supplier would become too complex. Some comments express concern that we would be creating “an environment where our supply chain is required to be disclosed to our

customers via product testing, audits and supplier verification,” asserting that this would discourage customers from buying from entities such as repackers when they could go to the source. Some comments state that we have not taken into account the low-risk nature of some industries. Other comments ask us to confirm that distributors and warehouses are not included in the requirements for a supplier program because they would not likely meet the definition of a receiving facility or a supplier.

(Response 429) We agree with comments recommending additional flexibility in the supply-chain program with regard to who can perform certain activities and have added this flexibility to the final rule (see § 507.115). Because the receiving facility and the supplier may be separated by several entities in a supply chain, we are allowing such entities (e.g., distributors, brokers, aggregators) to determine, conduct, and document supplier verification activities as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. However, because the approval of suppliers is ultimately the responsibility of the receiving facility, the rule specifies that only a receiving facility can approve suppliers (see §§ 507.115(a)(1) and 507.120(a) and Response 430).

We disagree that complex supply chains make a supply-chain program too difficult and that a receiving facility cannot be expected to reach further back in a supply chain than the entity immediately before it in the supply chain. Supply-chain programs are currently used by facilities as a standard business practice and we understand that some of those supply chains are complex, with entities between the receiving facility and the supplier. We acknowledge that complex supply chains present a challenge because information will need to flow through several entities to allow the link between the receiving facility and the



supplier. However, we believe a supply-chain program is a critical preventive control for receiving facilities that will rely on suppliers to control hazards in raw materials and other ingredients. Although distributors, brokers, and other entities in the supply chain between a receiving facility and its supplier are not required to have a role in supplier verification, they have the option to determine, conduct, and document supplier verification activities as a service to the receiving facility if they so choose. If these entities choose not to participate in supplier verification, the receiving facility will need to reach back in the supply chain past them. In such situations, it may be necessary for the entities between the receiving facility and the supplier to provide the identity of the supplier to the receiving facility, if that identity is not available on the raw material or other ingredient or otherwise apparent. In such cases, the role that distributors, brokers, aggregators and similar entities would play in supplier verification would be minimal. We cannot determine whether having to provide the identity of the supplier to the receiving facility would change buying practices. However, we believe that manufacturers consider a number of factors in determining who they will purchase from, including the services provided, and that there will continue to be a role for aggregators, repackers, brokers and others. We have provided flexibility for these entities to play a role in supplier verification if the receiving facility and the business entity determine there is a benefit to do so.

See also the discussion in section XLIII regarding the specific provisions of § 507.115. Although comments focus on flexibility for an entity in the supply chain between the supplier and the receiving facility to perform supplier verification activities, and such entities are the most likely to be determining, conducting, and documenting supplier verification activities, the flexibility provided by the rule is not limited to such entities.

(Comment 430) Some comments ask us to establish a general requirement for a supplier program without specifying roles and responsibilities for the various entities involved. Other comments ask us to define “supplier” as the entity with which the receiving facility has a commercial relationship.

(Response 430) We disagree that we should establish a general requirement

for a supply-chain program without specifying roles and responsibilities for the various entities involved. Although we have added flexibility to provide that an entity other than the receiving facility may determine, conduct, and document supplier verification activities (see § 507.115), we continue to believe it is important to clearly define two roles in the supply chain that share the primary responsibility in the supplier verification process—*i.e.*, the receiving facility and the supplier. In all cases where we have added flexibility for participation by an entity other than the receiving facility, the responsibility for the supply-chain program is clearly lodged with the receiving facility, and linked to the supplier (see § 507.115). To emphasize the responsibility of the receiving facility and its link to the supplier, the final rule clearly states that the receiving facility must approve its suppliers before receiving raw materials and other ingredients (see § 507.120(a)).

For the supply-chain program to be meaningful and robust, there must be an exchange of information between these two entities—the entity receiving the animal food and the entity that controlled the hazard—even when an entity other than the receiving facility participates by determining, conducting, and documenting some supplier verification activities. The ultimate responsibility for supplier verification rests with the receiving facility through its determination in approving suppliers and in reviewing and assessing applicable documentation provided by another entity. Therefore, we also disagree that the definition of “supplier” should be revised to be the next entity back in a supply chain (*e.g.*, the entity with which a receiving facility has a commercial relationship). The entity with which a receiving facility has a commercial relationship might be a distributor, broker or aggregator. A distributor, broker or aggregator does not control an identified hazard and, therefore, cannot assume the same role as an establishment that manufactures/processes the animal food, raises the animal, or grows the food.

(Comment 431) Some comments ask us to provide flexibility in the content of the supplier program. Some comments assert that specifying the content of the supplier program would result in duplicative requirements on suppliers, who must first comply with certain regulations and then

demonstrate that compliance in order to comply with a different regulation.

(Response 431) We disagree that a requirement for a supply-chain program in which compliance with an underlying regulation is demonstrated is duplicative with the need to comply with the underlying regulation. The requirement for a supply-chain program is not mandating that the facility or farm comply twice with the animal food preventive controls rule or the produce safety rule; it is merely requiring that the compliance by the facility or the farm with the applicable regulation be verified to ensure that hazards requiring a preventive control are being controlled.

We are continuing to specify the basic content of a supply-chain program, *i.e.*, using approved suppliers; determining appropriate supplier verification activities; conducting supplier verification activities; and establishing records documenting these activities (see § 507.110(a)). However, the rule provides flexibility in the choice of supplier verification activities and how often such activities must be performed. (See §§ 507.110(b)(4) and 507.130(b)(2), (c), (d), and (e)). In addition, the rule provides for an alternative supplier verification activity for certain entities (see § 507.130(c), (d), and (e) regarding alternative supplier verification activities for qualified facilities, certain produce farms, and certain shell egg producers, respectively).

#### **XLI. Subpart E: Comments on Requirement To Establish and Implement a Supply-Chain Program**

We proposed that the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient (proposed § 507.37(a)). We also proposed circumstances when a receiving facility would not be required to have a supplier program.

In the following sections, we discuss comments that ask us to clarify the proposed requirement to establish and implement a written supplier program or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the regulatory text as shown in table 24.

TABLE 24—REVISIONS TO THE PROPOSED REQUIREMENTS TO ESTABLISH AND IMPLEMENT A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
N/A .....	507.37(a)(1)(ii) .....	A supplier program is not required when there are no hazards requiring a preventive control.	Deleted as unnecessary.
N/A .....	507.37(a)(1)(ii) .....	A supplier program is not required when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards requiring a preventive control.	Deleted as unnecessary.
507.36(a)(2) .....	507.37(a)(1)(ii) .....	A supplier program is not required when the hazard will be controlled by the receiving facility's customer in the distribution chain.	Shifted to be in provisions outside the framework of the supply-chain program in subpart E.
507.105(a)(2) .....	N/A .....	Circumstances that do not require a supply-chain program even though the receiving facility's hazard analysis determines that a hazard requires a supply-chain-applied control.	A receiving facility is an importer, is in compliance with the FSVP requirements, and has documentation of verification activities conducted under the FSVP program.
507.105(a)(3) .....	N/A .....	Exemption from the requirements for a supply-chain program.	Exemption for animal food supplied for research or evaluation.
507.105(c) .....	N/A .....	Requirements applicable to non-suppliers .....	When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier, the receiving facility must (1) verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity in the supply chain, review and assess the entity's applicable documentation, and document that review and assessment.

*A. Requirement for a Written Supply-Chain Program (Final § 507.105(a)(1) and (b))*

We proposed that the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. We also proposed that the supplier program must be written. (See proposed § 507.37(a)(1)(i) and (2).) To improve clarity, we have revised the provision to substitute the phrase “hazard requiring a supply-chain-applied control” for the phrase “significant hazard when the hazard is controlled before receipt of the raw material or ingredient.” We have added a definition for the term “supply-chain-applied control” to mean a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt (see § 507.3) and use the more specific term “supply-chain-applied control,” rather than the broader term “preventive control,” throughout the provisions for a supply-chain program.

(Comment 432) As discussed in Comment 428, several comments ask us to issue guidance rather than establish requirements for a supplier program in the rule.

(Response 432) See Response 428 for a discussion of our reasons for declining this request and establishing requirements for a supply-chain program in the rule.

(Comment 433) Some comments ask us to revise the regulatory text to remove the condition that all hazards be foreseeable so that the supplier program can address economically motivated adulteration.

(Response 433) This comment is unclear. The requirement for a supply-chain program applies when the outcome of a hazard analysis is that a known or reasonably foreseeable hazard requires a preventive control, and the hazard would be controlled by the receiving facility's supplier. The requirement applies regardless of whether the hazard requiring a preventive control is, or is not, a hazard that would be introduced into a food for the purposes of economic gain.

(Comment 434) Some comments ask us to specify that a Certificate of Analysis or other documentation of the existence and/or level of a hazard could be provided to the receiving facility to indicate the potential for an actual existence of a hazard so that the receiving facility could evaluate whether the hazard requires a preventive control. Some comments state that chemical hazards such as nutrient imbalances are not controlled through easily described “procedures”

but are instead controlled through factors such as product formulation (e.g., controlling the levels of required or contaminating chemicals in each ingredient depending on the proportion of the ingredient in the finished animal food) and the amount fed. For example, some comments explain that mineral content of certain raw materials or ingredients may require control in some situations (e.g., copper content in food for sheep) but not in other situations (e.g., copper content in swine food). One comment expresses concern about whether customers would be willing to provide the receiving facility with confidential information about the customer's own hazard analysis with respect to sensitive topics. Furthermore, in such cases the receiving facility will not even know whether the chemical contaminant constitutes an actual “hazard” for the purposes of the customer's finished food. This comment also asserts that a Certificate of Analysis provided to a receiving facility constitutes “control before receipt of the raw material or ingredient.”

(Response 434) We do not understand the concern of this comment. A receiving facility and a supplier do not need to share all of the details of product formulation for a receiving facility to communicate its requirements to a supplier. In the example provided by the comment, the receiving facility could provide the supplier with a

written specification for a contaminant such as lead, and the supplier could demonstrate that it satisfied the receiving facility's specification by providing a Certificate of Analysis showing the results of laboratory testing for lead. Neither the written specification provided by the receiving facility, nor the Certificate of Analysis provided by the supplier, would disclose confidential information about the formulations or procedures of either entity.

This comment also appears to misunderstand the applicability of the supply-chain program. The rule requires a supply-chain program when the receiving facility has identified, through its hazard analysis, that there is a hazard requiring a supplier-applied control. In the circumstances described by the comment, a Certificate of Analysis or other documentation of test results from the supplier to the receiving facility could demonstrate that the supplier has controlled the hazard to the receiving facility's specifications, but would not overturn the outcome of the receiving facility's hazard analysis that there is a hazard requiring a preventive control, and that the appropriate control is applied by the supplier. On the contrary, the Certificate of Analysis simply demonstrates that the supply-chain-applied control functioned as intended.

(Comment 435) One comment asks us to specify in the regulatory text that the supplier program must be written "if required" because there are specified circumstances when a supplier program is not required.

(Response 435) We decline this request. Although the rule provides circumstances when a supply-chain program is not required (see § 507.105(a)(2)), it is not necessary to specify, for all other provisions of the supply-chain program, that the provision only applies "if required."

*B. Circumstances That Do Not Require a Written Supply-Chain Program (Final § 507.105(a)(2))*

We proposed that the receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which there are no significant hazards; the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly

minimize or prevent the hazard. (See proposed § 507.37(a)(1)(ii)(A), (B), and (C).)

We are deleting the proposed provision that a supplier program is not required for raw materials and ingredients for which there are no "significant hazards" (which we now refer to as "hazards requiring a preventive control") because it is unnecessary. The supply-chain program is required when a hazard identified in the receiving facility's hazard analysis identifies a hazard requiring a supply-chain-applied control; it is not necessary to also state the converse. Likewise, we are deleting the proposed provision that a supplier program is not required if the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards. In such a case, the outcome of the hazard analysis would not be that the hazard requires a supply-chain-applied control.

As discussed in section XXVII, after considering comments, we are shifting the provision in which the receiving facility relies on its customer to control the hazard from the requirements for a supply-chain program to a series of provisions that apply when a manufacturer/processor identifies a hazard requiring a preventive control, but can demonstrate and document that the hazard will be controlled by an entity in its distribution chain (see §§ 507.36 and 507.37). However, as discussed in Response 428 and section XLI.C, we also are establishing two additional circumstances when a supply-chain program is not required (see § 507.105(a)(2) and (3)).

(Comment 436) As noted in Comment 428, some comments single out our request for comment, in the proposed FSVP rule, on whether to allow an entity that would be both an importer (under the FSVP rule) and a receiving facility (under animal food the preventive controls rule) to be deemed in compliance with the FSVP rule if it was in compliance with the supplier verification provisions of the animal food preventive controls rule, and agree with such an approach (78 FR 45730 at 45748).

(Response 436) As noted in Response 428, we have aligned the provisions for supplier verification in the FSVP rule with the provisions for a supply-chain program in this rule, and we are allowing importers and receiving facilities to take advantage of that fact in considering compliance with our forthcoming FSVP regulations that we proposed to establish in part 1, subpart L, so that they do not have to

duplicate verification activities (see § 507.105(a)(2)).

(Comment 437) Some comments support the specified criteria for when a receiving facility would not be required to establish and implement a supplier program. Other comments express concern that these criteria suggest no supplier verification is needed at all in some circumstances despite supplier verification activities being potentially informative about a particular supplier. These comments ask us to establish some general requirement to perform verification activities for all suppliers.

(Response 437) We decline this request because it is neither risk-based nor consistent with the nature and purpose of the supply-chain program, which is to provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented (see the regulatory text of § 507.110(c)). We agree that some degree of verification of all suppliers may prove useful to a receiving facility for various purposes, and the rule would not prevent a receiving facility from establishing a supply-chain program for all of its suppliers regardless of risk and regardless of whether the applicable hazard in a raw material or other ingredient is controlled before its receipt.

(Comment 438) Some comments ask us to specify that a "kill step" would be an adequate indicator to significantly minimize or prevent significant hazards identified by the receiving facility when the receiving facility controls the hazard.

(Response 438) These comments appear to misunderstand the applicability of the supply-chain program. The rule requires a supply-chain program when the receiving facility has identified, through its hazard analysis, that there is a hazard requiring a preventive control and the receiving facility's manufacturing/processing will not control the hazard. In the circumstances described by the comment, the receiving facility is controlling the hazard and a supply-chain program for the raw material or other ingredient is not required. It is not necessary to specify the types of controls that the receiving facility may use to control the hazard.

(Comment 439) Some comments ask us to specify that a receiving facility need not establish and implement a supplier program for raw materials and ingredients if those raw materials or ingredients were received from an affiliated party within the same corporate or controlling entity.

(Response 439) We decline this request. With the revisions we have made to the proposed requirements for a supplier program, the supply-chain program that we are establishing in this rule provides ample opportunities for an affiliated party within the same corporate or controlling entity to establish and implement a supply-chain program that is suited to its relationship to these entities. For example, as discussed in Response 458, a receiving facility might be able to determine and document a justification for a supplier verification activity other than an annual audit when a supplier is an affiliated party based on the receiving facility's knowledge of the corporate policies regarding animal food safety practices (see § 507.130(b)(2)). In addition, as discussed in Response 461, we have agreed that the corporate parent of a facility can be active in developing and implementing the facility's food safety plan (see section XXIV.A). If, for example, a corporate headquarters establishes and implements a supply-chain program for use company-wide, a receiving facility could rely on supplier verification activities conducted by its corporate headquarters, with applicable documentation available during inspection.

*C. Exemption for Animal Food Supplied for Research or Evaluation (Final § 507.105(a)(3))*

We are establishing an exemption from the requirement for a receiving facility to establish and implement a supply-chain program when it receives animal food for the purposes of research or evaluation, provided that certain conditions are met (see § 507.105(a)(3)). Those conditions are that the animal food: (1) Is not intended for retail sale and is not sold or distributed to the public; (2) is labeled with the statement "Animal food for research or evaluation use"; (3) is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the animal food is used only for this purpose, and any unused quantity is properly disposed of; and (4) is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public. The exemption is analogous to an exemption we proposed for the FSVP rule under section 805(f) of the FD&C Act. (See proposed § 1.501(c), 78 FR 45730 at 45745.) We believe it is not necessary to conduct supplier verification activities when animal food is obtained in this limited circumstance.

*D. Additional Requirements for Non-Suppliers (Final § 507.105(c))*

As discussed in section IV.B of this rule and in section IV.B of the final rule for preventive controls for human food as published elsewhere in this addition of the **Federal Register**, the final rule for preventive controls for human food includes several revisions to the "farm" definition in response to comments. One change includes adding a new definition for a "secondary activities farm," which provides for practices such as packing by cooperatives and packing houses under the ownership of multiple growers to remain within the "farm" definition (see Response 25 in the final rule for preventive controls for human food). Another change to the "farm" definition accommodates business models in which one operation grows crops but does not harvest them, and another operation, not under the same management, harvests crops but does not grow them (see Response 32 in the final rule for preventive controls for human food). This revision is a change from the "farm" definition established in the section 415 registration regulations in 2003, and the proposed revisions to the "farm" definition in the 2013 proposed human food preventive controls rule and the 2014 supplemental human food preventive controls notice, which all describe a "farm" as an entity "devoted to the growing and harvesting of crops" (emphasis added).

We proposed the requirements for a supplier program in the context of a single business entity "devoted to the growing and harvesting of crops" (emphasis added) in which packing operations were often done by that same business entity. The final "farm" definition accommodates business models where growing, harvesting, and packing operations will be done by different business entities. Harvesting and packing operations include some supply-chain-applied controls, such as controls on worker hygiene, quality of water used during harvesting and packing operations, and establishing and following water-change schedules for recirculated water, even though the harvesting and packing operations do not fall within the definition of "supplier."

A receiving facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (see section 418(c) of the

FD&C Act and § 507.34(a)). That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier. To clarify the receiving facility's responsibilities when a supply-chain-applied control is applied by a non-supplier, we are establishing a requirement specifying that when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier, the receiving facility must: (1) Verify the supply-chain-applied control or (2) obtain documentation of an appropriate verification activity from another entity in the supply chain, review and assess the entity's applicable documentation, and document that review and assessment. See § 507.105(c). Because § 507.105(c) refers to provisions in a future produce safety rule, we will publish a document in the **Federal Register** announcing the effective date of that provision when we finalize the produce safety rule.

We do not expect the receiving facility to follow all of the requirements of subpart E applicable to "suppliers" when verifying a control by a "non-supplier," as required by § 507.105(c). Instead, we expect the receiving facility to take steps such as a review of the non-supplier's applicable food safety records. For example, if a receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer, the grower is the supplier and the requirements of subpart E applicable to "suppliers" apply to the grower. To verify controls applied by the harvester, the receiving facility could review the harvester's records, such as records of training for harvest workers and records of agricultural water quality used in harvest operations. To verify controls applied by the packer, the receiving facility could review the packer's records, such as records of agricultural water quality used in packing operations. As discussed in Response 429, we are allowing entities such as distributors, brokers, and aggregators to determine, conduct, and document verification activities that apply to suppliers as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. Likewise, under § 507.105(c)(2) a receiving facility could obtain documentation of review of applicable records maintained by the harvester or packer from another entity, review and assess the entity's applicable

documentation, and document that review and assessment.

We recognize that 507.105(c) may have limited applicability to raw material and other ingredients used in animal food. At this time, we do not have an example of when we would expect an animal food manufacturer to verify non-supplier controls for its raw materials or other ingredients. Although we do not have examples and expect limited applicability of § 507.105(c)(2), we have included these provisions to provide for instances when an animal food facility identifies situations in which controls applied by a “non-supplier” need to be verified as part of the facility’s supply-chain program.

*E. Proposed General Requirements for the Supply-Chain Program That We Are Not Including in the Final Rule (Proposed § 507.37(a)(4) and (5))*

We proposed that when supplier verification activities are required for more than one type of hazard in a food,

the receiving facility must conduct the verification activity or activities appropriate for each of those hazards. We also proposed that for some hazards, in some situations it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented. We have concluded that these provisions are largely self-evident and need not be included in the regulatory text. Therefore, we are not finalizing these proposed provisions. We will consider whether it will add value to discuss the principles in these proposed provisions in guidance that we intend to develop for the supply-chain program.

**XLII. Subpart E: Comments on General Requirements for the Supply-Chain Program**

We proposed several requirements generally applicable to the supplier

program (such as factors to consider in determining appropriate supplier verification activities (proposed § 507.37(b)), as well as several requirements more narrowly targeted to specific aspects of the supplier program (such as requirements applicable to onsite audits). As part of the redesignation of proposed § 507.37 into subpart E, with eight distinct sections, we are establishing the more general requirements in § 507.110 (see table 25).

Most comments that support the proposed provisions suggest alternative or additional regulatory text. In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the regulatory text as shown in table 25.

TABLE 25—REVISIONS TO THE PROPOSED GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
507.110(a)	507.37(a)(3)	What the supply-chain program must include.	Add that the supply-chain program includes, when applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility’s supplier and documenting that verification, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment.
507.110(b)	507.37(c)(1)	Appropriate supplier verification activities.	N/A.
507.110(c)	507.37(a)(3)(ii)	Purpose of supplier verification activities for raw materials and other ingredients.	Specify only that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.
507.110(d)	507.37(b)	Factors that must be considered when approving suppliers and determining appropriate supplier verification activities for raw materials and other ingredients.	Clarify that the factors apply in approving suppliers, as well as in determining appropriate supplier verification activities.
507.110(d)	507.37(b)	Factors that must be considered when approving suppliers and determining appropriate supplier verification activities for raw materials and other ingredients; Supplier performance..	<ul style="list-style-type: none"> <li>Specify that three of the factors relate to “supplier performance”</li> <li>Specify “The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control” rather than “Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier’s supplier”.</li> <li>Add “other FDA compliance actions related to food safety” as an example of information relevant to the supplier’s compliance with applicable FDA food safety regulations.</li> <li>Clarify that consideration of supplier performance includes, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States and information relevant to the supplier’s compliance with those laws and regulations.</li> </ul>

TABLE 25—REVISIONS TO THE PROPOSED GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM—  
Continued

Final section designation	Proposed section designation	Description	Revision
507.110(e) .....	507.37(f) .....	Supplier non-conformance	<ul style="list-style-type: none"> <li>• Provide flexibility in the factors that must be considered if a supplier is a qualified facility, a produce farm that will not be subject to the forthcoming produce safety rule on the basis of size and/or direct farm marketing, or a shell egg producer that is not subject to the requirements of 21 CFR part 118 (production, storage, and transportation of shell eggs) because it has less than 3,000 laying hens.</li> </ul> N/A.

*A. Description of What the Supply-Chain Program Must Include (Final § 507.110(a))*

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers) (proposed § 507.37(a)(3)(i)). We also proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities. We also proposed requirements applicable to the determination and documentation of appropriate supplier verification activities (proposed § 507.37(b)). We also proposed specific documentation requirements for records associated with the supplier program (proposed § 507.37(g)).

The final rule specifies that the supply-chain program must include: (1) Using approved suppliers; (2) determining appropriate supplier verification activities (including determining the frequency of conducting the activity); (3) conducting supplier verification activities; and (4) documenting supplier verification activities. For clarity, § 507.110(a) states this general requirement for the supply-chain program and §§ 507.120, 507.125, 507.130, 507.135, and 507.175 provide the specific requirements for using approved suppliers, determining appropriate supplier verification activities, conducting verification activities, specific requirements for onsite audits, and records, respectively. See the discussion of the specific requirements of §§ 507.120, 507.125, 507.130, 507.135, and 507.175 in sections XLIV, XLV, XLVI, and XLVII, respectively.

As discussed in section XLID, the final rule establishes a verification

requirement when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (see § 507.105(c)). For clarity, § 507.110(a) states this general requirement for the supply-chain program in § 507.105(a)(5), and § 507.105(c) provides the specific requirements that apply when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

*B. Appropriate Supplier Verification Activities ((Final § 507.110(b))*

We proposed to require that appropriate supplier verification activities include: (1) Onsite audits; (2) sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; or (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier (proposed § 507.37(c)(1)).

(Comment 440) Some comments support the inclusion of onsite audits as an appropriate supplier verification activity. However, other comments oppose it, and ask us to remove the onsite audit requirement from the supplier verification program, stating that Congress prohibited FDA from requiring third parties to verify or audit compliance with the rules. These comments express concern that the supplier verification program effectively imposes an "entire second layer of regulation" on farms that are supplying ingredients to processors, and claim this is an unnecessary burden that is not authorized by FSMA.

(Response 440) We are retaining onsite audits as an appropriate supplier verification activity. Onsite audits may be less commonly used by the animal food industry than the human food industry. However, onsite audits provide the opportunity to review the

food safety plan and written procedures and to observe the implementation of animal food safety procedures, as well as to review the records related to the past application of control measures, including laboratory test results. Audits also provide the opportunity to interview employees to assess their understanding of the animal food safety measures for which they are responsible. Thus, an audit can provide for a more comprehensive assessment of animal food safety implementation by a facility. Comments that oppose including onsite audits as a verification activity are concerned that farms will be required to have audits to verify that they are in compliance with produce safety standards or facilities will be required to have audits to verify preventive controls. These comments apparently refer to the provision in section 419(c)(1)(E) of the FD&C Act that the regulation issuing standards for the safety of produce "not require a business to hire a consultant or other third party to identify, implement, certify compliance with these procedures, processes and practices," or the provision in section 418(n)(3)(D) of the FD&C Act that the preventive controls regulation "not require a facility to hire a consultant or other third party to identify, implement, certify or audit preventative controls." The regulations proposed under section 419 of the FD&C Act would not impose such requirements. The requirements for supplier verification in this rule (under section 418 of the FD&C Act) provide for audits as one supplier verification activity. Although the rule does specify an annual onsite audit as the appropriate supplier verification activity when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the receiving facility is not required to hire a third

party to conduct the audit. Any qualified auditor, other than the supplier, may conduct the audit, including an employee of the receiving facility or another entity, such as an entity in the supply chain between the supplier and the receiving facility. The rule also provides that a receiving facility may determine and document that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (see § 507.130(b)(1) and (2)). Audits already conducted on a supplier's facility or operation for other business purposes may meet the requirement for supplier verification. In addition, the rule provides alternative requirements for verification of suppliers that are farms that grow produce and are not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5 (see § 507.130(d)). Finally, we have also provided that inspections may substitute for an audit under specified circumstances (see § 507.135(c)).

While we realize that some farms may receive audits under the supplier verification provisions of part 507, we anticipate that onsite audits will be used as a verification activity more frequently for non-farm facilities because hazards associated with commercial animal food production are not typically controlled by the farm, but rather during manufacture or processing of the animal food.

(Comment 441) Some comments support the inclusion of sampling and testing of the raw material or other ingredient as an appropriate supplier verification activity, and note that verification testing is more effective when conducted by the supplier than the receiving facility because the supplier can control the lot of product tested. However, other comments oppose it, stating that sampling and testing is not useful for products for various reasons such as the non-homogeneous distribution of some hazards, or statistical limitations because of practical limits on number of samples or limited shelf life of some products.

(Response 441) We are retaining sampling and testing as an appropriate supplier verification activity. As noted in the FDA memorandum on supplier programs, sampling and testing are commonly used by industry in the verification of supplier performance (Ref. 53). We have previously discussed factors that impact the utility and frequency of raw material/ingredient testing (see the Appendix published in the 2013 proposed preventive controls

rule for animal food (78 FR 64736 at 64836)). We agree that there are benefits in having sampling and testing conducted by the supplier, because the supplier can then take appropriate action with respect to the findings, including not shipping contaminated product. However, because contamination with some hazards is likely to be non-homogeneous and for microbial pathogens or microbial toxins the numbers are likely to be low, a negative test result does not guarantee the absence of contamination. This should be taken into account when deciding which verification activity (or activities) is appropriate. Because of the limitations of sampling and testing, the controls the supplier has in place to minimize contamination, and the management of those controls, are key in determining when sampling and testing is appropriate as a verification activity. For short shelf life products, where holding product pending test results can negatively impact product quality and usefulness, an onsite audit to verify control of hazards may be more appropriate than sampling and testing.

(Comment 442) Some comments ask us to specify in the regulatory text that sampling and testing can be conducted by or on behalf of the supplier or the receiving facility.

(Response 442) The provisions of § 507.115 specify the responsibilities of the receiving facility, and allow a receiving facility to conduct all supplier verification activities, including sampling and testing. These provisions also provide that a supplier, or an entity other than the receiving facility (such as an entity in the supply chain between the supplier and the receiving facility), can conduct sampling and testing, provided that the receiving facility reviews and assesses the documentation provided by the supplier. The rule places no restrictions on when a receiving facility, a supplier, or an entity other than the receiving facility could have a business relationship with a third party (such as a contract laboratory) to conduct sampling and testing.

(Comment 443) Some comments suggest that, for a facility regularly undergoing audits, reviewing a "supplier's relevant food safety records" should allow for the receiving facility to review documentation related to pre-existing audits. These comments ask us to revise the provision to add "including, but not limited to, records related to audits previously performed on the supplier's facility."

(Response 443) We decline this request. The comment misinterprets what we mean by a "supplier's relevant

food safety records." The rule provides for onsite audits as a verification activity, as well as reviewing a "supplier's relevant food safety records." When an annual audit is determined to be an appropriate verification activity (see § 507.130(b)(1)), the audit would be reviewed by the receiving facility, but a review of this audit is not what we meant by a "supplier's relevant food safety records." As described in an FDA memorandum on supplier programs, food safety records are records documenting that the food safety procedures that have been established to control hazards are being followed and are adequately controlling such hazards (Ref. 53). Thus, a receiving facility may obtain documentation of a supplier's control measures for a particular lot of a raw material or other ingredient provided to the receiving facility, such as the records created when a process control measure was applied. The food safety records may also include supplier records that show that the supplier's supplier has controlled a hazard. Such records may include audits, for example, when the supplier's supplier controls the hazard and the supplier's records include records of an audit conducted with respect to the hazard control activities of the supplier's supplier. To emphasize that the review of a supplier's relevant food safety records can include records other than records of audits, we have revised the documentation requirements applicable to review of a supplier's food safety records to specify that the documentation must include the general nature of the records reviewed (see § 507.175(c)(9)). By "general nature of the records reviewed", we mean information such as "records of process controls."

(Comment 444) Some comments support the inclusion of other appropriate supplier verification activities based on the risks associated with the ingredient and the supplier, because it provides flexibility for facilities to design risk-based programs that are appropriate for their operations. Comments suggest other verification activities may include receiving raw materials and other ingredients from a supplier without a full audit report if the supplier maintains certification to a standard recognized by the Global Food Safety Initiative (GFSI); providing for documentary verification (such as fact-specific questionnaires and representations exchanged between the supplier and the receiving facility); and confirming that a facility, especially a small manufacturing facility, is licensed

by the appropriate State or local regulatory authority.

(Response 444) We are retaining this provision to allow other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient (§ 507.110(b)(4)). We have revised the regulatory text to refer to “supplier performance and the risk associated with the raw material or other ingredient” because “supplier performance” is more appropriate than “risk associated with the supplier.” We use the term “risk” as defined by the Codex Alimentarius Commission to be “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food” (Ref. 54). As discussed in section XLII.D, the considerations for supplier performance, which can be related to the probability of a hazard in the raw material or ingredient and the severity of adverse health effects that can result, are broader than this.

We do not believe that a supplier maintaining certification to an industry standard would, by itself, serve as verification that a supplier is controlling the hazard; however we agree that this can be a consideration in the determination of the type and frequency of the verification activity conducted. Similarly, fact-specific questionnaires and representations exchanged between the supplier and the receiving facility can be a consideration in the determination of the type and frequency of the verification activity conducted. Confirming that a facility is licensed by the appropriate State or local regulatory authority should not serve as the only verification that a supplier is controlling the hazard, because the requirements for a license and the degree of inspectional oversight could vary greatly. We do provide for modified supplier verification activities for qualified facilities, which are very small businesses (§ 507.130(c)).

#### *C. Purpose of Supplier Verification Activities for Raw Materials and Other Ingredients (Final § 507.110(c))*

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to verify that: (1) The hazard is significantly minimized or prevented; (2) the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act of the FD&C Act; and (3) the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 507.37(a)(3)(ii)). We have

revised the provision to specify that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. If the supply-chain program provides assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented, it is not necessary to also specify that the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act. We also have deleted the requirement that the verification activities must verify that the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations and instead focused that requirement as a factor that must be considered in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted rather than as one of the stated purposes of the supply-chain program. See the regulatory text of § 507.110(d)(i)(iii)(B).

(Comment 445) Some comments ask us to revise this provision to state that the receiving facility’s use of the incoming raw material or ingredient will not cause the finished food to be adulterated under section 402 of the FD&C Act. These comments assert that FSMA does not mandate, nor is it reasonable to expect, that incoming raw materials and ingredients will not be adulterated under section 402, and that it is acceptable for a receiving facility to control the “adulterating hazard,” even if it relies on the supplier to control other hazards.

(Response 445) We decline this request. We acknowledge that in some circumstances a receiving facility may rely on the supplier to control certain hazards, while controlling other hazards itself. For example, a receiving facility that produces dry dog food that contains corn could rely on its supplier for the control of the chemical hazard aflatoxin, but control the biological hazard *Salmonella* through its own heat-treatment process. However, the supply-chain program applies to hazards requiring a supply-chain-applied control, and the purpose relates to those hazards. In the example where the receiving facility is relying on the supplier to control aflatoxin, the provision would require the receiving facility to verify that the hazard (aflatoxin) has been significantly minimized or prevented by the supplier and that the level of aflatoxin in the corn does not render it adulterated under the FD&C Act.

#### *D. Factors That Must Be Considered When Approving Suppliers and Determining Appropriate Supplier Verification Activities for Raw Materials and Other Ingredients (Final § 507.110(d))*

We proposed that in determining and documenting the appropriate verification activities, the receiving facility must consider the following: (1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients; (2) where the preventive controls for those hazards are applied for the raw material and ingredients, such as at the supplier or the supplier’s supplier; (3) the supplier’s procedures, processes, and practices related to the safety of the raw material and ingredients; (4) applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food; (5) the supplier’s food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation practices (proposed § 507.37(b)).

As discussed in Responses 429 and 430 and section XLIV.A, we have revised the regulatory text regarding use of approved suppliers to more explicitly state that the receiving facility must approve suppliers. The factors that must be considered in determining the appropriate supplier verification activities are equally relevant to approving suppliers, and the final rule requires that these factors must be considered in approving suppliers, as well as in determining appropriate supplier verification activities. For clarity and consistency with terms used throughout the final provisions for a supply-chain program, the final rule specifies “the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control” rather than “Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier’s supplier.”

As discussed in Response 444, we are using the term “supplier performance,” rather than “risk of supplier,” when discussing factors associated with



suppliers. The final rule groups three of the proposed factors as “supplier performance.” As a companion change to emphasize that “supplier performance” applies to all three of these factors, we refer to the supplier’s “food safety history” rather than “food safety performance history.”

We also have revised the regulatory text to clarify that consideration of supplier performance includes, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States and information relevant to the supplier’s compliance with those laws and regulations. We made this change because the final rule includes several provisions that acknowledge that some animal food establishments, including animal food establishments that are “suppliers” as that term is defined in this rule, operate in a foreign country. (See, e.g., the definition of “qualified auditor” in § 507.3 and §§ 507.7(a)(2)(ii), 507.7(e), 507.105(a)(2), 507.130(c), 507.135(c)(1)(ii), 507.135(c)(2), and 507.175(c)(15)). Some of these provisions (e.g., §§ 507.105(a)(2), 507.130(c), 507.135(c)(1)(ii), 507.135(c)(2), and 507.175(c)(15)) are in the requirements for a supply-chain program. When the supplier is in a foreign country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, a receiving facility may substitute the written results of an inspection by the applicable food safety authority for an audit, provided that certain conditions are met (see § 507.135(c)(1)(ii) and (2)). However, as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food. The final rule provides flexibility for alternative verification requirements for certain entities (see § 507.130(c), (d), and (e)). We have revised the factors that must be considered regarding supplier performance to reflect the flexibility the rule provides for conducting supplier verification activities for these entities (see § 507.110(d)(2)).

(Comment 446) Some comments support the flexibility for receiving facilities to determine the appropriate supplier verification activities and frequency with which to conduct these

activities. Some comments state that not all of the factors that we proposed a receiving facility consider are relevant for the process of selecting the verification activity. These comments suggest changing the regulatory text to require a receiving facility to consider “both food and supplier related risks, including the following, as appropriate” and then listing the factors as proposed. Other comments suggested similar changes to the regulatory text.

(Response 446) We disagree that not all of the factors that we proposed a receiving facility to consider are relevant to determining the appropriate verification activity. Every factor might not be determinative in all cases, and our requirement merely to consider each factor does not assume so. However, any one of these factors could be crucial depending on the animal food, the hazard, and the nature of the preventive control. We continue to consider it appropriate to require receiving facilities to consider each of these factors in making their determinations about the appropriate verification activities.

(Comment 447) Some comments ask us to clarify that the phrase “the nature of the hazard” means the nature of the hazard requiring control.

(Response 447) We have revised the regulatory text to specify “the nature of the hazard controlled before receipt of the raw material or other ingredient.” The revised regulatory text is consistent with regulatory text in the provisions for the preventive control management components (see § 507.39(b), which specifies “taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient”).

(Comment 448) Some comments agree that a receiving facility must consider where the preventive controls for hazards are applied for the raw materials and ingredients, such as at the supplier or the supplier’s supplier. Other comments assert that this consideration should not be used to determine if supplier oversight is needed. Other comments state that it may be hard to review the procedures used by a supplier’s supplier and beyond and ask us to provide clear flexibility regarding requirements for the content and performance of a receiving facility’s supplier program.

(Response 448) The purpose of the requirement to consider where the hazard is controlled is to assist a receiving facility in determining what supplier verification activities are appropriate, not to determine whether supplier oversight is needed. Once a receiving facility has determined that a

hazard requiring a preventive control is controlled before receipt of a raw material or other ingredient, supplier oversight is needed.

We recognize that there is need for additional flexibility regarding conducting supplier verification activities. As discussed in Response 429, we are providing significant additional flexibility to address this situation in the final rule.

(Comment 449) Some comments object to the proposed requirement to consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food. These comments assert that it is difficult for a receiving facility to know a supplier’s compliance status, because it is not easy to obtain this kind of information in a timely fashion. Some comments ask us to develop an online database to house this information to help make it easier to find. Some comments ask us to replace the broad requirement to consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations with a narrower requirement to only consider any FDA warning letter or import alert relating to the safety of the food.

(Response 449) We are retaining the broad requirement to consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations. Such information is relevant to supplier performance regardless of whether there is an applicable warning letter or import alert.

We currently have a searchable online database for warning letters (Ref. 55) and another searchable online database for import alerts (Ref. 56). Both of these databases are available to the public from our homepage at <http://www.fda.gov>. We also publicize actions to suspend a facility’s registration, such as in our 2012 suspension of registration due to *Salmonella* contamination of nut butter and nut products (including ingredients used in animal foods) manufactured, processed, packed, and held by the facility (Ref. 57). Under the requirement to consider supplier performance with respect to applicable food safety regulations, a receiving facility cannot ignore published information relating to a supplier’s compliance with applicable FDA food safety regulations in determining the appropriate verification activities, such as publicized information regarding suspension of registration. To

emphasize this point, we have revised the regulatory text to specify that the applicable information includes “other FDA compliance actions related to animal food safety.” We also have revised the regulatory text to specify that the compliance relates to an FDA warning letter or import alert relating to the “safety of animal food,” rather than the “safety of the animal food,” to provide flexibility for a receiving facility to identify information that may raise a question about a supplier’s compliance history in a more general way, rather than only with respect to a particular animal food.

(Comment 450) Some comments state we should only require consideration of the supplier’s food safety performance history relevant to the hazards requiring control in the raw materials or ingredients that the receiving facility receives from the supplier.

(Response 450) Consideration of the supplier’s animal food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier will be focused on the hazard that the supplier is controlling because that is the food safety information the receiving facility will consider to be relevant and for which the receiving facility would develop a history. The information could indicate that certain verification activities may be more appropriate than others for verifying the control of the hazard at that particular supplier or provide information useful in determining a frequency for the verification activity. However, we decline to revise the provision to specify that consideration should be limited to the hazards requiring control. Even though this is the most relevant information, a facility may become aware of information with respect to a raw material or other ingredient provided to another customer of the supplier that may suggest the need to conduct a different verification activity. For example, if the receiving facility is obtaining mineral premix from a supplier that is controlling for a nutrient imbalance of copper and molybdenum and becomes aware that mineral premixes from this supplier have been associated with a recall due to contamination with a physical hazard, the receiving facility would determine

that it should implement verification activities related to controlling for physical hazards.

(Comment 451) Some comments ask us to replace the phrase “examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation” with “such as storage and transportation.”

(Response 451) We have made this editorial change.

*E. Supplier Non-Conformance (Final § 507.110(e))*

We proposed that if the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the FD&C Act (proposed § 507.37(f)).

(Comment 452) Some comments object to the use of the word “significant” in this proposed provision, recommending that we replace it with “requiring control by the supplier.” These comments reason that these activities are only necessary if the receiving facility is relying on the supplier to control the specific hazards.

(Response 452) We have revised the regulatory text to state “a hazard requiring a supply-chain-applied control” rather than “significant.”

**XLIII. Subpart E: New Requirement Specifying the Responsibilities of the Receiving Facility (Final § 507.115)**

As discussed in Response 429, after considering comments we are providing flexibility for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities, provided that the receiving facility reviews and assesses the entity’s applicable documentation, and documents the receiving facility’s review and assessment. We are specifying that flexibility in § 507.115. We have titled this section

“Responsibilities of the receiving facility” to emphasize the responsibility of the receiving facility for its supply-chain program. (See Responses 429 and 430.) Although comments focus on flexibility for an entity in the supply chain between the supplier and the receiving facility to perform supplier verification activities, and such entities are the most likely entities to be the entities determining, conducting, and documenting supplier verification activities, the flexibility provided by the rule is not limited to such entities.

The rule does, however, set some bounds on the flexibility for determining, conducting, and documenting appropriate supplier verification activities. For example, as discussed in Responses 429 and 430, only the receiving facility can approve its suppliers. As another example, although it would not be appropriate for a supplier to determine the appropriate supplier verification activities for itself, we had proposed that it would be appropriate for a supplier to conduct sampling and testing of raw materials and ingredients as a supplier verification activity (proposed § 507.37(c)(1)(ii)), and we are retaining that provision in the final rule (see § 507.115(a)(4)). Likewise, it is common industry practice for a supplier to arrange for an audit by a third party (Ref. 53), and the new flexibility provision does not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with the requirements of the rule applicable to audits (§ 507.135). See § 507.115 for the full text of this new flexibility provision.

**XLIV. Subpart E: Comments on Using Approved Suppliers and Determining Appropriate Supplier Verification Activities**

We proposed requirements for the use of approved suppliers (proposed § 507.37(a)(3)(i)) and for determining and documenting appropriate supplier verification activities (proposed § 507.37(b)). See table 26 for a description of the final provisions and the changes we have made to clarify the requirements.

TABLE 26—REVISIONS TO THE PROPOSED REQUIREMENTS FOR APPROVING SUPPLIERS AND FOR DETERMINING AND DOCUMENTING APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES

Final section designation	Proposed section designation	Description	Revision
507.120(a) .....	507.37(a)(3)(i) .....	The receiving facility must approve suppliers and document that approval.	Explicit statement of this requirement.

TABLE 26—REVISIONS TO THE PROPOSED REQUIREMENTS FOR APPROVING SUPPLIERS AND FOR DETERMINING AND DOCUMENTING APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES—Continued

Final section designation	Proposed section designation	Description	Revision
507.120(b)(1) .....	507.37(a)(3)(i) .....	Written procedures for receiving raw materials and other ingredients must be established and followed.	Explicit requirement for written procedures.
507.120(b)(2) .....	.....	The purpose of the written procedures is to ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients the receiving facility subjects to adequate verification activities before acceptance for use).	N/A.
507.120(b)(3) .....	507.37(a)(3)(i) .....	Use of the written procedures for receiving raw materials and other ingredients must be documented.	Conforming change associated with the explicit requirement to establish and follow written procedures.
507.125 .....	507.37(b) .....	Requirement to determine and document appropriate supplier verification activities.	N/A.

*A. Using Approved Suppliers (Final §§ 507.120)*

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 507.37(a)(i)).

This proposed requirement included an implicit requirement that a facility must approve suppliers. For clarity, we make that requirement, and documentation of that approval, explicit in the final rule. (See § 507.120(a)).

The rule continues to require that a receiving facility ensure raw materials and other ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or other ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to adequate verification activities before acceptance for use), but we revised the provision to specify that the receiving facility must do so by establishing and following written procedures, and require documentation that these procedures were followed. To simplify the provisions, we also established a definition for the term “written procedures for receiving raw materials and other ingredients” to mean written procedures to ensure that raw materials and other ingredients are

received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use), and use that term throughout subpart E. For example, a facility could design a checklist for employees to use when raw materials and other ingredients are delivered to the facility. We decided to specify use of written procedures for receiving raw materials and other ingredients in light of the flexibility the final rule provides for an entity other than the receiving facility (such as an entity in the supply chain between the supplier) to conduct this activity (see § 507.115(a)(2)). Although we agree that such an entity can do this as a service to the receiving facility, a written procedure is appropriate to ensure a robust and meaningful verification. As a companion change, we revised the associated documentation requirement to specify documentation of use of the written procedures.

(Comment 453) Some comments support the requirement to approve suppliers. Other comments ask us to provide guidance for use of unapproved suppliers on a temporary basis, because the use of unapproved suppliers could be a high risk situation. Other comments emphasize that if the final supplier approval process is significantly changed compared to the proposed supplier approval process, industry must have enough time to plan and develop supplier verification plans and a process for unapproved sources.

(Response 453) We will consider including guidance for use of unapproved suppliers on a temporary

basis in guidance that we intend to issue regarding the supply-chain program. We do not believe that the final requirements regarding the use of approved suppliers will require increased implementation time. The principal change is to allow flexibility for entities in the supply chain other than the receiving facility to establish written procedures for receiving raw materials and other ingredients and document that written procedures for receiving raw materials and other ingredients are being followed.

*B. Determining Appropriate Verification Activities (Final § 507.125)*

The rule requires that a supply-chain program include determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (see § 507.110(a)(2)). Comments that addressed the proposed provision for determining appropriate verification activities (which provides flexibility to the facility to determine the appropriate verification activities) did not disagree with it. The rule also requires that certain factors must be considered in determining appropriate verification activities (§ 507.110(d)). We discuss those factors, and comments that addressed those factors, in section XLII.D. Both of these provisions (*i.e.*, § 507.110(a)(2) and § 507.110(d)) derive from the proposed requirement regarding factors that must be considered in determining appropriate supplier verification activities (proposed § 507.37(b)). To give prominence to both the responsibility and the flexibility to determine appropriate supplier verification activities, and emphasize the factors

that must be considered in addressing this responsibility, new § 507.125 specifies that appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d).

**XLV. Subpart E: Comments on Conducting Supplier Verification Activities for Raw Materials and Other Ingredients**

We proposed requirements applicable to conducting supplier verification activities (proposed § 507.37(c)). Most comments that support the proposed provisions suggest alternative or

additional regulatory text or ask us to clarify how we will interpret the provision. In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 27.

**TABLE 27—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS**

Final section designation	Proposed section designation	Description	Revision
507.130(a) .....	507.37(c)(1) .....	Requirement to conduct one or more appropriate supplier verification activities.	Add reference to an additional provision that provides for alternative supplier verification activities for shell egg producers that have less than 3,000 laying hens.
507.130(b)(1) .....	507.37(c)(2)(i) .....	Requirement to conduct an onsite audit as the supplier verification activity when the hazard being controlled by the supplier is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.	N/A.
507.130(b)(2) .....	507.37(c)(2)(ii) .....	Exception to the requirement to conduct an annual onsite audit with a written determination.	N/A.
507.130(c) .....	507.37(c)(3) .....	Alternative supplier verification activity when the supplier is a qualified facility.	<ul style="list-style-type: none"> <li>• Modify the regulatory text to better align with the responsibilities of a qualified facility to submit an attestation to FDA about its food safety practices or its compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.</li> <li>• Clarify that the date for a receiving facility to obtain written assurance that a supplier is a qualified facility is before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year for the following calendar year.</li> <li>• Provide for written assurance that, when applicable, the supplier is producing the raw material or other ingredient in compliance with relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.</li> </ul>
507.130(d) .....	507.37(c)(4) .....	Alternative supplier verification activity when the supplier is a farm that is not a “covered farm” under part 112 in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5.	<ul style="list-style-type: none"> <li>• Clarify that the applicable farms are “not covered farms” rather than “not subject to part 112” because some of these farms are subject to modified requirements in § 112.6.</li> <li>• Clarify that the date for a receiving facility to obtain written assurance from the farm about its status is before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year for the following calendar year.</li> </ul>

TABLE 27—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS—Continued

Final section designation	Proposed section designation	Description	Revision
507.130(e) .....	N/A .....	Alternative supplier verification activity when the supplier is a shell egg producer that has fewer than 3,000 laying hens.	<ul style="list-style-type: none"> <li>Clarify that the written assurance from the farm is an acknowledgement that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). Specify an additional situation where the receiving facility can consider an alternative supplier verification activity.</li> </ul>

*A. Requirement To Conduct One or More Supplier Verification Activities (Final § 507.130(a))*

With two exceptions, we proposed that the receiving facility must conduct and document one or more specified supplier verification activities for each supplier before using the raw material or ingredient and periodically thereafter (proposed § 507.37(c)(1)). See section XLII.B for a discussion of comments regarding the appropriate verification activities (*i.e.*, onsite audits, sampling and testing, records review, and other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient). See sections XLV.C and XLV.D for a discussion of the proposed exceptions to this requirement to conduct and document verification activities. As discussed in section XLV.E, the final rule provides for an additional circumstance in which an alternative supplier verification activity may be conducted, *i.e.*, when the supplier is a shell egg producer that has fewer than 3,000 laying hens.

*B. Requirement for an Onsite Audit as a Verification Activity When a Hazard Has a Reasonable Probability of Resulting in Serious Adverse Health Consequences or Death to Humans or Animals (Final § 507.130(b))*

We proposed that when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. We also proposed that this requirement does not

apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (Proposed § 507.37(c)(2)).

(Comment 454) Some comments support the provision for audits when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. Some of these comments state that audits should be the default verification activity in order to eliminate facilities choosing the lowest cost option regardless of whether it was best for food safety. Other comments state that audits would be the best option for facilities that cannot visit each supplier annually and that onsite inspection can identify problems in ways that paperwork reviews cannot.

However, other comments oppose this requirement. Some of these comments state that facilities should have flexibility in choosing verification activities, regardless of whether or not the hazards could result in serious adverse health consequences or death to humans or animals and express concern that this requirement does not allow the necessary flexibility for a facility to tailor an effective supplier program based upon risk. Other comments express concern that the provision sets a precedent that annual audits are the preferred or most effective verification measure and that other verification activities often can help paint a more accurate picture of a supplier over time. Other comments express concern that audits only give a “snapshot” of a supplier’s performance at a given time and ask that we not overemphasize audits.

(Response 454) We are retaining this provision as proposed. As we indicated in the Appendix of our 2013 proposed preventive controls rule, an increasing number of establishments are requiring,

as a condition of doing business, that their suppliers become certified to food safety management schemes that involve third-party audits (78 FR 64736 at 64836 through 64837). We agree that onsite audits can identify problems in ways that paperwork reviews cannot. Because an audit involves more than simply observing the facility producing an animal food product, we believe it is more than just a “snapshot” of the supplier’s programs. As discussed in Response 440, onsite audits can include observations, records review and employee interviews.

The requirement to conduct an annual audit in specified circumstances is risk-based because the specified circumstances are limited to situations where there is a reasonable probability that exposure to the hazard in the raw material or other ingredient will result in serious adverse health consequences or death to humans or animals. The food safety controls applied by suppliers of such raw materials or other ingredients are more important than for other types of hazards because of the serious adverse health consequences that can occur if the hazards are not controlled. Annual audits are required of certification schemes that are benchmarked to the Global Food Safety Initiative Guidance Document for GFSI recognition (Ref. 58). We disagree that this requirement does not provide flexibility in choosing verification activities; in recognition that other verification activities can help paint a more accurate picture of a supplier over time, we have provided for alternative verification activities or audit frequencies if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (see § 507.130(b)(2)).

(Comment 455) Some comments ask us to define those products that may trigger the requirement for an audit, especially with respect to farms. These comments question how to assess whether a hazard could result in serious adverse health consequences or death to humans or animals.

(Response 455) We decline this request. Any list of such products would be extensive and it is unlikely we could capture all the circumstances in which this could apply. Hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death are those for which a recall of a violative product posing such a hazard is designated as “Class 1” under 21 CFR 7.3(m)(1). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans or animals include pathogens or their toxins in animal food. Animal food containing a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals are considered reportable foods; examples of foods FDA has considered to present a reasonable probability of serious adverse health consequences or death can be found in our Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Refs. 19 and 20).

(Comment 456) Some comments ask us to clarify the role of third-party audits and the Good Agricultural Practice (GAP) program and ask us to allow GAPs to be a voluntary mechanism to satisfy buyer demands for food safety certification.

(Response 456) Although the rule would not require a receiving facility to hire a third party to conduct an audit, onsite audits can include third-party audits. There are likely to be benefits for suppliers having a third-party audit, because the same audit may be acceptable to multiple receiving facilities as an appropriate supplier verification activity. For farms, GAPs audits may be viewed as an appropriate supplier verification activity. GAPs audits and other third-party audits would need to comply with the requirements of this rule applicable to onsite audits (see § 507.135).

(Comment 457) Some comments assert that we should delete this provision entirely, stating that this requirement for an audit is “outside the scope of FSMA.”

(Response 457) We disagree that a requirement for an audit is “outside the scope of FSMA.” See the discussion in Response 440 regarding the provision in section 419(c)(1)(E) of the FD&C Act that the regulation issuing standards for the safety of produce “not require a business to hire a consultant or other third party to identify, implement, certify compliance with the procedures, processes and practices” and the provision in section 418(n)(3)(D) of the FD&C Act that the preventive controls regulation “not require a facility to hire a consultant or other third party to identify, implement, certify or audit preventive controls.” As noted in that response, a facility is not required to hire a third party to conduct an audit.

(Comment 458) Some comments support the flexibility to not conduct an annual onsite audit if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Other comments question how a facility would prove that alternative measures are equally effective as an annual audit, when it is not known how effective an annual audit is. Other comments assert that the provision is meaningless because a farm or facility would not take the legal risk of verifying it has received “adequate assurance,” because this would be subject to an FDA inspector’s interpretation.

(Response 458) This provision requires a facility to use a verification activity that provides adequate assurance that a hazard is controlled, not to determine how effective an audit is and assess whether alternative measures are equally effective.

As an example of using an alternative approach to an annual onsite audit, consider the situation in which a receiving facility is part of a large corporation, is making a pet food, and obtains meat and bone meal from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as the receiving facility. The receiving facility could determine that the food safety requirements established by the parent company and applied at the subsidiary provide the needed assurance that *Salmonella* in meat and bone meal is adequately controlled. The facility could support its decision by documenting this determination, including the procedures in effect at the supplier and the activities used by the corporation to verify that the subsidiary operates in accordance with corporate food safety policies and practices to

ensure that hazards are adequately controlled.

We disagree that the provision is meaningless because a farm or facility would see a legal risk in using an alternative to annual onsite audits as a supplier verification activity. First, a farm would be a supplier and would not be the entity that would determine whether an onsite audit or some other supplier verification activity is appropriate. As established in § 507.115, determining the appropriate supplier verification activity would be the responsibility of a receiving facility, and although appropriate supplier verification activities could be determined by another entity in the receiving facility’s supply chain as a service, the supplier verification activities could not be determined by the supplier itself. Second, although there is always a potential for differences in interpretation between an FDA inspector and an inspected firm, we are establishing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance. For example, FDA intends to deploy specialized investigators, backed up by technical experts, to assess the soundness and performance of a facility’s food safety system (Ref. 10). In addition, a central element of FDA’s strategy to gain industry compliance is to help make available to farmers, food processors, and importers, especially small businesses, the education and technical assistance they need to understand and implement FSMA’s new prevention-oriented standards (Ref. 5). The new inspection paradigm and the assistance and training for industry should help minimize different interpretations between industry and regulators.

(Comment 459) Some comments ask us to require facilities to notify us when they determine that an alternative to an audit is an appropriate supplier verification activity and be able to justify and document how an alternative verification activity provides the same level of assurance as an onsite audit.

(Response 459) We decline this request. We will assess a facility’s supplier verification activities during a facility inspection, including the documentation that an alternative verification activity provides the same level of assurance as an onsite audit.

(Comment 460) Some comments ask us to specify the type of documentation required for our investigators to determine when the activities are “in

compliance with the law and sufficient to protect public health.”

(Response 460) We decline this request. The facility’s approach to the determination, and the applicable documentation required to support that determination, would depend on the circumstances. For example, in Response 458, we discuss a possible approach in a situation in which a receiving facility is part of a corporation and obtains an ingredient from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as the receiving facility. Another situation could be when a receiving facility has many years of experience with the same supplier, but the approach and documentation in that situation likely would be different from an approach and documentation used when the supplier and the receiving facility are part of the same corporation.

(Comment 461) Some comments ask that we not limit the determination for a supplier verification activity other than an onsite audit to a determination by the receiving facility. These comments explain that the corporate parent of a facility can be the entity that makes this determination. These comments suggest that we can account for the role of the corporation by specifying that a facility documents “the determination” (rather than “its” determination).

(Response 461) We have agreed that the corporate parent of a facility can be active in developing and implementing the facility’s food safety plan (see section XXIV.A). However, the specific suggestion of these comments is not necessary to achieve the outcome requested by the comments because of editorial changes we made to provide for entities other than the receiving facility to determine and conduct the appropriate supplier verification activities.

### *C. Alternative Verification Activity When the Supplier Is a Qualified Facility (Final § 507.130(c))*

We proposed that if a supplier is a qualified facility the receiving facility need not comply with the specified verification requirements if the receiving facility: (1) Documents, at the end of each calendar year, that the supplier is a qualified facility and (2) obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. The written assurance must include a brief

description of the processes and procedures that the supplier is following to ensure the safety of the animal food.

This rule has several provisions that require written assurances. We have established specific elements that each of these written assurances must include, *i.e.*, the effective date; printed names and signatures of authorized officials; and the applicable assurance (see § 507.215).

We have revised the provision to clarify that the receiving facility must have written assurance that a facility is a qualified facility: (1) Before first approving the supplier for an applicable calendar year and (2) by December 31 of each calendar year (rather than “at the end of the calendar year”) and that the written assurance is regarding the status of the qualified facility for the following calendar year. By specifying “by December 31,” a receiving facility can work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify the receiving facility about its status. See also Responses 76, 139, 140, the requirements in § 507.7(a) for an annual determination of the status of a facility as a qualified facility, and the requirements in § 507.7(d) that apply when the status of a facility changes from “qualified facility” to “not a qualified facility.” A receiving facility and its suppliers have flexibility to approach the potential for the status of a facility to shift between “qualified facility” and “not a qualified facility” (or vice versa) in a way that works best for their specific business relationship.

As discussed in section XLII.D, we have revised the requirements for considering supplier performance to provide that the receiving facility may, when applicable, consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier’s compliance with those laws and regulations, rather than consider applicable FDA food safety regulations and information relevant to the supplier’s compliance with applicable FDA food safety regulations. We have made a conforming change to the alternative verification activities for a qualified facility (see the regulatory text of § 507.130(c)(2)).

(Comment 462) Some comments support this alternative supplier verification activity because it provides flexibility. Other comments ask us to revise the provision so that it only requires that the supplier document its

status as a qualified facility. Still other comments ask us to remove all provisions on qualified facilities because they view these provisions as effectively adding a second layer of regulations on produce farms, and claim this is not authorized by FSMA. Other comments ask us to delete the requirement that the written assurance include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

(Response 462) We have revised the provisions for an alternative verification activity for a qualified facility to better align with the responsibilities of a qualified facility to submit an attestation to FDA about its food safety practices (§ 507.7(a)(2)(i)) or its compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries (§ 507.7(a)(2)(ii)) (see the regulatory text of § 507.130(c)). Importantly, a qualified facility is still subject to CGMPs and the FD&C Act, and, if the qualified facility is a supplier controlling a hazard, it is reasonable for a receiving facility to expect the qualified facility to provide to the receiving facility, an assurance that reflects an attestation the facility has made to FDA. As modified, one possibility is for a qualified facility to provide a receiving facility with a brief description of the preventive controls it is implementing to control the applicable hazard, consistent with an attestation of its food safety practices in accordance with § 507.7(a)(2)(i). For example, the qualified facility could state that its manufacturing processes include a lethality step for microbial pathogens of concern. As required by § 507.7(f), a qualified facility that submits an attestation to FDA about its animal food safety practices would have documentation of those practices to support its attestation to FDA and, thus, would have documentation to support its written assurance to the receiving facility. Although a qualified facility that submits an attestation to FDA about its food safety practices also would have documentation of monitoring the performance of the preventive controls to ensure that such controls are effective as required by § 507.7(a)(2)(i), we are not requiring the qualified facility to describe its monitoring of the performance of preventive controls to ensure that they are effective. Alternatively, a qualified facility could provide a receiving facility with a statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal

food safety law, including relevant laws and regulations of foreign countries.

We disagree that the alternative verification activity for produce farms would add a second layer of regulations on produce farms and are retaining this provision.

(Comment 463) Some comments ask us to remove the requirement that the written assurance be obtained at least every 2 years. Other comments ask us to revise the purpose of the written assurance from “the raw material or ingredient is not adulterated” to “the receiving facility’s use of the raw material or ingredient will not cause the finished food to be adulterated.”

(Response 463) We decline these requests. A supplier verification activity needs to consider supplier performance on an ongoing basis. Procedures and practices evolve over time, and it is appropriate for a receiving facility that is obtaining written assurance from a supplier as an alternative verification activity to be aware of both procedures and practices that have changed, as well as procedures and practices that have stayed the same. The specified timeframe for updating the written assurance, *i.e.*, at least every two years, is reasonable.

A supplier can only provide assurance about raw materials and other ingredients that it supplies to the receiving facility, not about the animal food product that the receiving facility will produce using the supplier’s raw material or other ingredients.

*D. Alternative Verification Activity When the Supplier Is a Produce Farm That Is Not a “Covered Farm” for the Purposes of the Future Produce Safety Rule (Final § 507.130(d))*

We proposed that if a supplier is a farm that is not subject to the requirements that we have proposed to be established in the produce safety rule in accordance with proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with the verification requirements if the receiving facility: (1) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to the produce safety rule and (2) obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. See also § 507.215, which establishes specific elements that this written assurance must include, *i.e.*, the

effective date; printed names and signatures of authorized officials; and the applicable assurance.

Produce farms that are not “covered farms” under § 112.4 of the forthcoming produce safety rule have less than \$25,000 in annual sales averaged over the previous 3-year period, or satisfy the requirements for a qualified exemption in § 112.5 and associated modified requirements in § 112.6 based on average monetary value of all food sold (less than \$500,000) and direct farm marketing (during the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual monetary value of the food sold to all other buyers). In the 2014 supplemental notice, we erroneously referred to these farms as farms “not subject to the requirements established in part 112.” While produce farms that make less than \$25,000 are not subject to the requirements in part 112, produce farms that satisfy the requirements for a qualified exemption are not subject to the full requirements of part 112, but they do have certain modified requirements that they must meet, as described in § 112.6. We have corrected the description of these farms in § 507.130(d).

We have revised the provision to clarify that the receiving facility must have documentation that the raw material or other ingredient provided by the supplier is not subject to part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5: (1) Before first approving the supplier for an applicable calendar year and (2) by December 31 of each calendar year (rather than “at the end of the calendar year”) and that the documentation is regarding the status of supplier for the following calendar year. By specifying “by December 31,” a receiving facility can work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify the receiving facility about its status. See also the discussion in section XLV.C regarding a similar revision we made when the supplier is a qualified facility.

(Comment 464) Some comments support the proposed alternative supplier verification activity. Other comments support applying the proposed alternative supplier verification activity more broadly, *i.e.*, to any farm that will not be subject to part 112 (*e.g.*, a farm that grows wheat), stating that both small and large non-produce farms should have the same option as farms that are exempted under § 112.4. Some comments ask us to revise the alternative verification requirements

to apply to raw materials from farms that do not grow and harvest “produce” as we proposed to define it in § 112.3(c) so that the alternative verification requirements would apply to grain. Some comments assert that it is not possible to receive “written assurances” of compliance from growers of grain because there is no safety standard for grain growers, and that any such documents would be essentially meaningless.

Some comments ask us to revise the requirement to obtain written assurance so that it does not apply to “food not subject to the requirements of part 112 of this chapter pursuant to part 112.2.” Other comments assert that a documentation requirement for commodities that will be exempt from the produce safety rule would increase recordkeeping burdens without added benefit because produce that will be exempt from the produce safety rule is low risk.

Some comments assert that farms should not have to provide written assurances because the requirement is ambiguous. These comments assert that exempt farmers are small-scale producers who are subject primarily to state and local laws and this provision would require them to provide written assurances that they are complying with unspecified Federal regulations. The comments claim that, without seeking legal counsel, many exempt farmers would be unable to provide such assurances, limiting the ability of these farmers to market their products to non-exempt facilities (the overwhelming majority of the food market).

(Response 464) We have revised the to specify that the written assurance from the farm must state that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). Any business that introduces food into interstate commerce is subject the prohibited acts provisions in section 301 of the FD&C Act, and is accountable if it produces food that is adulterated.

As discussed in Response 284, new § 507.36(a) allows a manufacturer/processor to not implement a preventive control if it determines and documents that the type of animal food (*e.g.*, soybeans) could not be consumed without application of the appropriate control. We believe most receiving facilities will take advantage of this provision, and not establish supply-chain controls under the supply-chain



program in subpart E for some specific RACs.

This alternative supplier verification activity is intended to minimize the burden on suppliers that are small farms. The amount of food produced by such farms is small, and the exposure to food from such farms therefore is low. We disagree that a written assurance from such a farm would be meaningless. Any business that distributes food in interstate commerce is subject to the FD&C Act, and must produce food that is in compliance with the FD&C Act, regardless of whether FDA has established a specific regulation governing the production of the food.

(Comment 465) Some comments ask us to delete this alternative supplier verification activity because they see it as a contradiction to the traceability provisions of the Bioterrorism Act and FSMA, because “trace back” is only required for “one step back” or for a single supplier for a particular shipment of food.

(Response 465) The supply-chain program that is being established in this rule is a preventive control for the ongoing production of safe animal food, not a “trace back” provision, established under the Bioterrorism Act, to help address credible threats relating to food that is reasonably believed to be adulterated and to present a threat of serious adverse health consequences or death to humans or animals.

(Comment 466) Some comments ask us to specify 3 options for verification if a supplier is a farm subject to the requirements of part 112: (1) Documentation at the end of each calendar year that the raw material or ingredient provided by the supplier is subject to part 112; (2) written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under the FD&C Act; or (3) evidence that the supplier is certified to a recognized third-party GAP/GHP/GMP/HACCP audit scheme. (We note that we are assuming that “GHP” is an abbreviation for “Good Hygienic Practice.”)

(Response 466) We decline this request. Documenting that a raw material or other ingredient is subject to the produce safety rule has no bearing on whether the farm is complying with that rule to control the hazards. With respect to all farms subject to the requirements of part 112 providing a written assurance, as discussed in Response 464, the amount of food produced by the small farms that could provide written assurance to a receiving

facility is small, and the exposure to food from such farms therefore is low. We disagree that it is appropriate to extend this alternative supplier verification activity to larger farms because such farms provide a larger volume of produce.

A farm that has been subject to an audit that complies with the requirements of this rule can provide the results of the audit; a mere statement that the farm has been certified based on an audit is insufficient.

*E. Alternative Verification Activity When the Supplier Is a Shell Egg Producer That Has Less Than 3,000 Laying Hens (Final § 507.130(e))*

We are establishing an additional alternative supplier verification activity when a supplier is a shell egg producer that is not subject to the requirements of 21 CFR part 118 because it has less than 3,000 laying hens. See the regulatory text of § 507.130(e). The provision is analogous to the alternative supplier verification activity when a supplier is a farm that meets the criteria in § 507.130(d) and would account for a very small amount of eggs in the food supply. See also § 507.215, which establishes specific elements that the required written assurance must include, *i.e.*, the effective date; printed names and signatures of authorized officials; and the applicable assurance.

*F. Independence of Persons Who Conduct Supplier Verification Activities (Final § 507.130(f))*

In the 2014 supplemental notice, we requested comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements.

(Comment 467) Some comments request that requirements to address conflicts of interest should not be implemented or ask that conflict of interest provisions not be written too broadly, and be limited to circumstances where the individual employee carrying out the verification activities has a direct personal financial interest in or financial ties to the supplier (*e.g.*, owns a substantial amount of stock in the supplier or is personally paid directly by the supplier). Comments state that it would not be uncommon for a receiving facility to have a shared financial interest in the supplier (*e.g.*, partial ownership of one by the other or both being owned by the same parent company). Thus, employees that have an indirect financial interest (*e.g.*, owning stock in a supplier because they own stock in

their own company, which in turn owns an interest in the supplier) should not be disqualified from performing verification activities. Comments also indicate that a laboratory analyst performing ingredient testing should not be precluded from testing ingredients from a supplier in which the analyst has a potential conflict of interest, as long as the analyst is not aware of the identity of the supplier at the time the test is performed.

(Response 467) We are establishing a requirement that there must not be any financial conflicts of interests that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity. This does not prohibit employees of a supplier from performing the functions specified in § 507.115 in accordance with § 507.115. For example, this provision would not prohibit an employee of a supplier from conducting sampling and testing so that the supplier could provide the results in documentation provided to the receiving facility. The provisions would not prevent a person who is employed by a receiving facility from having an indirect financial interest in a supplier (*e.g.*, if a company in which the employee owns stock owns an interest in the supplier).

(Comment 468) Comments ask that we not preclude a supplier from hiring an outside party to perform onsite audits, food certifications, or sampling and testing.

(Response 468) We have specified that the requirements do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor (see § 507.115(c)). We also have specified that a supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide the documentation to the receiving facility (see § 507.115(a)(4)). This acknowledges that it is common for suppliers to include Certificates of Analysis for tests conducted on specific lots of product along with the shipment to the receiving facility.

**XLVI. Subpart E: Comments on Onsite Audit**

We proposed requirements that would apply to an onsite audit. Most comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision. In the following sections, we

discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 28.

TABLE 28—REVISIONS TO THE PROPOSED REQUIREMENTS FOR ONSITE AUDITS

Final section designation	Proposed section designation	Description	Revision
507.135(a) .....	507.37(d)(1) .....	An onsite audit of a supplier must be performed by a qualified auditor.	N/A.
507.135(b) .....	507.37(d)(2) .....	An onsite audit must consider applicable FDA regulations.	Clarify that, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.
507.135(c)(1)(i) .....	507.37(e)(1) .....	Substitution of inspection for domestic suppliers.	Broaden the list of applicable inspections to include inspections by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies.
507.135(c)(1)(ii) and 507.135(c)(2) ...	507.37(e)(2) .....	Substitution of inspection for foreign suppliers.	N/A.
507.135(d) .....	N/A .....	Use of a third-party auditor that has been accredited in accordance with regulations that will be established in the forthcoming third-party certification rule.	If the onsite audit is solely conducted to meet the requirements of the animal food preventive controls rule by an audit agent of a certification body that is accredited in accordance with regulations that will be established in part 1, subpart M, the audit is not subject to the requirements in those regulations.

*A. Requirements Applicable to an Onsite Audit (Final § 507.135(a) and (b))*

We proposed that an onsite audit of a supplier must be performed by a qualified auditor. If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit would need to consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited (proposed § 507.37(d)). We have revised "including its implementation" to "and its implementation" to emphasize that implementation of the plan is distinct from the plan itself (e.g., § 507.31(c) establishes the recordkeeping requirement for the food safety "plan," and § 507.55 lists implementation records.)

As discussed in section XLII.D, we have revised the requirements for considering supplier performance to provide that the receiving facility may, when applicable, consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance

with those laws and regulations, rather than consider applicable FDA food safety regulations and information relevant to the supplier's compliance with applicable FDA food safety regulations. We have made a conforming change to the requirements for an onsite audit to clarify that an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States. However, as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food.

(Comment 469) Comments support a requirement that an onsite audit be performed by a qualified auditor, provided that we finalize provisions (in proposed § 507.37(e)) whereby an inspection by certain authorities could substitute for an audit. Some comments ask us to specify that the rule permits the use of audits conducted by private third-party food safety auditing firms.

Other comments ask us to provide a list of recognized private third-party food safety schemes and consider making third-party food safety certification to a recognized audit scheme mandatory for all food operations that grow, pack, hold and manufacture/process food for wholesale markets. Other comments ask us to further specify that FDA will audit all food facilities no less than once every 5 years to verify that private third-party audits are consistent with FDA audits and findings.

(Response 469) See our discussion in section XLVI.B of the final provisions governing substitution of inspection for an audit. We agree that onsite audits may be conducted by third parties, but disagree that it is necessary to specify this in the rule. Nothing in this rule prevents a facility from hiring a third party to conduct audits.

We decline the requests to provide a list of recognized private third-party food safety schemes or to make third-party food safety certification to a recognized audit scheme mandatory for all food operations that grow, pack, hold and manufacture/process animal food for wholesale markets. The rule provides flexibility regarding use of third-party auditors and the information is easily obtained from other sources.

Private third-party food safety audit schemes are a function of the private sector, not a function of the Federal government. Likewise, we decline the request to specify that FDA will “audit” all food facilities no less than once every 5 years to verify that private third-party audits are consistent with FDA audits and findings. We will inspect food facilities for compliance with this rule, not to verify the findings of a third-party audit, with a frequency consistent with our responsibilities under the FD&C Act.

(Comment 470) Some comments express concern about the multiple audits that facilities are subject to each year and ask us to encourage those subject to the rule to accept an audit performed by any of the “bona fide authorities” where it is warranted. Other comments note that food manufacturers conduct their own audits and have developed extensive expertise in doing so, and oppose any supplier verification requirement that would affect those audits. Other comments ask us to allow audits to industry standards (such as GFSI or ISO) to satisfy supplier verification requirements to avoid adding a new audit to audits currently being conducted. Some comments assert that audits to industry standards (such as GFSI or ISO) and other similarly accredited audits should be considered equivalent to onsite audits. Some comments express concern that requiring a new audit in addition to audits already being conducted could lead to auditor shortages and unnecessary additional costs.

(Response 470) We expect that a facility will adopt an approach to audits that works best for the facility and minimizes the number of audits conducted for the same facility. An employee of a receiving facility may perform an audit, provided that the employee satisfies the criteria established in the rule for qualified auditors. Under § 507.3 and § 507.53, a qualified auditor is a qualified individual (as defined in § 507.3) and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. For additional information, see Response 700 in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**, in which we discuss auditor qualifications with respect to the GFSI’s auditor competency model.

(Comment 471) Some comments ask us to delete the proposed requirement for a review of the supplier’s written plan as part of an audit because review of the supplier’s food safety plan should

be part of an overall supplier verification program when the supplier is controlling a hazard that could cause serious adverse health consequences or death, but should not be tied to an audit. These comments state that receiving facilities may choose to use an unannounced audit program where the auditor spends time focusing on the actual conditions on the production floor, with a review of the supplier’s food safety plan being done as a separate verification activity.

(Response 471) We decline this request. We agree that review of an applicable food safety plan should be part of an overall supplier verification program and that the review of the food safety plan may be conducted separately from the observation of actual conditions on the production floor, provided that both are conducted within the annual timeframe. However, we believe it important that the audit address whether the food safety plan is being implemented as designed and other comments to this rule support that view. For example, as discussed in Comment 493 regarding our inspection of a food facility, some comments assert that our access to company records must be conducted onsite in the course of an authorized inspection so that we may understand the full context of what the records show. Thus, the onsite observations and the food safety plan review cannot be entirely separated, as the comment seems to suggest.

We note that the requirement to include a review of the supplier’s food safety plan only applies when the supplier has a food safety plan. For example, we did not propose a requirement for a farm that would be subject to the forthcoming produce safety rule to have a food safety plan.

#### *B. Substitution of Inspection by FDA or an Officially Recognized or Equivalent Food Safety Authority*

We proposed that instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, the food that is the subject of the

onsite audit would need to be within the scope of the official recognition or equivalence determination, and the foreign supplier would need to be in, and under the regulatory oversight of, such country (proposed § 507.37(e)).

As of August 30 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority for animal food. A signed systems recognition agreement for human food does not apply to animal food.

(Comment 472) Some comments ask us to allow State or local inspection reports, as well as FDA inspection reports, to substitute for an onsite audit for small and very small facilities. Other comments ask us to create a “safe harbor” provision in which a supplier providing a copy of permits obtained from the most recent inspection done by Federal, State, or local health authorities satisfies the supplier verification requirement; if there are no permits, review of relevant records and/or sampling of raw material based on scale of production should be adequate.

(Response 472) We have revised the regulatory text to provide for an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as USDA), or by representatives of State, local, tribal, or territorial agencies. We are specifying that the inspection must be “appropriate” and be conducted for compliance “with applicable FDA food safety regulations” to make clear that the inspection must be sufficiently relevant to an onsite audit to credibly substitute for an onsite audit. For example, inspection by USDA to determine whether a farm satisfies the requirements of the produce safety rule could constitute an appropriate inspection that could substitute for an audit, but an inspection by USDA to determine whether a farm satisfies the requirements of the National Organic Program could not.

We have not provided for substitution of a “permit obtained from the most recent inspection” for an onsite audit. We do not see how a “permit” could shed light on whether a business is complying with specific applicable FDA regulations. We have provided for an alternative verification activity to the annual onsite audit (such as a review of relevant records and/or sampling of raw material) with a written justification (see § 507.130(b)). The rule would not preclude an appropriate review of records, or sampling and testing of raw

materials, by other Federal Agencies, or by representatives of State, local, tribal, or territorial agencies, provided that the receiving facility satisfies the requirements for an adequate written justification.

(Comment 473) Some comments ask us to clarify what we mean by “food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.” These comments also ask whether a specific country qualifies and whether HACCP certificates issued by a specific foreign government agency would replace an onsite audit.

(Response 473) A country whose food safety system FDA has officially recognized as “comparable” to that of the United States would be one for which there is a signed systems recognition arrangement or other agreement between FDA and the country establishing official recognition of the foreign food safety system. Information on FDA systems recognition can be found on the FDA Web site (Ref. 59). As of August 30 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food. We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit, but a receiving facility could consider whether such a certificate could be part of its justification for conducting another supplier verification activity in lieu of an annual onsite audit, or for conducting an audit on a less frequent basis than annually.

(Comment 474) Some comments ask us to clarify that the applicable standards will be those applied by the food safety authority of a country with a food safety system recognized as comparable or equivalent rather than having to achieve compliance with the applicable U.S. FDA food safety regulations.

(Response 474) The applicable standards will be those applied by the food safety authority of a country with a food safety system recognized as comparable or equivalent to that of the United States. As of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems

recognition agreement relates solely to human food and does not apply to animal food.

#### *C. Onsite Audit by a Third-Party Auditor Accredited for the Purposes of Section 808 of the FD&C Act*

We have proposed to establish regulations (in part 1, subpart M) to provide for accreditation of third-party auditors/certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications (78 FR 45782, July 29, 2013). The purpose of the proposed third-party certification rule is to help us ensure the competence and independence of third-party auditors/certification bodies who conduct foreign food safety audits and to help ensure the reliability of food and facility certifications issued by third-party auditors/certification bodies that we will use in making certain decisions relating to imported animal food, such as animal food certifications required by FDA as a condition of granting admission to an animal food determined to pose a safety risk.

(Comment 475) Comments support use of third-party auditors, but emphasize that such auditors need not be accredited under the requirements to be established under our forthcoming third-party certification rule.

(Response 475) We agree that a third-party auditor who conducts an audit as a supplier verification activity to satisfy the requirements of this rule need not be accredited under our forthcoming third-party certification rule. In addition, we see no reason that any requirements of our forthcoming third-party certification rule should apply to an audit merely because it was conducted by a person who had been accredited under that rule. To make this clear, we have added a provision to specify that if an onsite audit is solely conducted to meet the requirements of this rule by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, the audit is not subject to the requirements in those regulations. See § 507.135(d). Because § 507.135(d) refers to provisions in a future third-party certification rule, we will publish a document in the **Federal Register** announcing the effective date of § 507.135(d) when we finalize the third-party certification rule.

#### **XLVII. Subpart E: Comments on Records Documenting the Supply-Chain Program (Final § 507.175)**

We proposed to require documentation of verification activities

in records, including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier’s relevant food safety records. We also proposed that the receiving facility must review such records in accordance with the requirements applicable to review of records as a verification activity (*i.e.*, in accordance with § 507.49(a)(4)).

We did not receive comments on the documentation requirements associated with a written supplier program, determination of appropriate supplier verification activities, review of records, supplier verification activities other than an annual onsite audit when the hazard being controlled by the supplier is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, alternative supplier verification activity when the supplier is a qualified facility, substitution of inspection for an audit, or supplier nonconformance (proposed § 507.37(g)(1), (2), (7), (9), (10), (12), and (13), respectively). We are finalizing these documentation requirements with editorial and conforming changes associated with the final requirements of the supply-chain program.

The supply-chain program includes two provisions that are explicit requirements of the final animal food preventive controls rule, but had been implicit requirements of the 2014 supplemental notice. The first of these provisions is the explicit requirement that the receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients from those suppliers (see § 507.120(a)). The second of these requirements is that written procedures for receiving raw materials and other ingredients must be established and followed (see § 507.120(b)(1)). We are including in § 507.175 the documentation associated with these requirements (see § 507.175(c)(3) and (4)).

The supply-chain program includes four provisions that were not in the 2014 supplemental notice: (1) A receiving facility that is an importer can comply with the foreign supplier verification requirements in the FSVP rule rather than conduct supplier verification activities for that raw material or other ingredient under this rule (§ 507.105(a)(2)); (2) a receiving facility may use an alternative verification activity for a supplier that is

a shell egg producer that is not subject to the requirements established in part 118 because it has less than 3,000 laying hens (§ 507.130(e)); (3) when applicable, a receiving facility must verify a supply-chain-applied control applied by an entity other than the receiving facility's supplier (§ 507.105(c)); and (4) entities other than the receiving facility may

determine, conduct, and document certain specified supplier verification activities, provided that the receiving facility reviews and assesses the other entity's applicable documentation, and documents its review and assessment (§ 507.115). We are establishing the associated documentation requirements

in § 507.175(c)(2), (14), (17), and (18), respectively.

In the following sections, we discuss comments on the proposed records for the supplier program. After considering these comments, we have revised the proposed requirements as shown in table 29.

TABLE 29—REVISIONS TO THE PROPOSED REQUIREMENTS FOR RECORDS FOR THE SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Did we receive comments regarding the proposed requirement?	Did we revise the documentation requirement other than editorial and conforming changes associated with the final requirements for the supply-chain program?
507.175(a) .....	N/A .....	The records documenting the supply-chain program are subject to the requirements of subpart F.	N/A .....	Consequential change associated with establishing the requirements for a supplier in subpart E rather than subpart C.
507.175(b) .....	507.37(g) .....	The receiving facility must review the records in accordance with § 507.49(a)(4).	Yes .....	No.
507.175(c)(1) .....	507.37(g)(1) .....	The written supply-chain program .....	No .....	N/A.
507.36(b)(2) .....	507.37(g)(3) .....	Annual written assurance from a receiving facility's customer.	Yes .....	Shifted to be in provisions outside the framework of the supply-chain program in subpart E.
507.175(c)(2) .....	N/A .....	Documentation obtained from an importer	N/A .....	N/A.
507.175(c)(3) .....	507.37(g)(1) .....	Documentation of the approval of a supplier.	No .....	No.
507.175(c)(4) .....	507.37(g)(1) .....	Written procedures for receiving raw materials and other ingredients.	No .....	No.
507.175(c)(5) .....	507.37(g)(4) .....	Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients.	Yes .....	Yes.
507.175(c)(6) .....	507.37(g)(2) .....	Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients.	No .....	No.
507.175(c)(7) .....	507.37(g)(5) .....	Documentation of the conduct of an onsite audit.	Yes .....	Added a requirement for the documentation to include the name of the supplier subject to the onsite audit.
507.175(c)(8) .....	507.37(g)(6) .....	Documentation of sampling and testing conducted as a supplier verification activity.	Yes .....	Specify that the documentation include the date(s) on which the test(s) were conducted and the date of the report.
507.175(c)(9) .....	507.37(g)(7) .....	Documentation of the review of the supplier's relevant food safety records.	No .....	Specify that the documentation must include the general nature of the records reviewed and conclusions of the review.
507.175(c)(10) .....	507.37(g)(8) .....	Documentation of other appropriate supplier verification activities.	Yes .....	Specify that the other appropriate supplier verification activities are based on supplier performance and the risk associated with the raw material or other ingredient.
507.175(c)(11) .....	507.37(g)(9) .....	Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.	No .....	No.

TABLE 29—REVISIONS TO THE PROPOSED REQUIREMENTS FOR RECORDS FOR THE SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Did we receive comments regarding the proposed requirement?	Did we revise the documentation requirement other than editorial and conforming changes associated with the final requirements for the supply-chain program?
507.175(c)(12) .....	507.37(g)(10) .....	Documentation of an alternative verification activity for a supplier that is a qualified facility.	No .....	Provide for documentation, when applicable, of a written assurance that the supplier is producing the raw material or other ingredient in compliance with relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.
507.175(c)(13) .....	507.37(g)(11) .....	Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient that would not be a covered farm subject to the forthcoming produce safety rule.	Yes .....	No.
507.175(c)(14) .....	N/A .....	Documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 because it has less than 3,000 laying hens.	N/A .....	N/A.
507.175(c)(15) .....	507.37(g)(12) .....	The written results of an appropriate inspection of the supplier by FDA, by representatives of other Federal Agencies (such as USDA), or by representatives from State, local, tribal, or territorial Agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit.	No .....	No.
507.175(c)(16) .....	507.37(g)(13) .....	Documentation of actions taken with respect to supplier non-conformance.	No .....	No.
507.175(c)(17) .....	N/A .....	Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier.	N/A .....	N/A.
507.175(c)(18) .....	N/A .....	When applicable, documentation of the receiving facility's review and assessment of documentation of a supplier verification activity provided by a supplier or by an entity other than the receiving facility.	N/A .....	N/A.

*A. Applicability of the Recordkeeping Requirements of Subpart F*

We have added new § 507.175(a) to specify that the records documenting the supply-chain program in subpart E are subject to the requirements of subpart F. Under the 2014 supplemental notice, the documentation requirements would have been in subpart C, and the applicability of subpart F was specified in § 507.55 in subpart C. The new provision specifying the applicability of subpart F to the records associated with the supply-chain program is a consequential change associated with establishing the requirements for a supply-chain program in subpart E, rather than in subpart C.

*B. Requirement To Review Records of the Supply-Chain Program (Final § 507.175(b))*

We proposed that a receiving facility must review records documenting the supplier program in accordance with the requirements applicable to review of records as a verification activity (*i.e.*, in accordance with § 507.49(a)(4)). (Proposed § 507.37(g).)

(Comment 476) Some comments ask us to provide consideration for records associated with the supplier program to be administered and maintained at corporate headquarters rather than at individual facilities, because this is common industry practice.

(Response 476) We are aware that certain programs are administered, and records are maintained, at corporate headquarters rather than at individual

facilities. The rule provides that offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review and electronic records are considered to be onsite if they are accessible from an onsite location (see § 507.208(c)). We expect that the facility would be able to access information and records relevant to the supply-chain program within 24 hours (*e.g.*, electronically) when the records are maintained at corporate headquarters. As necessary and appropriate, we intend to work with facilities on a case-by-case basis to determine the best way to review records associated with the supply-chain program when the supply-chain program is administered at the corporate level.

(Comment 477) Some comments ask us to clarify in the regulatory text that the required records are “as appropriate to the supplier program.”

(Response 477) We have revised the regulatory text to specify that the required records are “as applicable to its supply-chain program” (see § 507.175(c)).

*C. Documentation Demonstrating Use of the Written Procedures for Receiving Raw Materials and Other Ingredients (Final § 507.175(c)(5))*

We proposed to require documentation demonstrating that products are received only from approved suppliers (proposed § 507.37(g)(4)).

(Comment 478) Some comments support the proposed requirement with no changes. Other comments ask us to specify “raw materials and ingredients” rather than “products” in the regulatory text.

(Response 478) We have revised the regulatory text to specify “raw materials and other ingredients” with associated conforming changes.

*D. Documentation of the Conduct of an Onsite Audit (Final § 507.175(c)(7))*

We proposed to require documentation of an onsite audit. This documentation must include: (1) Documentation of audit procedures; (2) the dates the audit was conducted; (3) the conclusions of the audit; (4) corrective actions taken in response to significant deficiencies identified during the audit; and (5) documentation that the audit was conducted by a qualified auditor. For clarity, we have revised the regulatory text to specify documentation of the “conduct” of an audit and added a requirement for the documentation to include the name of the supplier subject to the onsite audit.

(Comment 479) Some comments ask that we add “if applicable” to the requirement to maintain documentation of an audit because an audit may not be necessary if a receiving facility has documented that other verification activities are appropriate.

(Response 479) We decline this request. The documentation is always necessary if an audit is used as a verification activity. The provision is about maintaining documentation when an audit is conducted, not about when an audit needs to be conducted.

(Comment 480) Some comments ask us to maintain the confidentiality of audit reports and exempt such audit reports from disclosure under the Freedom of Information Act (FOIA).

(Response 480) These comments are similar to comments we received related

to disclosure of other records required by this part (see Comments 490 and 491). We would establish the status of supply-chain program records, such as audit reports, as available for, or protected from, public disclosure on a case-by-case basis. As discussed in Response 491, we primarily intend to copy such records when we conduct an inspection for cause or if the preliminary assessment by our investigator during a routine inspection is that regulatory followup may be appropriate (e.g., if the report indicates that a significant food safety problem was noted). See Response 491 for a discussion of situations in which records would, or would not, be protected from disclosure.

(Comment 481) Some comments express concern about maintaining documentation of the conclusions of an audit and documentation of corrective actions taken in response to significant deficiencies identified during the audit. These comments explain that FDA’s access to such documentation during inspection might discourage suppliers from allowing unannounced audits. These comments ask us to delete these proposed requirements. If the requirement regarding documentation of corrective actions remains in the final rule, these comments ask us to limit such documentation to situations in which the identified deficiencies posed a risk to public health.

(Response 481) We are retaining these documentation requirements as proposed. These comments appear to be suggesting that documentation requirements be established based on whether a business entity would want us to see information during inspection rather than on the utility and value of the documentation. We expect that receiving facilities, in general, maintain documentation of the conclusions of audits that they have conducted or arranged to have conducted. A receiving facility must approve all of its suppliers, and documentation of corrective actions taken in response to significant deficiencies identified during an audit has value to a receiving facility in determining whether to approve a supplier before first receiving any raw materials or other ingredients and then on an ongoing basis.

The rule does not require that onsite audits be unannounced, although we acknowledge that some receiving facilities may see value in unannounced audits. We decline the request to require a receiving facility to maintain documentation of corrective actions only if the identified deficiencies posed a risk to public (human and animal) health. The purpose of an audit, like the

purpose of all the supplier verification activities, is broader than identifying deficiencies that pose a risk to public (human and animal) health and includes verifying whether a raw material or other ingredient is adulterated under section 402 of the FD&C Act and is produced in compliance with applicable FDA food safety regulations (see § 507.110(c)). If, for example, a supplier’s facility has filthy conditions or the raw materials and other ingredients it supplies are contaminated with filth, a receiving facility may find it inappropriate to approve that supplier. Even though filth often does not pose a risk to public (human and animal) health, a food may be deemed to be adulterated under section 402(a)(4) of the FD&C Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

*E. Documentation of Sampling and Testing (Final § 507.175(c)(8))*

We proposed to require records of sampling and testing. These records must include: (1) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested; (2) identification of the test(s) conducted, including the analytical method(s) used; (3) the date(s) on which the test(s) were conducted and the date of the report; (4) the results of the testing; (5) corrective actions taken in response to detection of hazards; and (6) information identifying the laboratory conducting the testing.

(Comment 482) Some comments ask us to not apply the requirement to maintain records related to sampling and testing to the receipt of RACs because sampling and testing of RACs is neither common nor effective for detecting biological or chemical hazards, especially in raw, intact produce.

(Response 482) We decline this request. These comments appear to suggest that documentation requirements be established based on the frequency and utility of sampling and testing a particular commodity rather than on a determination by a receiving facility that sampling and testing is an appropriate supplier verification activity for a particular supplier. We disagree with such a suggestion. A receiving facility that has determined that sampling and testing is an appropriate supplier verification activity needs to maintain records of those results as it would for any other supplier verification activity. To the extent that these comments are concerned that the supply-chain

program requires sampling and testing of RACs, we emphasize that this is not the case. See also Response 350 for a discussion of the usefulness of sampling and testing as a verification measure for RACs.

(Comment 483) Some comments ask us to allow documentation of testing to include the date the test results were reported as an alternative to the date(s) on which the test(s) were conducted.

(Response 483) We have revised the provision to require “The date(s) on which the test(s) were conducted and the date of the report.” We agree that the date on which the test results are reported can be important, but it should not be a replacement for the date of the test.

(Comment 484) Some comments ask us to add “if necessary” to the end of the proposed requirement for documentation of corrective actions taken in response to detection of hazards.

(Response 484) We decline this request. The documentation is always necessary if corrective actions are taken. The provision is about maintaining documentation when corrective actions are taken, not about the fact that corrective actions may not always be needed.

*F. Documentation of Other Appropriate Supplier Verification Activity (Final § 507.175(c)(10))*

We proposed to require records of other appropriate verification activities based on the risk associated with the ingredient. For clarity and consistency, we have revised the proposed requirement to specify “documentation” of the other appropriate supplier verification activity rather than “records” of the activity. As a conforming change associated with using the term “supplier performance,” rather than “risk of supplier,” when discussing factors associated with suppliers, the final requirement specifies that the other appropriate supplier verification activities are based on the supplier performance and the risk associated with the raw material or other ingredient.

(Comment 485) Some comments ask us to also specify that an “other” appropriate supplier verification

activity be based on the risk associated with raw materials and suppliers.

(Response 485) We have revised the regulatory text to specify “Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient.” The revised regulatory text of the documentation tracks the regulatory text of this “other” appropriate supplier verification activity (see § 507.110(b)(4)). As discussed in Response 444, “supplier performance” is more appropriate than “risk associated with the supplier.”

*G. Documentation of an Alternative Verification Activity for a Supplier That Is a Farm That Is Not a “Covered Farm” for the Purposes of the Future Produce Safety Rule (Final § 507.175(c)(13))*

We proposed to require documentation of an alternative verification activity for a supplier that is a farm that is not a “covered farm” for the purposes of the future produce safety rule, including: (1) The documentation that the raw material or ingredient provided by the supplier is not subject to the produce safety rule and (2) the written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. We have revised the documentation to reflect the final requirements of § 507.130(d)—*i.e.*, to require: (1) Written assurance that the supplier is not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter and (2) the written assurance that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). However as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety

authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food.

(Comment 486) Some comments ask us to delete this documentation requirement because RACs except fruits and vegetables should be exempt from supplier verification.

(Response 486) See Response 464. This alternative supplier verification activity is intended to minimize the burden on suppliers that are small farms.

(Comment 487) Some comments ask us to include a cross-reference to the applicable requirement.

(Response 487) We have not added this cross-reference. We agree that adding the cross-reference has the potential to be helpful, but it also has the potential to clutter the regulatory text. We considered it would be more useful to specify what the documentation needs to be rather than to specify the cross-reference to the applicable alternative supplier verification activity.

**XLVIII. Subpart F: Comments on Proposed New Recordkeeping Requirements**

We proposed to establish in subpart F requirements that would apply to all records that would be required by the various provisions of proposed part 507, including general requirements related to the content and form of records; additional requirements specific to the food safety plan; requirements for record retention; requirements for official review of records by FDA; and public disclosure.

Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following paragraphs, we discuss comments that disagree with or suggest one or more changes to the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 30 with editorial and conforming changes as shown in table 31.

TABLE 30—REVISIONS TO THE PROPOSED RECORDKEEPING REQUIREMENTS

Section	Description	Revision
507.200(b) .....	Requirements for public disclosure ..	Specify that the requirement applies to records “obtained by FDA.”
507.200(c) .....	Requirements for official review .....	Clarify that FDA may copy records upon oral or written request by a duly authorized representative of the Secretary of Health and Human Services.



TABLE 30—REVISIONS TO THE PROPOSED RECORDKEEPING REQUIREMENTS—Continued

Section	Description	Revision
507.202(b) .....	General requirements applying to records.	Provide that the time of an activity being documented only include the time of the activity when appropriate.
507.202(c) .....	General requirements applying to records.	Specify that electronic records are exempt from the requirements of 21 CFR part 11.
507.208(a)(2) .....	Requirements for record retention ....	Specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility for as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
507.208(c) .....	Requirements for record retention ....	Provide for offsite storage of all records other than the food safety plan, provided that the offsite records can be retrieved and provided onsite within 24 hours of request for official review.
507.208(d) .....	Requirements for record retention ....	Provide that the food safety plan may be transferred to some other reasonably accessible location if the plant or facility is closed for a prolonged period, provided that it is returned to the plant or facility within 24 hours of request for official review.
507.215 .....	Special requirements applicable to a written assurance.	<ul style="list-style-type: none"> <li>• Establish requirements applicable to all written assurances required by the rule.</li> <li>• Establish additional requirements applicable to written assurances that are required when a food product distributed by manufacturer/processor requires further processing for food safety by a subsequent manufacturer.</li> </ul>

*A. Proposed § 507.200—Records Subject to the Requirements of Subpart F and Requirements for Official Review*

We proposed that all records required by part 507 would be subject to all requirements of subpart F, except that certain specific requirements (proposed § 507.206) would apply only to the written food safety plan. We also proposed that certain proposed requirements (*e.g.*, for records to contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities) would not apply to the records that would be kept by qualified facilities. We proposed that records required by proposed part 507 are subject to the disclosure requirements under part 20 (21 CFR part 20). We proposed that all records required by proposed part 507 be made promptly available to a duly authorized representative of the Secretary of HHS upon oral or written request. We also asked for comment on whether we should require a facility to send records to us rather than make the records available for review at a facility’s place of business and, if so, whether we should require that the records be submitted electronically.

(Comment 488) Some comments disagree with the proposal to exempt the records that would be kept by qualified facilities from requirements to keep accurate, detailed records. The comments note that the proposed exemption would apply to qualified facilities regardless of whether they operate under the first option for documentation (*i.e.*, food safety

practices) plans or under the second option for documentation (*i.e.*, compliance with non-Federal food safety laws). These comments assert that the proposed detailed record keeping requirements should apply to records relating to monitoring food safety practices and ask us to revise the proposed requirements so that this exemption would apply only to those qualified facilities that operate under non-Federal food safety laws.

(Response 488) We decline this request. We based the proposed exemption on a statutory provision that a qualified facility is not subject to certain requirements, including the statutory recordkeeping requirements (see section 418(l)(2) of the FD&C Act). Although the requirements that apply to a qualified facility require submission of certain attestations to FDA (see § 507.7(a) and (b)), and these attestations must be supported by documentation (see § 507.7(f)), the rule does not require that records kept by a qualified facility to support its attestations be the same type of records that would be kept by a facility subject to subparts C and E. For example, if the facility attests that it has identified the potential hazards associated with the animal food being produced, implemented preventive controls to address the hazards, and is monitoring the performance of the preventive controls, the qualified facility might support its attestation by having a standard operating procedure for monitoring preventive controls rather than detailed records of actual monitoring.

(Comment 489) Some comments assert that the proposed requirements governing public disclosure are not aligned with other risk-based preventive controls programs, such as HACCP programs. These comments argue that these proposed requirements should be realigned with other risk-based preventive controls programs to preserve the privacy of information maintained in required records unless that information has been otherwise made publicly available. Some comments suggest that we revise the proposed requirements to be analogous to the public disclosure requirements in our HACCP regulations for seafood and juice (see §§ 123.9(d) and 120.12(f), respectively).

(Response 489) We disagree that the proposed provisions governing public disclosure are not aligned with the public disclosure provisions of our HACCP regulations for seafood and juice. Our regulations in part 20 regarding public information apply to all Agency records, regardless of whether a particular recordkeeping requirement says so. In the case of the recordkeeping requirements for our HACCP regulations for seafood and juice, we framed the provisions regarding public disclosure by providing specific details about how particular provisions in part 20 (*i.e.*, § 20.61 (Trade secrets and commercial or financial information which is privileged or confidential) and § 20.81 (Data and information previously disclosed to the public)) would apply to the applicable records. In the case of the recordkeeping requirements for this

rule, we framed the provisions regarding public disclosure by more broadly referring to all the requirements of part 20, consistent with our more recent approach for framing the provisions regarding public disclosure in the rule “Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation” (part 118; see § 118.10(f)). Provisions such as § 20.20 (Policy on disclosure of Food and Drug Administration records) apply to all records that we have in our system, including HACCP records, even though the HACCP regulations do not specify that this is the case.

(Comment 490) Some comments ask us to clarify that the disclosure requirements of part 20 include protections for trade secrets and privileged or confidential commercial information and financial information. Other comments ask us to clarify that written food safety plans and associated records are not subject to public disclosure because they represent trade secret or confidential commercial information. Other comments ask us to clarify how the disclosure requirements of part 20 would apply to verification records (such as testing records).

(Response 490) The questions raised in these comments are similar to some of the questions raised during the rulemaking to establish FDA’s HACCP regulation for seafood (see the discussion at 60 FR 65096 at 65137 through 65140, December 18, 1995). FDA’s experience in conducting CGMP inspections in processing plants, our experience with enforcing the HACCP regulations for seafood and juice, and our understanding from the Final Regulatory Impact Analysis (FRIA) for this rule (Ref. 60) make it clear that food safety plans will take each facility some time and money to develop. Thus, we conclude that food safety plans generally will meet the definition of trade secret, including the court’s definition in *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983). Plans that incorporate unique regimens or parameters to achieve product safety, which are the result of considerable research and effort, will surely meet this definition.

We would establish the status of verification records, such as the results of product testing and environmental monitoring, as available for, or protected from, public disclosure on a case by case basis. As discussed in Response 491, we primarily intend to copy such records when we conduct an inspection for cause. We also intend to copy such records if the preliminary assessment by our investigator during a routine inspection is that regulatory followup

may be appropriate (e.g., if these records demonstrate that an environmental pathogen has become established in a niche environment in an animal food processing plant).

(Comment 491) Some comments assert that we should not copy documents as part of routine investigations so as to prevent critical documents from release under the FOIA. These comments are particularly concerned that our ability to copy verification records (such as testing records) and potentially release these records under the FOIA would discourage facilities from testing as a verification activity. These comments also express concern that some facilities would include in their food safety plans elements, not required by the proposed rule, that address food defense, as well as food safety, and that disclosure of such a food safety plan without proper redaction could provide useful information to persons seeking to defeat the facility’s food defense strategies. In addition, these comments express concern that the task of reviewing all of these records and redacting trade secrets and confidential information would further set back FDA’s already overburdened FOIA offices and create even longer delays in responding to FOIA requests.

(Response 491) We have revised the proposed requirement to specify that all required records must be made promptly available “for official review and copying” to increase the alignment of the recordkeeping requirements of this rule with those of our HACCP regulations for seafood and juice. The issues raised by these comments are similar to some of the issues raised by comments during the rulemaking to establish our HACCP regulations for seafood (see the discussion at 60 FR 65096 at 65137 through 65140) and our regulations in part 118 for the prevention of *Salmonella* Enteritidis in shell eggs. We intend to copy records on a case-by-case basis as necessary and appropriate. We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators’ notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions.

We primarily intend to copy records such as the results of product testing or environmental monitoring when we conduct an inspection for cause, e.g., as a result of an outbreak investigation, violative sample results, or followup to

a consumer complaint. See Response 490 for a discussion of how the FOIA would apply to records, such as records of testing as a verification activity, that we copy during an inspection and maintain in our system.

(Comment 492) Some comments ask us to modify the proposed requirement to clarify that it is “records required by this part and provided to the Agency,” rather than “records obtained by the Agency” that are subject to public disclosure.

(Response 492) We agree that it is appropriate to specify that the disclosure requirements of this rule apply to information that we maintain as a record (see the description of “record” in § 20.20(e)). (See also the discussion (in the proposed rule to establish our seafood HACCP regulation, 59 FR 4142 at 4160, January 28, 1994) that there are significant legal and practical questions as to whether FDA has the authority to require disclosure of industry records that are not in FDA’s possession.) However, we see no meaningful distinction between records “provided to FDA” and records “obtained by FDA,” and have revised the provision to specify that records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20. The revised regulatory text makes clear that the requirements of part 20 attach to those documents obtained by FDA. To the extent that these comments are addressing the difference between records provided during inspection and records submitted to us, as already discussed we have decided not to require submission of certain records to us (see Response 493).

(Comment 493) Some comments strongly oppose any requirement for submission of records to FDA remotely and assert that there is no basis in FSMA for such a requirement. Some comments express concern about our ability to protect confidential information (such as supplier and customer records received by a facility under the protection of confidentiality agreements) that is transmitted electronically (e.g., the information that might be released through computer hacking or leaks). Some comments note that inadvertent disclosure of information related to specific products, hazards, and preventive controls implemented at food facilities could both prove harmful from a commercial or competitive standpoint and expose existing vulnerabilities in the U.S. food supply, thus potentially rendering food facilities susceptible to malicious attack.

Some comments express concern over any potential requirements to submit

reports from third-party audits to FDA. The comments state that a requirement to submit audit reports, which may be included as voluntary or required components of a facility's food safety plan, would not be of public health benefit and could potentially impact a facility's willingness to use audits in their food safety program.

Some comments offered that instead of submission of the food safety plan, a facility should submit a "certification" that the facility has a food safety plan during the course of the facility registration process.

Some comments oppose the concept of a "desk audit" whereby our investigators conduct their inspections from a remote office without actually visiting the facility and assert that our access to company records must be conducted on-site in the course of an authorized inspection so that we may understand the full context of what the records show. Some comments point out that there would be challenges associated with credential validation when we asked for records to be sent remotely, such as in an email request. Some comments ask that we modify the proposed requirement to specify that records would only be made available to us during a facility inspection.

(Response 493) We have decided not to establish any requirements for a facility to send records to us. We will review records when we are onsite in the course of an authorized inspection, and copy records as necessary and appropriate.

We are not modifying the proposed requirement to specify that records would only be made available to us during a facility inspection because it is not necessary to do so. The regulatory text specifying that the records be made available to a duly authorized representative of the Secretary of HHS provides the context that the records would be made available during inspection.

#### *B. Proposed § 507.202—General Requirements Applying to Records*

We proposed that the records must: (1) Be kept as original records, true copies, or electronic records (and that electronic records must be kept in accordance with part 11 (21 CFR part 11)); (2) contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities; (3) be accurate, indelible, and legible; (4) be created concurrently with performance of the activity documented; (5) be as detailed as necessary to provide history of work performed; and (6) include the name and location of the plant or facility, the

date and time of the activity documented, the signature or initials of the person performing the activity, and, where appropriate, the identity of the product and the production code, if any.

We have revised the provision to require information adequate to identify the plant or facility (*e.g.*, the name, and when necessary, the location of the plant or facility) rather than to always require both the name and location of the plant or facility (see § 507.202(b)(1)). In some cases, the name of the plant or facility will be adequate to identify it, *e.g.*, when a plant or facility is not part of a larger corporation that has facilities at more than one location. In other cases, the name of the plant or facility may not, by itself, be adequate to identify the plant or facility, *e.g.*, when a plant or facility is part of a larger corporation with more than one location and the "name" of each plant or facility is the same.

(Comment 494) Some comments express concern about "apparent mandates" that we will require records to be kept as paper copies, even if the records were generated electronically, for 2 years.

(Response 494) We did not propose to require that all records must be kept as paper copies. A facility has the choice to keep records as original records, true copies, or electronic records.

(Comment 495) Some comments assert that compliance with part 11 for the secure operation of many systems currently in use is unnecessary and would create the need to redesign and recreate existing systems, thus leading to considerable cost and complexity. These comments identify the requirement for hardware and software to be validated as a key cost concern and assert that validation activities would be difficult to maintain and would not deliver added value. As an example, these comments explain that an expectation for validation of electronic recordkeeping software and hardware would be particularly problematic because software patches and security updates are distributed on a nearly weekly basis, and express the view that validation procedures are most appropriately applied before use of a new system and after major software changes or updates. These comments also assert that it would be costly, burdensome, and require specialized resources to modify or replace existing electronic systems to comply with part 11. These comments provide an example in which a facility needed more than 9 months to upgrade one system alone to comply with part 11, and note that it would not be unusual for companies to employ multiple

systems, so the burden and cost would exponentially increase. These comments ask us to instead require facilities that use electronic records to a use secure system that ensures records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Other comments express concern about the financial burden for small facilities such as farm mixed-type facilities and ask us to either modify requirements for farm mixed-type facilities, very small businesses, and small businesses or provide that such facilities be fully exempt from part 11 requirements for electronic records. Other comments state that, as with the recordkeeping requirements under the Bioterrorism Act, such requirements are disproportionate to the regulatory need.

Some comments state that major advances in software technology have been made since part 11 published in 1997, and such advances must be carefully considered in evaluating any potential expansion or new applications of part 11. These comments also state that we already are in the process of reevaluating part 11 for the regulations for which it currently applies, citing industry guidance issued more than 10 years ago in which we acknowledged that part 11 is unworkable in many respects and decided to exercise enforcement discretion for part of the regulations and announced plans to reexamine part 11 as a whole.

Some comments recommend that we develop guidance, with input from key stakeholders, to describe the kinds of systems and steps that can be used to assure records meet the required standard. This guidance should clearly establish that specific security needs will depend on the circumstances, including the system at issue, its intended use, the criticality of the preventive control or other food safety measure it is used to manage, and other relevant factors. For example, these comments explain that a quality system used to manage CCP documentation would have greater security needs than a review of a Certificate of Analysis for a non-sensitive ingredient.

(Response 495) In light of the substantial burden that could be created by the need to redesign large numbers of already existing electronic records and recordkeeping, we are providing in new § 507.202(c) that records that are established or maintained to satisfy the requirements of part 507 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. As we did in the section 414 recordkeeping

regulations, we also are specifying that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. The rule provides that a facility may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. As we did in the rulemaking to establish the section 414 recordkeeping regulations, we are establishing a conforming change in part 11 to specify in new § 11.1(j) that part 11 does not apply to records required to be established or maintained under part 507, and that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

Although we are not specifying that part 11 applies, facilities should take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(Comment 496) Some comments assert that certain production and associated activities are not time-sensitive and would not require documentation of the time the activity is performed. These comments ask us to modify the proposed requirements so that the records would only require the time of the activity documented where appropriate for food safety.

(Response 496) We agree that certain activities (e.g., record review and verification activities) are not time-sensitive and, thus, would not need to include the time that the activity was performed. The final rule provides flexibility for the facility to determine when to document the time by specifying that the time be documented “when appropriate” (see § 507.202(b)(2)).

(Comment 497) Some comments assert that concurrent record creation will prove difficult in many animal food-processing environments. These comments ask us to modify the proposed requirement that records be created concurrently with the performance of the activity documented to qualify that the requirement only applies where feasible, and that the records could be created as soon as possible thereafter under circumstances where concurrent record creation is not feasible.

(Response 497) We decline this request. The comments did not provide any examples of activities where concurrent record creation in animal

food manufacturing/processing, packing, or holding environments would prove difficult, and we are not aware of any such example. For example, we are not aware of any difficulty complying with longstanding similar requirements associated with our HACCP regulations for seafood and juice (see §§ 123.9(a)(4) and 120.12(b)(4), respectively).

#### *C. Proposed § 507.206—Additional Requirements Applying to the Food Safety Plan*

We proposed that the food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

(Comment 498) Some comments ask for clarification on who can sign and date the food safety plan. Some comments state that the proposed rule would exclude the preventive controls qualified individual from signing and dating the food safety plan unless the preventive controls qualified individual is the owner, operator, or agent in charge of the facility. These comments ask us to revise the rule to allow the preventive controls qualified individual to sign and date the food safety plan (e.g., because it is the preventive controls qualified individual who prepares (or oversees the preparation of) the food safety plan). One comment suggests that “agent in charge” be defined to include all preventive controls qualified individuals. Some comments ask us to require that any preventive controls qualified individuals who prepare (or oversee the preparation of) specific sections of the food safety plan sign and date applicable sections.

(Response 498) We decline these requests. The statute expressly directs the owner, operator, or agent in charge of a facility to prepare the food safety plan (see section 418(h) of the FD&C Act). As previously discussed, such a signature would provide direct evidence of the owner, operator or agent’s acceptance of the plan and commitment to implementation of the plan (78 FR 64736 at 64816). A facility has flexibility to require the signature of one or more preventive controls qualified individuals who prepared, or oversaw the preparation of, its food safety plan in addition to the minimum signature requirement specified in the rule. Likewise, a facility also has flexibility to require the signature of one or more members of its food safety team who contributed to the preparation of the food safety plan, even if those individuals are not serving as the

preventive controls qualified individual for the facility.

#### *D. Proposed § 507.208—Requirements for Record Retention*

We proposed that: (1) All required records must be retained at the plant or facility for at least 2 years after the date they were prepared; (2) records relating to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued; (3) except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the records were made if such records can be retrieved and provided onsite within 24 hours of request for official review; and (4) if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

(Comment 499) Some comments ask us to clarify that the 2-year record retention requirement only applies to records created after the compliance date for the final rule.

(Response 499) The retention requirements only apply to records created after the applicable compliance date for the final rule. See Response 76 and section LIII.A, which explain that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. See also Response 502, which explains that we have revised the record retention provisions to specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility for as long as necessary to support the status of facility as a qualified facility during the applicable calendar year.

(Comment 500) Some comments ask us to delete the proposed requirement to keep records on site for 6 months or 2 years (depending on the record) and assert that it should suffice to require that records be available within 24 hours of request or within a reasonable period of time. Some comments assert that records should be able to be kept in the location where they are created, which may be at corporate headquarters. Other comments state that it may be difficult to obtain records within 24 hours and requested additional time. Comments also assert that specifying the location for record storage will increase costs but will not contribute to improvements in public health. Some

comments ask us to permit offsite storage for all records over 6 months old, in contrast to the 2-year retention period we proposed for records relating to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations.

(Response 500) We have revised the provisions to provide for offsite storage of all records (except the food safety plan), provided that the records can be retrieved and made available to us within 24 hours of request for official review. We have determined that in order to maintain inspectional efficiency, 24 hours is a reasonable period to allow for retrieval of any offsite records. We expect that many records will be electronic records that are accessible from an onsite location and, thus, would be classified as being onsite (see § 507.208(c)). As a companion change, we have revised the proposed provision directed to the special circumstance of storing records when a facility is closed for prolonged periods of time so that it only relates to the offsite storage of the food safety plan in such circumstances (see § 507.208(d)).

(Comment 501) Some comments assert that a 2-year retention period for records is much longer than needed for animal food products, as animal food is often consumed within a short time after manufacture. These comments ask us to establish a 1-year period for record retention, which would be similar to record retention periods required in other FDA regulations. Some comments assert that records should be required to be kept for the shelf life of the product plus an additional 6 months, for certain animal foods such as pet foods.

(Response 501) We decline these requests. The proposed 2-year retention period is authorized by the statute (see section 418(g) of the FD&C Act). Moreover, the reasons discussed by the comments for linking the retention period to shelf life are more relevant to the record retention requirements for the purpose of tracking potentially contaminated food (part 1, subpart J; see § 1.360) than to the record retention requirements for the purpose of evaluating compliance with this rule.

(Comment 502) Some comments ask us to require that qualified facilities keep financial and sales records for 3 or 4 years, because a qualified facility must document that the average value of food it sold over the prior 3 years did not exceed \$500,000 annually.

(Response 502) We have revised the record retention provisions to specify that records that a facility relies on during the 3-year period preceding the

applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year. As discussed in section VIII.A, the definition of very small business established in this rule is based on an average (of sales plus market value of animal food held without sale) during the 3-year period preceding the applicable calendar year. Thus, both of the criteria for the qualified facility exemption are based on financial records associated with the preceding 3-year period. The actual retention time necessary to support the status of a qualified facility during the applicable calendar year could be as long as 4 years. For example, if we inspect a facility on May 1, 2024, the facility would have retained the records from 2021 to 2023 for 3 years and 4 months. If we inspect the facility on December 28, 2024, the facility would have retained the records from 2021 to 2023 for nearly 4 years.

#### *E. Proposed § 507.212—Use of Existing Records*

We proposed that existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of subpart F. We also proposed that the information required by part 507 does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by part 507 may be kept either separately or combined with the existing records.

Comments that address this proposed requirement support it. For example, some comments state that this provision would provide flexibility to facilities to comply with the record requirements in an efficient manner. Other comments state that this provision would prevent companies from having to duplicate records or create new records solely to satisfy recordkeeping requirements.

(Comment 503) Some comments state that food safety plan records are a “web of related documents” that may be used in other programs and cannot be collected or reduced to a “binder.”

(Response 503) We agree that food safety plan records could be considered a “web of related documents,” *i.e.*, a set of records that could include documents used in other programs. We also agree

that the food safety plan records need not be collected in a single location or “reduced to a binder.” Likewise, the records documenting implementation of the plan could be a “web of related documents.” For example, a facility that collects samples of product and sends them to a laboratory for testing would have records documenting its collection of samples, as well as records documenting the laboratory’s test results. Consistent with the requirements of the rule for written procedures for product testing (§ 507.49(b)(2)) and the general recordkeeping requirements of subpart F (§ 507.202), the sampling records would contain information such as the name and location of the facility, the date when the samples were collected, the signature or initials of the person collecting the samples, and the identity and lot code of the sampled product.

Likewise, the laboratory report would contain information identifying the laboratory, the product tested (and associated lot code), the test analyte, the test(s) conducted (including the analytical method(s) used), the date of the test(s), the test results, and the signature or initials of the person who conducted the test. Alternatively, it would be acceptable to have the signature or initials of the person who approved the release of the test results from the laboratory. Together, these records contain all the required information to associate them with a facility, a specific lot of product, and the results of laboratory testing on that product.

Although the provisions for use of existing records provide flexibility, there are some limitations. For example, monitoring records must be created concurrently with the monitoring activity and contain the signature or initials of the person conducting the monitoring. If the facility has an existing form that it uses to document the monitoring activity, and that form does not provide (or have space to add) information adequate to identify the plant or facility (*e.g.*, the name and, when necessary, the location of the facility), and does have (or have space to add) a place for the signature of the person performing the activity, we expect the facility to modify the form rather than use the existing form. The provisions for “supplementing” existing records do not extend to providing information identifying the facility, or signatures, on separate pages.

(Comment 504) Some comments state that our review of records should be limited to issues under our jurisdiction, regardless of the other information that may be contained in the record. Other

comments ask us to ensure that inspectors are adequately trained on how to review facility records for the requisite information across multiple sets of documents, as needed.

(Response 504) Section 418(h) of the FD&C Act requires that the written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418, together with the documentation of monitoring of preventive controls, instances of nonconformance material to food safety, the results of testing and other means of verification, instances when corrective actions were implemented and the efficacy of preventive controls and corrective actions, be made available to FDA. Our inspectors will be trained to focus on the written food safety plan and the records documenting implementation of the plan during inspections. Our inspectors have experience in the review of records that an animal food business establishes and maintains for more than one purpose—*e.g.*, during the review of records kept under the section 414 recordkeeping regulations during the investigation of an outbreak of foodborne illness.

For further discussion of comments received on recordkeeping requirements, see section XLI in the final rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

#### *F. Final § 507.215—Special Requirements Applicable to a Written Assurance*

As discussed in section XXVII, new § 507.215 establishes requirements applicable to the written assurance a manufacturer/processor obtains from its customer. New § 507.215(a) applies to all written assurances required by the rule, *i.e.*, the assurance must contain the effective date; printed names and signatures of authorized officials; and the applicable assurance.

The provisions of § 507.215(b), together with another new provision (§ 507.37), establish legal responsibilities under the rule for a facility that provides a written assurance regarding a food product that a manufacturer/processor distributes without application of a preventive control that is needed to control a hazard. This responsibility exists even for a facility that is not itself a manufacturer/processor, such as for a facility that is a distributor. We are establishing legal responsibilities for the facilities that provide these written assurances because following these assurances is critical to ensuring that required preventive controls are applied

to the food by an entity in the distribution chain before the food reaches consumers.

#### **XLIX. Comments by Foreign Governments and Foreign Businesses**

We received several comments from foreign governments and foreign businesses covering a wide range of issues. Many of those comments were similar to comments made on certain topics by domestic stakeholders, so we are addressing those comments in other sections throughout this preamble. In this section, we are responding to comments that are primarily focused on international issues, such as the obligations of the United States under the World Trade Organization Agreement (WTO).

(Comment 505) Some comments by foreign government representatives ask us to provide extended periods of time for the implementation of the rule for facilities in foreign countries.

(Response 505) The concept of special and differential treatment is incorporated in the WTO Agreements. Article 10.2 of the WTO Sanitary and Phytosanitary (SPS) Agreement states: “Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction . . . longer timeframes for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.”

In 2001, at the WTO Ministerial Conference in Doha, WTO Members issued a Ministerial Decision that interpreted the special and differential obligations of the SPS Agreement (Ref. 61). The Ministerial Decision defined “longer timeframe for compliance” to normally mean a period of not less than 6 months.

We recognize that businesses of all sizes may need more time to comply with the new requirements established under this rule. As discussed in section LIII, the compliance date for implementation of subpart C, Hazard Analysis and Preventive Controls is extended one year beyond the compliance date for the implementation of subpart B, Current Good Manufacturing Practice. Businesses other than small and very small businesses will have 1 year after the date of publication to comply with the CGMP requirements and 2 years after publication to comply with preventive controls requirements. Small businesses will have 2 years after publication to comply with the CGMP requirements and 3 years after publication to comply with preventive controls requirements. Very small businesses will have 3 years

after publication to comply with the CGMP requirements and 4 years after publication to comply with preventive controls requirements. We anticipate that these extended implementation periods for small businesses and very small businesses will apply to a number of businesses in developing countries. Because all of these time periods are longer than the 6 month minimum defined in the WTO Ministerial Decision, we believe these implementation periods are sufficient to address the needs of businesses in developing countries, particularly for small and very small businesses in such countries.

In addition to the extended time periods for compliance for small and very small businesses, we have also established modified requirements for very small businesses, which we define as a business (including any subsidiaries; and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year, in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale). These modified requirements for very small businesses are less burdensome and are described in § 507.7 of this regulation.

In addition to the extended and staggered time periods for compliance for all firms, and modified requirements for very small businesses, we intend to work with the animal food industry, education organizations, USDA, the United States Agency for International Development, and foreign governments to develop tools and training programs to facilitate implementation of this rule.

(Comment 506) Some comments assert that the food safety systems of the European Union and other countries afford a similar level of food safety protection and must therefore be recognized by FDA as equivalent under the WTO SPS Agreement. These comments urge FDA to accept the HACCP plans and other steps taken to comply with European food safety laws as being sufficient to comply with this rule.

(Response 506) The concept of “equivalence” for food safety regulatory measures is contained in Article 4 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”) (Ref. 62). That article provides that WTO Member countries “shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from

those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection." This provision of the SPS Agreement envisions a process in which the exporting country provides evidence to the food safety regulator in the importing country in order to "objectively demonstrate" that the food safety system in the exporting member meets the level of food safety protection established by the importing country. To date, FDA has considered equivalence as most appropriately applied to the assessment of a foreign government's specific programs for specific types of foods, such as shellfish and dairy products. In that context, the equivalence assessment provides a very detailed comparison of each measure that a country applies in controlling risks associated with the particular commodity under review. FDA continues to have latitude to engage in equivalence determinations for market access and as required by our regulations for certain commodities.

In contrast to the assessment of equivalence for the regulation of specific foods based upon a detailed review of an individual food safety measure or group of measures applied to a specific food, FDA has established a process of assessing foreign food safety systems to identify systems that offer a comparable level of public health protection as the U.S. food safety system for FDA regulated foods. We refer to that process as "systems recognition," which we discuss in Response 507.

(Comment 507) Some comments urge FDA to include a provision in this rule that would reflect a determination made by FDA in the "systems recognition" process so that FDA's compliance framework, including audit and inspection activities, takes into account the effectiveness of the regulatory or administrative control of food safety systems. These comments ask us to include a provision in this rule establishing that an affirmative systems recognition determination by FDA for an exporting country would be a sufficient basis to exempt exporting businesses from that country from their

obligation to comply with the requirements of this rule. Another comment urges FDA to utilize the systems recognition process to recognize the effectiveness of the European Union (EU) system in order to avoid unnecessary or duplicative requirements and controls on food imports from the EU. Another comment requests that FDA coordinate inspection and audits with the relevant competent authority.

(Response 507) We agree, in part, with this comment. We agree that the systems recognition program can allow FDA to take into account the effectiveness of a foreign food safety regulatory system as we develop a compliance framework for imported foods from a country for which we have made an affirmative determination of comparability via the systems recognition program. While we decline to add an exemption for food imported from a country with affirmative systems recognition determination by FDA, we note that the systems recognition program is based upon the concept that foreign food businesses can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country that FDA has found to be comparable or equivalent to that of the United States. Several provisions of the supply-chain program specifically provide for consideration of relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States (see §§ 507.110(d)(1)(iii)(B); 507.130(c)(2), (d)(2), and (e)(2); and 507.135(b) and (c)(1)(ii)). However, as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food. For further discussion of the systems recognition program, see Response 718 of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

We also note that we intend to publish a final FSVP rule in the near future. There, we intend to establish modified requirements for food imported from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as "comparable" to that of the United States.

Section 507.105(a)(2) of this rule provides the option for a receiving facility that is an importer to comply with the supplier verification requirements in this rule or with the foreign supplier verification program requirements that we will establish in part 1, subpart L for a raw material or other ingredient. We intend that the final FSVP rule will contain a similar provision (derived from proposed § 1.502), so that only one supplier verification procedure needs to be undertaken in order to comply with both rules when the specified conditions are met.

(Comment 508) Some comments assert that a proper harmonization is needed with international standards and ask us to harmonize the FSMA requirements for the food safety plan with international and domestic HACCP programs. These comments also ask us to explain any differences between the FSMA food safety plan and the existing HACCP programs and ask us to provide exporters with background information and specific examples of differences, including how firms are directed to set their CCPs and critical limits.

(Response 508) We currently have no HACCP requirements applicable to animal food. For discussion of this comment, see Response 725 in the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

#### **L. Editorial and Conforming Changes**

The revised regulatory text includes several changes that we have made to make the requirements more clear and improve readability. The revised regulatory text also includes several conforming changes that we have made when a change to one provision affects other provisions. We summarize the principal editorial and conforming changes in table 31.

TABLE 31—PRINCIPAL EDITORIAL AND CONFORMING CHANGES

Designation in the revised regulatory text (§)	Revision	Explanation
• 11.1(j) .....	Specify that part 11 does not apply to records required to be established or maintained under part 507, and that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.	Conforming change associated with the recordkeeping requirements in §507.202, which provide that part 11 does not apply to records required to be established or maintained under part 507.
Throughout part 507 .....	<ul style="list-style-type: none"> <li>• Substitute the term “adequate” for the term “sufficient”.</li> <li>• Substitute the term “inadequate” for the term “insufficient”.</li> </ul>	Conforming change associated with our proposal, in the 2014 supplemental animal preventive controls notice, to make this substitution so that the rule consistently uses the term “adequate.”
Throughout part 507 .....	Substitute the term “pathogen” for the term “microorganism of public health significance”.	Conforming change associated with the definition of “pathogen.”
Throughout part 507 .....	Substitute the term “preventive controls qualified individual” for the term “qualified individual”.	Conforming change associated with adding the term “preventive controls qualified individual”.
Throughout part 507 .....	Substitute the term “unexposed packaged animal food” for the phrase “packaged animal food that is not exposed to the environment”.	Conforming change associated with the definition of “unexposed packaged animal food”.
Throughout part 507 .....	Substitute the phrase “chemical (including radiological) hazards” for phrases such as “chemical and radiological hazards”.	Conforming change associated with the definition of “hazard”.
Throughout part 507 .....	Substitute the term “hazard requiring a preventive control” for the term “significant hazard”.	Conforming change associated with the proposed definition of “significant hazard” (which we now refer to as “hazard requiring a preventive control”).
Throughout part 507 .....	Shorten “raw agricultural commodity as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act” to “raw agricultural commodity”.	Conforming change associated with the new definition of “raw agricultural commodity”.
507.1(a) .....	Redesignate subparagraphs to distinguish between applying the provisions in determining whether animal food is adulterated and applying the provisions in determining whether there is a violation of the PHS Act.	Improve clarity.
507.3 .....	Substitute “apply” for “are applicable” in the introductory paragraph.	Improve clarity.
507.3 .....	Alphabetize the examples of harvesting activities in the definition of “harvesting”.	Improve clarity.
507.3 .....	Alphabetize the examples of manufacturing/processing activities in the definition of “manufacturing/processing”.	Improve clarity.
507.3 .....	Specify that the definition of “very small business” includes any subsidiaries and affiliates.	Give prominence to this aspect of the definition of “very small business.” The relevance of subsidiaries and affiliates to the definition of “very small business” is established in the definition of “qualified facility,” but including it again in the definition of “very small business” will help to ensure that it is considered when determining whether the business is within the dollar threshold established in the definition of “very small business”.
<ul style="list-style-type: none"> <li>• 507.3 .....</li> <li>• 507.5 .....</li> <li>• 507.7(d) .....</li> <li>• 507.10(a) .....</li> <li>• 507.65(d)(1) .....</li> </ul>	Substitute “subparts C and E” for “subpart C”.	Conforming change associated with the redesignation of the requirements for a supply-chain program in new subpart E.



TABLE 31—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
507.7(a)(2)(ii) .....	Editorial change to place the clause “including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight” at the end of the provision, rather than in a parenthetical at the beginning of the provision.	Improve clarity.
<ul style="list-style-type: none"> <li>• 507.14 .....</li> <li>• 507.17(a) .....</li> <li>• 507.20(d) .....</li> <li>• 507.202(b) .....</li> </ul>	Conforming changes associated with the definition of “plant”.	The definition of “plant” focuses on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food. The term “establishment” focuses on a business entity rather than on buildings or other structures.
507.20(d) .....	Refer to “employees” rather than “its employees”.	Editorial change.
<ul style="list-style-type: none"> <li>• 507.25(a)(2) through(b)(1) .....</li> <li>• 507.33(d)(3) .....</li> <li>• 507.105(a)(1) .....</li> <li>• 507.110(b) through (e) .....</li> <li>• 507.115(a) .....</li> <li>• 507.120(a) and (b) .....</li> <li>• 507.130 .....</li> <li>• 507.175(c) .....</li> </ul>	Changes to consistently refer to raw materials and “other ingredients”.	Conforming change with preventive controls rule for human food.
507.31(b)(3), 507.34(c)(3), 507.39(b), 507.47(c)(3), 507.55(a)(5).	Refer to “supply-chain program” rather than “supplier program”.	Conforming change associated with the title of final subpart E (proposed §507.37).
• 507.47(b)(2) .....	Conforming changes associated with the definition of “validation”.	Improve clarity; consistency with the requirements for validation.
• 507.50(b)(4) .....	Refer to “supply-chain verification activities,” as well as “supplier verification activities”.	Consequential change as a result of the requirement in §507.105(c) for verification of an entity that is in the supply-chain but is not a supplier.
507.49(a)(4)(ii) .....	Changes to require written procedures for method and frequency of accuracy checks for process monitoring instruments and verification instruments.	Conforming change associated with the requirements to calibrate process monitoring instruments and verification instruments (or check them for accuracy).
507.49(b)(1) .....	Conforming changes associated with the timeframe for validating preventive controls.	Consistency with the requirements for validating preventive controls.
507.50(c)(2) .....	Editorial changes to the requirement to revise the written food safety plan or document why revisions are not needed.	Improve clarity.
507.50(d) .....	Editorial change to specify “provide assurance that the temperature controls are consistently performed” rather than “provide assurance that they are consistently performed”.	Improve clarity.
<ul style="list-style-type: none"> <li>• 507.51(a)(4)(ii) .....</li> <li>• 507.51(a)(4)(iii) .....</li> </ul>	Substitute the phrase “records are created” for the phrase “records are made”.	Consistency with other recordkeeping requirements of the rule.
507.51(a)(4)(iii) .....	Change “within a week” to “within 7 working days”.	Conforming change associated with review of records of monitoring and corrective action records.
507.53(a)(3) .....	Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for validation.	Conforming change associated with flexibility to determine the timeframe for validation of a preventive control.
507.53(a)(4) .....	Change to specify the role of the preventive controls qualified individual in determining that validation is not required.	Conforming change associated with flexibility to determine that validation of a preventive control is not required.
507.53(a)(6) .....	Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for review of records of monitoring and corrective actions.	Conforming change associated with flexibility to determine the timeframe for review of records of monitoring and corrective actions.

TABLE 31—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
507.53(a)(8) .....	Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for completing reanalysis.	Conforming change associated with flexibility to determine the timeframe for completing reanalysis.
Subpart D (title) .....	Substitute the term “qualified facility exemption” for the phrase	Conforming change associated with the definition of “qualified facility exemption”.
507.60 .....	“exemption applicable to a qualified facility” or the phrase	
507.62 .....	“exemption applicable to a qualified facility under §507.5(d)”.	
507.65 .....		
507.67 .....		
507.80 .....		
507.85 .....		
507.60(b)(1) .....	Change “import alert” to “refusal of animal food offered for import”.	Align with statutory language regarding imports rather than with specific procedures that FDA uses for refusing admission to animal foods offered for import.
507.62(a) .....	Change “FDA official senior to such Director” to “FDA official senior to either such Director”.	The provision refers to two “Directors” and the clause applies to either Director.
507.65(c)(2) .....	Refer to “conditions or conduct” rather than “conduct or conditions”.	Consistency with regulatory text in § 507.60(a)(2).
• 507.67(a)(2) .....	Change “within 10 calendar days” to “within 15 calendar days”.	Conforming change to reflect a timeframe of 15 calendar days, rather than 10 calendar days, in the order withdrawing a qualified facility exemption.
• 507.69(a)(1) .....		
• 507.71(a)(2), .....		
• 507.73(a) .....		
• 507.85(a) .....	Specify “any problems with the conditions and conduct” rather than “problems with the conditions and conduct” or “problems with the conditions or conduct”.	Clarify that reinstatement of a qualified exemption that was withdrawn requires resolution of any problems, regardless of whether the problems related to conditions, conduct, or both conditions and conduct.
• 507.85(b)(2) .....		
507.202 .....	Refer to “lot code” rather than “production code”.	Consistency with the definition of “lot”.
507.206 .....	Editorial changes to present the requirement in active voice.	Improve clarity.

**II. Comments on FSMA’s Rulemaking Provisions**

*A. Comments on Section 418(m) of the FDA&C Act Regarding Modified Requirements for Facilities Solely Engaged in the Production of Food for Animals Other Than Man*

Section 418(m) of the FD&C Act authorizes the Secretary, by regulation, to modify the requirements for compliance under the section with respect to facilities that are solely engaged in the production of food for animals other than man. We tentatively concluded that the requirements of section 418 of the FD&C Act are needed to ensure the safety of animal food and in turn the health of animals, the health of humans who are exposed to animal food, and the safety of animal derived products for human consumption. We proposed certain limited exemptions, described elsewhere in this rule, as provided by section 103 of FSMA. We sought comment on whether the requirements in section 418 of the FD&C Act should be modified further for facilities that are solely engaged in the production of food for animals other than man, based on scientific and public

health principles (78 FR 64736 at 64745).

(Comment 509) Some comments agree with our proposal to establish only minor modifications to the requirements of section 418 of the FD&C Act for facilities solely engaged in the production of food for animals other than man. Other comments ask that we consider proposing more extensive modified requirements for animal food, or exempting feed mills, using the authority under section 418(m).

(Response 509) We did not receive comments that provided sufficient data and rationale to support changing our proposed modifications to the requirements in section 418 of the FD&C Act. However, the final rule provides risk-based flexibility in the preventive controls requirements and their management components by recognizing the importance of the facility, the food, the nature of the preventive control, and its role in the facility’s food safety system. For our approach to feed mills, see our discussion in section IV.

*B. Comments on Requirements in Section 418(n)(3) of the FD&C Act Regarding Content*

FSMA specifies that this rule acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods (section 418(n)(3)(C) of the FD&C Act).

(Comment 510) Some comments agree that the proposed preventive controls requirements reflect a risk-based approach and recognition that a “one-size-fits-all” approach is not appropriate in the application of hazard analysis and risk-based preventive controls across the entire domestic and international food industry. These comments ask us to retain this flexibility in the final rule by describing the required and expected results of the program, but not going as far as prescribing the process and methodology taken to get there. Other comments emphasize that the final rule must provide sufficient flexibility to allow facilities to adopt practices that are practical and effective for their specific, individual operations. One comment expressed the opinion that

different manufacturing and distribution practices are necessary to ensure the safety of human food, pet food, and livestock food.

(Response 510) The final rule directs the owner, operator, or agent in charge of a facility to establish and implement a food safety plan that includes a written hazard analysis, preventive controls that the facility identifies to control hazards requiring a preventive control, and establish and implement appropriate preventive control management components to ensure the effectiveness of the preventive controls, taking into account the facility, the food, the nature of the hazard, the nature of the preventive control and its role in the facility's food safety system. As requested by the comments, the rule does not prescribe the process and methodology to "get there."

(Comment 511) Some comments interpret the statutory direction in section 418(n)(3)(C) of the FD&C Act to mean that Congress granted us authority to provide flexibility for businesses of all sizes and types (*i.e.*, not just small businesses), as well as to acknowledge differences in risk. These comments assert that section 418(n)(3)(C) grants us authority to exempt distribution centers from the requirements for hazard analysis and risk-based preventive controls because: (1) Distribution centers are very low-risk facilities and (2) requiring distribution centers to comply with those requirements would not be practicable.

(Response 511) We disagree with these comments. A pet food distribution center must register as a food facility because it holds food for animal consumption and does not satisfy any of the criteria for entities that are not required to register (see § 1.226). The preventive controls that such a facility would establish and implement would depend on the facility, the animal food, and the outcome of the facility's hazard analysis, and any preventive control management components associated with a facility's preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. In the case of a facility that is a pet food distribution center, the facility would, as part of its evaluation, determine whether any preventive controls are necessary for unexposed, non-refrigerated packaged animal foods. The facility might determine that the modified requirements in § 507.51 for unexposed, refrigerated, packaged TCS animal foods are appropriate to apply to

such foods that it holds. If so, the facility could establish its food safety plan by building on the provisions established in § 507.51.

### LII. Comments on Proposed Conforming Amendments

We proposed a series of conforming amendments to current regulations to add a reference to part 507. The affected sections in Title 21 CFR Chapter 1 are:

- § 11.1 Scope;
- § 16.1 Scope;
- § 117.95 Holding and distribution of human food by-products for use as animal food;
- § 225.1 Current good manufacturing practice;
- § 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers; and
- § 579.12 Incorporation of regulations in part 179.

We received no comments that disagree with the proposed conforming changes. Therefore, at this time we are amending each of these current regulations so that they refer to part 507 except for the amendment to part 225. We proposed to add a new paragraph (d) in § 225.1 stating that "In addition, nonmedicated feed is subject to part 507 of this chapter." All animal food facilities that are required to register as a food facility under section 415 of the FD&C Act are subject to the requirements of part 507. This would include those facilities that manufacture medicated animal feed, nonmedicated animal feed, or both. Because of this, we do not think the conforming change to part 225 is necessary and we are not finalizing this conforming change.

### LIII. Effective and Compliance Dates

#### A. Effective and Compliance Dates for Part 507

We proposed that the final rule based on proposed part 507 would become effective 60 days after its date of publication in the **Federal Register**, with staggered compliance dates (78 FR 64736 at 64751). We tentatively concluded that it was reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to comply with the rule. We also tentatively concluded that it was reasonable to allow for 2 years after the date of publication of the final rule for small businesses to comply with the rule, and 3 years after the date of publication of the final rule for very small businesses to comply with the rule.

We received one comment agreeing with our proposed compliance dates. In

the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, these proposed compliance dates. After considering these comments, we have concluded that additional time is needed for the animal food industry to comply with this final rule. Therefore, the compliance date for implementation of subpart C, Hazard Analysis and Preventive Controls and subpart E, Supply-Chain Program, is extended one year beyond the compliance date for the implementation of subpart B, Current Good Manufacturing Practice. Businesses other than small and very small businesses will have 1 year after the date of publication to comply with the CGMP requirements and 2 years after publication to comply with preventive controls and supply-chain requirements. Small businesses will have 2 years after publication to comply with the CGMP requirements and 3 years after publication to comply with preventive controls and supply-chain requirements. Very small businesses will have 3 years after publication to comply with the CGMP requirements and 4 years after publication to comply with preventive controls requirements.

In addition, we are establishing an earlier compliance date for the financial records that a facility maintains to support its status as a very small business that is eligible for the qualified facility exemption in § 507.5(d). Specifically, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. (See Response 76.)

We are also establishing separate compliance dates for the supply-chain program provisions. As discussed in Response 515, a receiving facility's compliance date for the supply-chain program provisions of this rule is the later of: (1) The receiving facility's compliance date for the other preventive controls requirements under this rulemaking; (2) for a raw material or other ingredient from a supplier subject to the preventive controls requirements of this rule, six months after the receiving facility's supplier of that raw material or ingredient is required to comply with the preventive controls requirements of this rule; or (3) for a raw material or other ingredient that from a supplier subject to CGMPs, but not the preventive controls requirements of this rule, 6 months after the receiving facility's supplier of that animal food is required to comply with the CGMP requirements of this rule. See tables 32 and 33 for a summary of these compliance dates.

TABLE 32—COMPLIANCE DATES FOR THE REQUIREMENTS OF PART 507 OTHER THAN THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM (SUBPART E)

Size of business	Compliance date for sub-part B and related requirements	Compliance date for subpart C and § 507.7
Qualified facility (including very small business) as defined in § 507.3.	September 17, 2018 .....	September 17, 2019, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017.
Small business as defined in § 507.3 .....	September 18, 2017 .....	September 17, 2018.
All other businesses .....	September 19, 2016 .....	September 18, 2017.

TABLE 33—COMPLIANCE DATES FOR THE REQUIREMENTS OF THE SUPPLY-CHAIN PROGRAM (SUBPART E)

Situation	Compliance date:
A receiving facility is a small business and its supplier will be subject to the CGMPs, but not the preventive control requirements, of the animal food preventive controls rule.	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule.
A receiving facility is a small business and its supplier is subject to the animal food preventive controls rule.	The later of: September 17, 2018 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with this rule.
A receiving facility is not a small business or a very small business and its supplier will be subject to CGMPs, but not the preventive control requirements, of the animal food preventive controls rule.	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule.
A receiving facility is not a small business or a very small business and its supplier will be subject to the animal food preventive controls rule.	The later of: September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.

We also are establishing two additional compliance dates applicable to qualified facilities. We are establishing *December 16, 2019* first as the compliance date for the initial submission of the attestation by a facility that it is a qualified facility (see § 507.7(a)(1)) and the attestation by a qualified facility about its food safety practices (see § 507.7(a)(2)(i)), or that it is in compliance with non-Federal food safety law (see § 507.7(a)(2)(ii)), and second as the compliance date for the notification requirement of § 507.7(e)(1). A qualified facility that submits an attestation that it is in compliance with applicable non-Federal food safety law must notify consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (see § 507.7(e)). If an animal food packaging label is required, the required notification must appear prominently and conspicuously on the label of the animal food (see § 507.7(e)(1)). This notification requirement may require some qualified facilities to update the labels of their packaged animal food products.

(Comment 512) Some comments disagree with the proposed compliance dates and our tentative conclusion that concepts in the CGMP regulations would not be new to the animal food industry. Comments state that both large and small facilities would need to expend considerable resources to

implement the practices and procedures to comply with the new requirements. A few comments note that the complexity of the proposed regulation presents a challenge for compliance within the proposed timeframes. Because both CGMPs and preventive controls are new for the animal food industry, comments request additional time to comply with the regulations. Some comments also note that manufacturers of human food have had many years to comply with CGMPs, and the expectation that the animal food industry will comply with both CGMP and preventive controls requirements in a narrow timeframe is not reasonable. The majority of comments agree that the implementation dates for the CGMP regulations should come before the implementation date of the preventive controls regulations.

(Response 512) We agree with the comments and are extending the compliance date for implementation of the preventive controls regulations 1 year beyond the compliance date for the implementation of CGMP requirements. Because both the CGMP and preventive controls regulations are new to the animal food industry, we understand that these facilities would have been learning and implementing many new requirements during the proposed timeframe. With an extra year before they must implement preventive controls requirements, animal food facilities will be able to focus on

developing and implementing the applicable CGMPs for their facilities. Many of these CGMPs are considered prerequisites for a preventive controls program. Having CGMPs well in place before having to implement the preventive controls requirements will provide the facility with a better understanding of the additional controls that might be needed to significantly minimize or prevent any significant hazards associated with the animal food that the facility has identified. In addition, facilities will have more time to educate and train their employees on the preventive controls requirements the facility will need to implement. FDA intends to work closely with the animal food industry, extension and education organizations, and state partners to develop the tools and training programs needed to facilitate implementation of the final rule.

(Comment 513) Some comments recommend that compliance dates for the preventive controls rule for animal food be set for 3 years after the 60-day effective date of the rule, regardless of firm size.

(Response 513) We disagree with this comment. Although the requirements in this final regulation are new for the animal food industry, some individual animal food facilities, either individually or through feed industry associations, have implemented some procedures that are consistent with the proposed requirements. Not all concepts

and processes are new to the entire animal food industry, especially the larger facilities. Therefore, we conclude that these larger facilities should not need 3 years to comply with the requirements of this final regulation, in contrast to some of the very small businesses.

(Comment 514) Some comments ask us to clarify when a very small business would need to comply with the rule if the business starts up after the rule goes into effect.

(Response 514) A very small business that is operating as of the date of publication of the final rule, or begins operating any time before the compliance date for very small businesses, must comply with the rule by the compliance date for very small businesses. A very small business that begins operation any time after the compliance date for very small businesses must comply with the rule when it begins operation, and should plan accordingly.

(Comment 515) Some comments request that compliance dates for the proposed preventive controls rule coincide with the requirements of the proposed foreign supplier verification program rule.

(Response 515) We are finalizing separate compliance dates for the supply-chain program provisions of this rule. While this adds complexity, we are doing this for two main reasons. First, we are aligning, to the extent feasible, the compliance dates of the supply-chain program provisions of this rule with the compliance dates of the forthcoming FSVP rule, which we intend to publish in the coming months. This will provide greater coordination across the programs, particularly with respect to the verification of domestic and imported raw materials and other ingredients. Second, we want to minimize the likelihood that a receiving facility will be required to comply with the supply-chain program provisions of this rule before its supplier is required to comply with applicable new food safety regulations implementing FSMA. Our goal is to avoid a situation in which a receiving facility would be required to develop a supply-chain program for an animal food from a particular supplier and then be required to revise this supply-chain program shortly thereafter once the supplier is subject to an applicable new food safety regulation—specifically, the preventive controls rule for animal food. Therefore, the compliance dates for the supply-chain program have been revised. A receiving facility's compliance date for the supply-chain program provisions of this rule is the later of: (1) The receiving

facility's compliance date for the other preventive controls requirements under this rulemaking; (2) for a raw material or other ingredient from a supplier subject to the preventive controls requirements of this rule, 6 months after the receiving facility's supplier of that raw material or ingredient is required to comply with the preventive controls requirements of this rule; or (3) for a raw material or other ingredient that from a supplier subject to CGMPs, but not the preventive controls requirements of this rule, 6 months after the receiving facility's supplier of that animal food is required to comply with the CGMP requirements of this rule.

#### *B. Effective Dates for Conforming Amendments*

The conforming amendments to regulations in parts 500 and 579 are technical amendments that add a cross-reference to part 507. The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 507 are not subject to part 11. The conforming amendment to part 16 adds a reference to the scope of part 16 for new procedures in part 507, subpart D that provide a person with an opportunity for a hearing under part 16. These conforming amendments are effective on November 16, 2015, the same date as the effective date of part 507. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance dates will be determined by the dates for compliance with part 507.

#### *C. Delayed Effective Dates for Provisions That Refer to the Forthcoming Rules for Produce Safety and Third-Party Certification*

The following provisions refer to provisions we intend to establish in the near future in part 112 (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption): §§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13). In addition, paragraph (2) of the definition of "qualified auditor" in § 507.3 and § 507.135(d) refers to provisions we intend to establish in the near future in part 1, subpart M (Accredited Third-Party Food Safety Audits and Food or Facility Certification). In addition, §§ 507.105(a)(2) and 507.175(c)(2) refer to provisions we intend to establish in the near future in part 1, subpart L (Foreign Supplier Verification Programs for Food Importers). We will publish a document in the **Federal Register** announcing the effective dates of paragraph (2) of the definition of "qualified auditor" in § 507.3, and

§§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2) and 507.175(c)(13).

#### **LIV. Compliance and Enforcement**

Gaining industry compliance with the provisions of this rule is as important as establishing the provisions. A central element of our strategy to gain industry compliance is to help make available to facilities subject to this rule the education and technical assistance they need to understand and implement the requirements (Ref. 5). Within the Agency we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 5). This will allow us to respond in a timely and consistent way to industry questions on preventive controls technical and compliance issues (Ref. 5).

We also are working in collaboration with the FSPCA to develop training materials and establish training and technical assistance programs (Ref. 4) and (Ref. 6). The FSPCA includes members from FDA, State food protection agencies, the animal food industry, and academia. It is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health, a nationally-recognized leader in food safety. In addition to developing a standardized preventive controls training curriculum, the FSPCA is developing selected sections of model food safety plans for several animal food types that will provide needed instructional examples. Although we have provided funding to the FSPCA to develop a standardized preventive controls training curriculum, we are unable to fund training for individual groups who might need particular training materials.

We also are partnering with the NIFA of USDA to administer the FSMA-mandated National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, a grant program to provide technical assistance for FSMA compliance to owners and operators of small and medium-size farms and small food processors (Ref. 7). Such efforts will help ensure widespread voluntary compliance by encouraging greater understanding and adoption of established food safety standards, guidance, and protocols.

With regard to inspections, we will conduct regular inspections of domestic facilities to ensure that facilities subject to this rule are adequately implementing

the required preventive controls and supply-chain program, pursuant to our inspection authority under section 704 of the FD&C Act. Our inspections will verify that such facilities are implementing systems that effectively protect against animal food contamination, and in particular, that they comply with the rule by implementing preventive controls, including supply-chain programs, to provide assurances that any hazard requiring a preventive control or supply-chain applied control has been significantly minimized or prevented.

In order to effectively carry out this new paradigm of animal food safety, we will need to reorient and retrain our staff. To this end, we are seeking additional funding, including for the training of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities (Ref. 10).

We also plan to leverage the resources of State, local, tribal, and territorial governments to conduct domestic verification activities. We are working with officials from these governments through the PFP to develop and implement a national Integrated Food Safety System, which will focus on establishing partnerships for achieving compliance (see section 209(b) of FSMA), and which will allow us to utilize the thousands of State, local, and tribal inspectors available to help with the domestic verification process.

Section 201 of FSMA mandates that FDA inspect domestic high-risk facilities no less than once every 3 years. Consistent with FSMA, FDA will use its current resources, new resources that it obtains, and its partnerships to conduct regular inspections of covered facilities, focusing on those facilities that pose the highest risk to animal food safety.

#### LV. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A tribal summary impact statement has been prepared that includes a summary of tribal officials' concerns and how FDA has addressed them (Ref. 63). Persons with access to the Internet may obtain the tribal consultation report at <http://www.fda.gov/pcafrule> or at <http://www.regulations.gov>. Copies of the tribal summary impact statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### LVI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866,

Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. FDA has developed an FRIA that presents the benefits and costs of this final rule (Ref. 60). The Office of Management and Budget (OMB) has determined that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

The summary analysis of benefits and costs included in this document is drawn from the detailed FRIA (Ref. 60) which is available at <http://www.regulations.gov> (enter Docket No. FDA–2011–N–0922), and is also available on FDA's Web site at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. Because the final rule would impose annualized costs that range from \$25,000 to \$34,000 on many small entities, the Agency determined that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule will likely result in a 1-year expenditure that will meet or exceed this amount.

#### LVII. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment (Ref. 64). Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### LVIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in this section with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.

*Description:* Regulations issued in the final rule entitled, “Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” implement section 418 of the FD&C Act, as amended by the FDA Food Safety Modernization Act (FSMA). The regulations establish science-based minimum standards for conducting a hazard analysis, documenting hazards requiring preventive controls, implementing preventive controls, and documenting the implementation of the preventive controls by domestic and foreign animal food facilities registered with FDA under section 415 of the FD&C Act. The regulations also establish current good manufacturing practice for the manufacturing, processing, packing, and holding of animal food.

The preventive controls regulations require animal food facilities to have a written food safety plan that includes a hazard analysis; a description of preventive controls (including recall procedures); a supply-chain program, a description of procedures for monitoring the preventive controls; corrective action if preventive controls are not properly implemented; and a description of procedures for verifying implementation and effectiveness of the preventive controls.

The regulations further require facilities to establish and implement verification procedures for product testing and environmental monitoring, and require that the hazard analysis and risk-based preventive controls for animal food take into account the possibility of economically motivated adulteration of animal food. Facilities that manufacture, process, pack, or hold food for animals and foods for human consumption and are subject to part 117 (as finalized elsewhere in this issue of the **Federal Register**) may choose to comply with part 117 with respect to the animal food, provided the food safety plan addresses the hazards specific to animal food where applicable.

The final rule also establishes certain exemptions, under applicable specific regulations. The rule imposes specific

reporting requirements on facilities claiming the very small business qualified facility exemption.

*Description of Respondents:* Facilities that manufacture, process, pack, or hold food for animals. Generally, a facility is required to register if it manufactures, processes, packs, or holds animal food for consumption in the United States. At the time of this analysis, the number of animal food facilities registered with the Agency was 7,469.

In the **Federal Register** of October 29, 2013 (78 FR 64736), FDA published a proposed rule including a Paperwork Reduction Act (PRA) analysis of the information collection provisions found in the regulations. In the **Federal Register** of September 29, 2014 (79 FR 58476), FDA published a supplemental notice of proposed rulemaking also including a PRA analysis. Although FDA did not receive comments

specifically addressing the four information collection topics solicited in both the 2013 proposed preventive controls rule for animal food and the 2014 supplemental notice, we have revised our burden estimate consistent with finalization of the rule's requirements.

FDA estimates the burden for this information collection as follows:

**Reporting Burden**

Table 34 shows the total estimated annual reporting burden associated with this final rule. This estimate is a revision from reporting estimates found in our proposed rulemaking, reflecting an updated count of the number of facilities registered with the Agency as animal food facilities, and resulting in an overall decrease from our previous estimate.

TABLE 34—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
507.7 exemption: submit attestation that facility is a qualified facility and attestation of preventive controls or compliance with non-Federal food safety laws .....	1,120	.5	560	*.5	280
507.67, 507.69, and 507.71; submission of an appeal, including submission of a request for an informal hearing .....	1	1	1	4	4
507.85(b); requests for reinstatement of exemption .....	1	1	1	2	2
<b>Total</b> .....	.....	.....	.....	.....	286

<sup>1</sup> Capital and other costs of implementation and compliance for this final rule are discussed in the FRIA (Ref. 60).  
\* (30 minutes).

Out of 7,469 animal food facilities registered with FDA, we estimate approximately 15% (1,120) could be “qualified” facilities under the “very small business” definition as discussed in the FRIA (Ref. 60), and thus eligible for certain limited exemptions under the applicable regulations. Section 507.5 exempts qualified facilities from subpart C and E of the regulations, which includes all of the hazard analysis and preventive controls requirements, including supply-chain program requirements. The number of respondents in table 34, row 1 is derived from Agency estimates of the number of qualified animal food facilities that must report their status as such a facility every 2 years. The number of total annual responses is calculated by multiplying the number of respondents by the number of responses submitted annually. The average hourly time burden per response found in table 34, column 5 is based on FDA’s assumption that a facility will report its status electronically through a Web

portal maintained by FDA, and that this will take approximately 0.5 hours (30 minutes).

The estimated burden associated with the requirements under §§ 507.67, 507.69, and 507.71 of the regulations is reflected in table 34, row 2. Based on the limited data on foodborne illness outbreaks originating at very small animal food facilities, FDA does not expect to withdraw many qualified facility exemptions and expects the number of appeals to be even fewer. The estimated number of respondents is based on the Agency’s expectation that the number of appeals will be very few. The number of responses per respondent reflects that the rule only requires one submission per appeal. Given that facilities must respond with particularity to the facts and issues contained in the withdrawal order, the Agency estimates an average burden of 4 hours per response.

The estimated burden associated with the requirements under § 507.85(b) is reflected in table 34, row 3. The Agency

expects few, if any, requests for reinstatement of an exemption that has been withdrawn under the regulations and thus is providing an estimate of only 1 per year at this time. We estimate the time necessary for making such a request to be no more than 2 hours, which includes submitting the written request and presenting information that the animal food safety problems were adequately resolved and continued withdrawal of the exemption is not necessary to protect public (human and animal) health.

**Recordkeeping Burden**

Table 35 shows the total estimated annual recordkeeping burden associated with this final rule. This estimate is a revision from the recordkeeping estimates found in our proposed rulemaking, reflecting an updated count of the number of registered animal food facilities, as well as additional recordkeeping requirements associated with the various preventive control provisions and recordkeeping

requirements associated with the supply-chain program implemented at Subpart E.

TABLE 35—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR part 507; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
<b>Subpart A—General Provisions</b>					
507.7(e); records attesting that the facility is a “qualified” facility.	1,120	.5	560	.1 (6 minutes) .....	56
507.4(d); documentation of animal food safety and hygiene training.	7,469	0.75	5,579	0.04 (2 minutes) ..	279
<b>Subpart C—Hazard Analysis and Risk-Based Preventive Controls</b>					
507.31–507.55; food safety plan, including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, and verification; recall plan; validation; reanalysis; modifications; and implementation records.	7,469	519	3,876,411	.10 (6 minutes) ....	387,641
<b>Subpart E—Supply-Chain Program</b>					
507.105–507.175; written supply-chain program, including records documenting program.	7,469	519	3,876,411	.10 (6 minutes) ....	387,641
<b>Subpart F—Requirements Applying to Records</b>					
507.200–507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	.10 (6 minutes) ....	387,641
Total .....	.....	.....	11,629,793	.....	1,163,258

<sup>1</sup> Capital and other costs of implementation and compliance with this final rule are discussed in the FRIA (Ref. 60).

Under the final rule, we estimate a total of 7,469 respondents (the number of registered animal food facilities) are subject to recordkeeping requirements found in the applicable regulations. Although FDA believes that, in some cases, all respondents will incur new recordkeeping activities as a result of the final rule (e.g., documentation of training in the principles of animal food hygiene and safety), we believe other provisions may apply only to certain respondents (e.g., documentation of a supply-chain program), depending upon the applicable regulation. With regard to

the hazard-analysis and risk-based preventive controls, the supply-chain program, and the requirements applying to records under part 507 subparts C, E, and F, respectively, we have provided a cumulative burden and averaged burden per recordkeeping that we believe will be incurred by the respondents under this final rule based on information available to us at this time. After allowing for implementation of the final rule and upon seeking reauthorization for its information collection provisions, FDA will reassess its burden estimate accordingly.

Third-Party Disclosure Burden

Table 36 shows the total estimated third-party disclosure burden associated with the final rule. This figure has been revised from the third-party disclosure estimates found in our proposed rulemaking. This revision reflects fewer than anticipated third-party disclosure requirements under the final rule and results in an overall decrease to our total estimated annual third-party disclosure burden by 36,315 hours.

TABLE 36—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

21 CFR Section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes).	825
507.7(e)(1); change labels on products with labels .....	1,526	4	6,104	1 .....	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	1,329	1	1,329	1 .....	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	330	312	102,960	.01 (1 minute)	1,030



TABLE 36—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>—Continued

21 CFR Section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
507.28(b); holding and distribution of human food by-products for use as animal food.	40,798	2	81,596	0.25 (15 minutes).	20,399
Total .....	.....	.....	.....	.....	29,687

<sup>1</sup> Capital and other costs of implementation and compliance for this final rule are discussed in the FRIAs (Ref. 60).

Under the final rule, we estimate all (7,469) respondents are subject to third-party disclosure requirements found in the applicable regulations. The number in column 2 represents an estimated annual number of those respondents we believe will incur third-party disclosure burdens under the respective regulation shown in column 1. This figure is derived from our familiarity with third-party burden associated with similar FDA regulations. Upon implementation of the final rule, the Agency will reevaluate its estimate accordingly.

To calculate the number of annual disclosures, we multiplied the number of respondents in column 2 by an estimated number of disclosures in column 3. This figure represents the estimated annual number of disclosures per respondent we attribute for the respective requirement. To calculate the annual hourly burden, we multiplied the number of annual disclosures by an estimated hourly burden in column 5. This figure represents the amount of time we attribute to conducting the respective disclosure activities identified in column 1.

Section 507.7(a)(2) provides that qualified facilities must either submit to FDA attestation of hazard identification, preventive controls implementation, and monitoring, or attestation that the facility is in compliance with applicable non-Federal food safety law.

Section 507.7(e) requires a qualified facility that chose the latter to notify consumers of the name and business address of the facility where the animal food was manufactured or processed: (1) On the label if a package label is required by other provisions of the FD&C Act or (2) on labeling at the point of purchase if no label is required.

Section 507.25(a)(2) provides that the management of the plant must ensure that animal food, including raw materials, other ingredients, or rework, is accurately identified as part of plant operations. (See §§ 7.49 and 7.42(b)(1) and (2) (21 CFR 7.49 and 7.42(b)(1) and (2)).)

Section 507.38(b)(1) and (2) does not add to the estimated hourly burden because facilities initiating recalls may

notify consignees and the public. (See §§ 7.49 and 7.42(b)(1) and (2)).

Under section 507.28(b), labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-product for use as animal food when distributed. The estimated number of disclosures per respondent and average burden per disclosure assumes that 60 percent of the 67,996 domestic human food manufacturing facilities (Ref. 65) or 40,798 facilities are affected, and that two sets of labeling per facility per year will be required. We estimate 0.25 hours per disclosure to prepare labeling, and affix to the containers, for a total of 20,399 burden hours.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**LIX. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**LX. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses in this section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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**List of Subjects**

**21 CFR Part 11**

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

**21 CFR Part 16**

Administrative practice and procedure.

**21 CFR Part 117**

Food packaging, Foods.

**21 CFR Part 500**

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

**21 CFR Part 507**

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

**21 CFR Part 579**

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

**PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES**

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.1, add paragraph (j) to read as follows:

**§ 11.1 Scope.**

\* \* \* \* \*

(j) This part does not apply to records required to be established or maintained by part 507 of this chapter. Records that satisfy the requirements of part 507 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

**PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

■ 3. The authority citation for 21 CFR part 16 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 4. In § 16.1(b)(2), add the following entry in numerical order to read as follows:

**§ 16.1 Scope.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

§§ 507.60 through 507.85 (part 507, subpart D of this chapter) relating to withdrawal of a qualified facility exemption.

\* \* \* \* \*

**PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK—BASED PREVENTIVE CONTROLS FOR HUMAN FOOD**

■ 5. The authority citation for 21 CFR part 117 continues to read as follows:

**Authority:** 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 6. Add § 117.95 to subpart B to read as follows:

**§ 117.95 Holding and distribution of human food by-products for use as animal food.**

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

**PART 500—GENERAL**

■ 7. The authority citation for 21 CFR part 500 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 8. Revise § 500.23 to read as follows:

**§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.**

Except as provided in § 507.5(b) of this chapter, the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

■ 9. Add part 507 to read as follows:

**PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK—BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS**

**Subpart A—General Provisions**

Sec.

507.1 Applicability and status.

507.3 Definitions.

507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.

507.5 Exemptions.

507.7 Requirements that apply to a qualified facility.

507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

**Subpart B—Current Good Manufacturing Practice**

507.14 Personnel.

507.17 Plant and grounds.

507.19 Sanitation.

507.20 Water supply and plumbing.

507.22 Equipment and utensils.

507.25 Plant operations.

507.27 Holding and distribution.

507.28 Holding and distribution of human food by-products for use as animal food.

**Subpart C—Hazard Analysis and Risk-Based Preventive Controls**

507.31 Food safety plan.

507.33 Hazard analysis.

507.34 Preventive controls.

507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).

507.38 Recall plan.

507.39 Preventive control management components.

507.40 Monitoring.

507.42 Corrective actions and corrections.

507.45 Verification.

507.47 Validation.

507.49 Verification of implementation and effectiveness.

507.50 Reanalysis.

507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.

507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

507.55 Implementation records required for this subpart.

**Subpart D—Withdrawal of a Qualified Facility Exemption**

507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.

507.62 Issuance of an order to withdraw a qualified facility exemption.

507.65 Contents of an order to withdraw a qualified facility exemption.

507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

507.69 Procedure for submitting an appeal.

507.71 Procedure for requesting an informal hearing.

507.73 Requirements applicable to an informal hearing.

507.75 Presiding officer for an appeal and for an informal hearing.

507.77 Timeframe for issuing a decision on an appeal.

507.80 Revocation of an order to withdraw a qualified facility exemption.

507.83 Final agency action.

507.85 Reinstatement of a qualified facility exemption that was withdrawn.

**Subpart E—Supply-Chain Program**

507.105 Requirement to establish and implement a supply-chain program.

507.110 General requirements applicable to a supply-chain program.

507.115 Responsibilities of the receiving facility.

507.120 Using approved suppliers.

507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

507.130 Conducting supplier verification activities for raw materials and other ingredients.

507.135 Onsite audit.

507.175 Records documenting the supply-chain program.

**Subpart F—Requirements Applying to Records That Must Be Established and Maintained**

507.200 Records subject to the requirements of this subpart.

507.202 General requirements applying to records.

507.206 Additional requirements applying to the food safety plan.

507.208 Requirements for record retention.

507.212 Use of existing records.

507.215 Special requirements applicable to a written assurance.

**Authority:** 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

**Subpart A—General Provisions**

**§ 507.1 Applicability and status.**

(a) The criteria and definitions in this part apply in determining whether an animal food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

(d) Except as provided by § 507.12, if a facility is required to comply with subpart B of part 507 and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control. When applying the requirements of part 117 of this chapter to animal food, the term “food” in part 117 includes animal food.

### § 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to

such terms when used in this part. The following definitions also apply:

*Adequate* means that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

*Affiliate* means any facility that controls, is controlled by, or is under common control with another facility.

*Animal food* means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

*Audit* means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier’s food safety processes and procedures.

*Calendar day* means every day shown on the calendar.

*Correction* means an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

*Critical control point* means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

*Environmental pathogen* means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

*Facility* means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

*Farm* means farm as defined in § 1.227 of this chapter.

*FDA* means the Food and Drug Administration.

*Food* means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

*Food-contact surfaces* are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the animal food or onto surfaces that contact the animal food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and animal food-contact surfaces of equipment.

*Full-time equivalent employee* is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

*Hazard* means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.

*Hazard requiring a preventive control* means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on

the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

*Holding* means storage of animal food and also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

*Known or reasonably foreseeable hazard* means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.

*Lot* means the animal food produced during a period of time and identified by an establishment's specific code.

*Manufacturing/processing* means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming,

washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

*Microorganisms* means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.

*Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

*Monitor* means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

*Packing* means placing animal food into a container other than packaging the animal food and also includes repacking and activities performed incidental to packing or repacking an animal food (e.g., activities performed for the safe or effective packing or repacking of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

*Pathogen* means a microorganism of public (human or animal) health significance.

*Pest* refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

*Plant* means the building or structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

*Preventive controls* means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe

food manufacturing, processing, packing, or holding at the time of the analysis.

*Preventive controls qualified individual* means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

*Qualified auditor* means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

*Qualified end-user*, with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

*Qualified facility* means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable

calendar year was less than \$500,000, adjusted for inflation.

*Qualified facility exemption* means an exemption applicable to a qualified facility under § 507.5(d).

*Qualified individual* means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

*Raw agricultural commodity* has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

*Receiving facility* means a facility that is subject to subparts C and E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

*Rework* means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

*Sanitize* means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

*Significantly minimize* means to reduce to an acceptable level, including to eliminate.

*Small business* means, for purposes of this part, a business employing fewer than 500 full-time equivalent employees.

*Subsidiary* means any company which is owned or controlled directly or indirectly by another company.

*Supplier* means the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

*Supply-chain-applied control* means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

*Unexposed packaged animal food* means packaged animal food that is not exposed to the environment.

*Validation* means obtaining and evaluating scientific and technical evidence that a control measure,

combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

*Verification* means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

*Very small business* means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

*Water activity* ( $a_w$ ) means a measure of the free moisture in an animal food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

*Written procedures for receiving raw materials and other ingredients* means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

*You* means, for purposes of this part, the owner, operator, or agent in charge of a facility.

#### **§ 507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.**

(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.

(b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 507.3, *i.e.*, have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties; and

(2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.

(c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.

(d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.

#### **§ 507.5 Exemptions.**

(a) This part does not apply to establishments, including "farms" (as defined in § 1.227 of this chapter), that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Subparts C and E of this part do not apply with respect to activities that are subject to § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at an animal food facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to those activities.

(2) The exemption in paragraph (b)(1) of this section is applicable only with respect to those microbiological hazards regulated under part 113 of this chapter.

(c) Subparts C and E of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, subparts C and E of this part do not apply to a qualified facility. Qualified facilities are subject to the requirements in § 507.7.

(e) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm packing or holding of processed animal food, and § 507.7 does not apply to on-farm packing or holding of processed animal food by a very small business, if the only packing or holding activities subject to section 418

of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations—*i.e.*, packing (or repacking) (including weighing or conveying incidental to packing or repacking); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Roughage products (*e.g.*, alfalfa meal, entire plant meal, stem meal, pomace, and pulp);

(2) Plant protein meals (*e.g.*, algae, coconut (copra), guar, and peanut);

(3) Grain by-products and processed grain products (*e.g.*, bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal);

(4) Oilseed products (*e.g.*, oil and meal of safflower, soybean, or sunflower);

(5) Molasses (*e.g.*, processed sugar cane, sugar beets, and citrus).;

(6) Animal protein meals (*e.g.*, blood, feather, meat, meat and bone, and marine (*e.g.*, crab, fish, shrimp));

(7) Milk products (*e.g.*, casein, cheese rind, and lactalbumin);

(8) Animal tissue-derived products (*e.g.*, fat);

(9) Vitamins, minerals, and concentrates;

(10) Processing aids (*e.g.*, enzymes, preservatives, and stabilizers); and

(11) Any other processed animal food that does not require time/temperature control for safety.

(f) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following low-risk manufacturing/processing activity/animal food combinations:

(1) Chopping or shredding hay;

(2) Cracking, crimping, flaking, pearling, peeling, shelling, or wafering—grain (*e.g.*, barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (*e.g.*, beans, canola, cottonseed, linseed, soybeans, and sunflowers);

(3) Crushing, dry rolling, grinding, milling, pulverizing—grain, oilseed, grain by-products and processed grain products, oilseed products, hay, ensiled

material, culled fruits and vegetables, roughage (*e.g.*, cobs, hulls, husks, and straws), or roughage products;

(4) Ensiling (including chopping, shredding, mixing, storing, or fermenting), that is, making silage or haylage from forage (*e.g.*, sorghum (milo), corn (maize), alfalfa, and grass), grain, culled fruits and vegetables, or roughage;

(5) Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;

(6) Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety; and

(7) Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

(g) Subparts C and E of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to any of the following:

(1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and

(3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).

#### § 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) The attestations required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) *Electronic submission.* To submit electronically, go to <http://www.fda.gov/furls> and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942b. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from <http://www.fda.gov/pcafrule/>;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c)(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By *December 16, 2019* for a facility that begins manufacturing, processing, packing, or holding animal food before *September 17, 2019*;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after *September 17, 2019*; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified



facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.

(d) When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) as follows:

(1) If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.

(2) If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f)(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

**§ 507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.**

(a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

**§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.**

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by that human food facility for distribution as animal food if:

(1)(i) The human food facility is subject to and in compliance with subpart B of part 117 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; or

(ii) For the off-farm packing and holding of produce (as defined in part 112 of this chapter), the human food facility is subject to and in compliance with § 117.8 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food facility does not further manufacture or process the by-products intended for use as animal food.

(b) The human food by-products for use as animal food identified in paragraph (a) of this section must be held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter.

**Subpart B—Current Good Manufacturing Practice**

**§ 507.14 Personnel.**

(a) The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.

(b) The methods for conforming to hygienic practices and maintaining cleanliness include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

**§ 507.17 Plant and grounds.**

(a) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.

(b) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must:

(1) Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(2) Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

(3) Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (e.g., steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;

(4) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured,

processed, packed, or held, and areas where equipment or utensils are cleaned; and

(5) Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.

(c) The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including:

(1) Using protective coverings where necessary and appropriate;

(2) Controlling areas over and around the bulk animal food to eliminate harborage for pests; and

(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

#### § 507.19 Sanitation.

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.

(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

(1) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and

(2) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.

(d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic materials described in paragraph (d)(1) of this section (e.g., cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and

(3) Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.

(e) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.

#### § 507.20 Water supply and plumbing.

(a) The following apply to the water supply:

(1) Water must be adequate for the operations and must be derived from an adequate source;

(2) Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities;

(3) Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use; and

(4) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be designed, installed, and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.

(c) Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

#### § 507.22 Equipment and utensils.

(a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:

(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

(b) Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.

(c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device.

(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH,  $a_w$ , or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.

#### § 507.25 Plant operations.

(a) Management of the establishment must ensure that:

(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

(2) Animal food, including raw materials, other ingredients, or rework is accurately identified;

(3) Animal food-packaging materials are safe and suitable;

(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(5) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;

(6) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;

(7) Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(8) All animal food manufacturing, processing, packing, and holding is

conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.

(b) Raw materials and other ingredients:

(1) Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize contamination; and

(iii) Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration, and held under conditions, *e.g.*, appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated;

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans; and

(3) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(c) For the purposes of manufacturing, processing, packing, and holding operations, the following apply:

(1) Animal food must be maintained under conditions, *e.g.*, appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;

(2) Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (*e.g.*, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling  $a_w$ ) must be adequate to prevent adulteration of animal food;

(3) Work-in-process and rework must be handled in such a way that it is

protected against contamination and the growth of undesirable microorganisms;

(4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;

(5) Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;

(6) Animal food that relies principally on the control of water activity ( $a_w$ ) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe  $a_w$  level;

(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(8) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

#### § 507.27 Holding and distribution.

(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and

(2) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.

(b) The labeling for the animal food product ready for distribution must contain, when applicable, information and instructions for safely using the animal food product for the intended animal species.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.

(d) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(e) Unpackaged or bulk animal food must be held in a manner that does not

result in unsafe cross contamination with other animal food.

**§ 507.28 Holding and distribution of human food by-products for use as animal food.**

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

**Subpart C—Hazard Analysis and Risk-Based Preventive Controls**

**§ 507.31 Food safety plan.**

(a) You must prepare, or have prepared, and implement a written food safety plan.

(b) One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.34(b);

(3) The written supply-chain program as required by subpart E of this part;

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the

preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

**§ 507.33 Hazard analysis.**

(a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and

(2) The hazard analysis must be written regardless of its outcome.

(b) The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or

otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and other ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of some natural toxins).

**§ 507.34 Preventive controls.**

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and animal food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product.

(3) Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart E of this part;

(4) A recall plan as required by § 507.38; and

(5) Other preventive controls. These include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

**§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.**

(a) If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of animal food could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to ensure that the identified hazard will be significantly minimized or prevented; and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified

hazard (except as provided in paragraph (c) of this section);

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements;

(4) You rely on your customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that your customer:

(A) Will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]”; and

(B) Will only sell to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part), except as provided in paragraph (d) of this section, or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part); or

(2) Obtain a similar written assurance from the entity’s customer, subject to the requirements of § 507.37, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(3) You have established, documented, and implemented a system that ensures

control, at a subsequent distribution step, of the hazards in the animal food product you distribute and you document the implementation of that system.

(b) You must document any circumstance specified in paragraph (a) of this section that applies to you, including:

(1) A determination in accordance with paragraph (a) of this section that the type of animal food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the animal food product you distribute.

(c) For the written assurance required by paragraph (a)(2)(ii) of this section, if your customer has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, your customer’s written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.

(d) For the written assurance required by paragraph (a)(4)(ii)(B) of this section, if the entity in the distribution chain subsequent to your customer is subject to subpart C of this part and has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, that entity’s written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance that the identified hazard will be significantly minimized or prevented.

**§ 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).**

A facility that provides a written assurance under § 507.36(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

**§ 507.38 Recall plan.**

(a) For animal food with a hazard requiring a preventive control you must:

(1) Establish a written recall plan for the animal food; and

(2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;

(3) Conduct effectiveness checks to verify the recall has been carried out; and

(4) Appropriately dispose of recalled animal food, *e.g.*, through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

#### **§ 507.39 Preventive control management components.**

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.34 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supply-chain program established in subpart E of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

#### **§ 507.40 Monitoring.**

As appropriate to the nature of the preventive control and its role in the facility's food safety system you must:

(a) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(b) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c)(1) You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i);

(2)(i) Records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control; and

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

#### **§ 507.42 Corrective actions and corrections.**

(a) As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected animal food is evaluated for safety; and

(iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem;

(ii) Reduce the likelihood that the problem will recur;

(iii) Evaluate all affected animal food for safety;

(iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(v) When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the sanitation controls in § 507.34(c)(2)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).

#### **§ 507.45 Verification.**

(a) Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

(b) All verification activities conducted in accordance with this section must be documented in records.

#### § 507.47 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with § 507.34 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan or;

(B) When necessary to demonstrate the control measures can be implemented as designed:

(1) Within 90 calendar days after production of the applicable animal food first begins;

(2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so.

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.

(c) You do not need to validate:

(1) The sanitation controls in § 507.34(c)(2);

(2) The recall plan in § 507.38;

(3) The supply-chain program in subpart E of this part; and

(4) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is

not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

#### § 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring and verification instruments (or checking them for accuracy);

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and

(ii) Records of calibration, testing (e.g., product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification

instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section;

(2) Product testing as required by paragraph (a)(2) of this section.

Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by

§ 507.42(a)(1)(ii).

#### § 507.50 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the animal food;

(3) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or,

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable animal food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

**§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.**

(a) If a facility that is solely engaged in the storage of unexposed packaged animal food stores any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged animal food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days;

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

**§ 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.**

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 507.31(b));

(2) Validation of the preventive controls (§ 507.47(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;

(4) Determination that validation is not required (§ 507.47(c)(4));

(5) Review of records (§ 507.49(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7-working days;

(7) Reanalysis of the food safety plan (§ 507.50(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food.

(b) A qualified auditor must conduct an onsite audit (§ 507.135(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility; and

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

**§ 507.55 Implementation records required for this subpart.**

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance with § 507.36(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;



(v) Product testing;  
 (vi) Environmental monitoring;  
 (vii) Records review; and  
 (viii) Reanalysis;  
 (5) Records that document the supply-chain program; and  
 (6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

#### **Subpart D—Withdrawal of a Qualified Facility Exemption**

##### **§ 507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.**

(a) FDA may withdraw a qualified facility exemption under § 507.5(d):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

##### **§ 507.62 Issuance of an order to withdraw a qualified facility exemption.**

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

##### **§ 507.65 Contents of an order to withdraw a qualified facility exemption.**

An order to withdraw a qualified facility exemption under § 507.5(d) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) Comply with subparts C and E of this part on the date that is 120 calendar days after the date of receipt of the order or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85.

(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same

information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(i) The name and the title of the FDA representative who approved the order.

##### **§ 507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.**

(a) If you receive an order under § 507.65 to withdraw a qualified facility exemption, you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If you appeal the order, and FDA confirms the order:

(1) You must comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) You are no longer subject to the requirements in § 507.7.

##### **§ 507.69 Procedure for submitting an appeal.**

(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), you may include a

written request for an informal hearing as provided in § 507.71.

**§ 507.71 Procedure for requesting an informal hearing.**

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 507.69 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

**§ 507.73 Requirements applicable to an informal hearing.**

If you request an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses)

whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under paragraph (c)(4) of this section are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3), and (a)(5), of this chapter, and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

**§ 507.75 Presiding officer for an appeal and for an informal hearing.**

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

**§ 507.77 Timeframe for issuing a decision on an appeal.**

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

**§ 507.80 Revocation of an order to withdraw a qualified facility exemption.**

An order to withdraw a qualified facility exemption is revoked if:

(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

**§ 507.83 Final agency action.**

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

**§ 507.85 Reinstatement of a qualified facility exemption that was withdrawn.**

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case

of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 507.60(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

### Subpart E—Supply-Chain Program

#### § 507.105 Requirement to establish and implement a supply-chain program.

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

(3) The requirements in this subpart do not apply to animal food that is supplied for research or evaluation use, provided that such animal food:

(i) Is not intended for retail sale and is not sold or distributed to the public;

(ii) Is labeled with the statement “Animal food for research or evaluation use”;

(iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the animal food is used only for this purpose, and any unused quantity is properly disposed of; and

(iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

#### § 507.110 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:

(1) Using approved suppliers as required by § 507.120;

(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 507.125;

(3) Conducting supplier verification activities as required by §§ 507.130 and 507.135;

(4) Documenting supplier verification activities as required by § 507.175; and

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 507.175, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 507.175.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

(4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the animal food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of animal food and other FDA compliance actions related to animal food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 507.3;

(ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or

(iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or other ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

**§ 507.115 Responsibilities of the receiving facility.**

(a)(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct, the appropriate supplier verification activities, with appropriate documentation.

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any

of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 507.110(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135.

**§ 507.120 Using approved suppliers.**

(a) The receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b)(1) Written procedures for receiving raw materials and other ingredients must be established and followed;

(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and

(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.

**§ 507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).**

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d).

**§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.**

(a) Except as provided by paragraphs (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 507.110(b), as determined under § 507.110(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals:

(i) The appropriate supplier verification activity is an onsite audit of the supplier; and

(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

(2) The requirements of paragraph (b)(1) of this section do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(c) If a supplier is a qualified facility as defined by § 507.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 507.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the animal food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interest that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity.

#### **§ 507.135 Onsite audit.**

(a) An onsite audit of a supplier must be performed by a qualified auditor.

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its

implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(c)(1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

#### **§ 507.175 Records documenting the supply-chain program.**

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 507.49(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification

activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(i) The name of the supplier subject to the onsite audit;

(ii) Documentation of audit procedures;

(iii) The dates the audit was conducted;

(iv) The conclusions of the audit;

(v) Corrective actions taken in response to significant deficiencies identified during the audit; and

(vi) Documentation that the audit was conducted by a qualified auditor;

(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:

(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted and the date of the report;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing;

(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:

(i) The name of the supplier whose records were reviewed;

(ii) The date(s) of review;

(iii) The general nature of the records reviewed;

(iv) The conclusions of the review; and

(v) Corrective actions taken in response to significant deficiencies identified during the review;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(11) Documentation of any determination that verification activities

other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals;

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

(i) The written assurance that the supplier is a qualified facility as defined by § 507.3; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable

or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

#### **Subpart F—Requirements Applying to Records That Must Be Established and Maintained**

##### **§ 507.200 Records subject to the requirements of this subpart.**

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.

(b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

(d) The requirements of § 507.206 apply only to the written food safety plan.

(e) The requirements of § 507.202(a)(2), (4), and (5) and (b) do not apply to the records required by § 507.7.

##### **§ 507.202 General requirements applying to records.**

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(c) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

##### **§ 507.206 Additional requirements applying to the food safety plan.**

The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification.

##### **§ 507.208 Requirements for record retention.**

(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the

applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.*, because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the written food safety plan (§ 507.45(b))).

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

**§ 507.212 Use of existing records.**

(a) Existing records (*e.g.*, records that are kept to comply with other Federal,

State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

**§ 507.215 Special requirements applicable to a written assurance.**

(a) Any written assurance required by this part must contain the following elements:

- (1) Effective date;
- (2) Printed names and signatures of authorized officials;
- (3) The applicable assurance under:
  - (i) § 507.36(a)(2);
  - (ii) § 507.36(a)(3);
  - (iii) § 507.36(a)(4);
  - (iv) § 507.130(c)(2);
  - (v) § 507.130(d)(2); or
  - (vi) § 507.130(e)(2).

(b) A written assurance required under § 507.36(a)(2), (3) or (4) must include:

- (1) Acknowledgement that the facility that provides the written assurance

assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and

(2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

**PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD**

■ 10. The authority citation for 21 CFR part 579 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 348, 371.

■ 11. In § 579.12, add the following sentence to the end of the paragraph to read as follows:

**§ 579.12 Incorporation of regulations in part 179.**

\* \* \* Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.

Dated: August 31, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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Part IV

## Department of Health and Human Services

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Food and Drug Administration

21 CFR Part 117

Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Final Rule



**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 117**

[Docket No. FDA-2012-N-1258]

**Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the RA). The purpose of the RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk when conducted in a food facility co-located on a farm. We conducted this RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

**DATES:** September 17, 2015.**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the RA.**FOR FURTHER INFORMATION CONTACT:** Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of January 16, 2013 (78 FR 3824), we announced the availability of a draft qualitative risk assessment (RA) (Ref. 1) related to manufacturing, processing, packing, and holding activities for human food when such activities are conducted in a food facility co-located on a farm. We reopened the comment period on March 13, 2013 (78 FR 15894) and also extended the comment period on April 26, 2013 (78 FR 24693). We gave interested parties an opportunity to submit comments by September 16, 2013, for us to consider on the approach used, the assumptions made, the

modeling techniques, the data used, and the clarity and the transparency of the RA documentation. We received more than two dozen comments on the draft RA and have revised it where appropriate (Refs. 2 and 3).

The purpose of the RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk when conducted in a food facility co-located on a farm. We conducted this RA to satisfy FSMA's requirements to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities involving specific foods that we determine to be low risk from requirements specified in sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350g and 21 U.S.C. 350j, respectively), or whether to modify such requirements for such facilities. See 78 FR 3824 at 3825 to 3826 for additional background information on FSMA, the requirements of sections 418 and 421 of the FD&C Act, the focus of the RA, the approach used, the nine specific questions addressed by the RA, and our request for comments.

Before making the draft RA available for public comment, we submitted an earlier version of the draft RA to a group of scientific experts external to FDA for peer review and revised that earlier version, as appropriate, considering the experts' comments. A report concerning the external peer review is available for public review and can be accessed from our Web site (Ref. 4).

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to implement section 418 of the FD&C Act for human food. That final rule establishes requirements for certain food facilities to conduct a hazard analysis and to identify and implement risk-based preventive controls. In that final rule, we use the results of the RA to exempt food facilities that are small or very small businesses, co-located on a farm, from these requirements when such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the RA as low-risk activity/food combinations.

**II. Electronic Access**

The RA and our response to comments on the draft RA are available electronically at <http://www.regulations.gov>, <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>, and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>, and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

**III. References**

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. FDA, "Draft Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2012. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>. See Reference 1 to the notice of availability of the draft risk assessment.

2. FDA, "Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2015. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

3. FDA, "Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm. Response to Public Comments," 2015. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

4. FDA, "Peer Review Report. External Peer Review of the FDA/CFR Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2012. Available at: <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>. See Reference 3 to the notice of availability of the draft risk assessment.

Dated: August 31, 2015.

**Leslie Kux,***Associate Commissioner for Policy.*

[FR Doc. 2015-21922 Filed 9-10-15; 8:45 am]

**BILLING CODE 4164-01-P**



# FEDERAL REGISTER

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Part V

## Department of Health and Human Services

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Food and Drug Administration

21 CFR Part 507

Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 507**

[Docket No. FDA-2013-N-1043]

**Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” (the RA). The purpose of the RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk when conducted in an animal food facility co-located on a farm. We conducted this RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

**DATES:** September 17, 2015.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the RA.

**FOR FURTHER INFORMATION CONTACT:** Mary J. Bartholomew, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6224.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 29, 2013 (78 FR 64428), we announced the availability of a draft qualitative risk assessment (RA) (Ref. 1) related to manufacturing, processing, packing, and holding activities for animal food when such activities are conducted in an animal food facility co-located on a farm. Interested parties were given the opportunity to submit comments by

February 26, 2014, for us to consider on the approach used, the assumptions made, how risk was determined, the data used, and the clarity and the transparency of the RA documentation. We extended the comment period on February 3, 2014 (79 FR 6116), to March 31, 2014. We received 11 comments on the draft RA and have revised it where appropriate (Ref. 2).

The purpose of the RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk when conducted in an animal food facility co-located on a farm. We conducted this RA to satisfy FSMA’s requirements to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities involving specific animal food that we determine to be low risk from requirements specified in sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350g and 350j, respectively), or whether to modify such requirements for such facilities. See 78 FR 64428 through 64429 for additional background information on FSMA, the requirements of sections 418 and 421 of the FD&C Act, the focus of the RA, the approach used, the nine specific questions addressed by the RA, and our request for comments.

Before making the draft RA available for public comment, we submitted an earlier version of the draft RA to a group of scientific experts external to FDA for peer review and revised that earlier version, as appropriate, considering the experts’ comments. A report concerning the external peer review is available for public review and can be accessed from our Web site (Ref. 3).

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to implement section 418 of the FD&C Act for food for animals. That final rule establishes current good manufacturing practice requirements for animal food facilities and establishes requirements for certain animal food facilities to conduct a hazard analysis and to identify and implement risk-based preventive controls. In that final rule, we use the results of the RA to exempt animal food facilities that are small or

very small businesses, co-located on a farm, from these requirements when such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the RA as low-risk activity/animal food combinations.

**II. Electronic Access**

The RA and our response to comments on the draft RA are available electronically at <http://www.regulations.gov>, <http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf>, and <http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM459595.pdf>.

**III. References**

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. FDA, “Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2012. Available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf>.
2. FDA, “Qualitative Risk Assessment. Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2015. Available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM459595.pdf>.
3. FDA, “Peer Review Report. External Peer Review of the FDA/CVM Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2013. Available at <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

Dated: August 31, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-21923 Filed 9-10-15; 8:45 am]

**BILLING CODE 4164-01-P**



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Part VI

The President

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Proclamation 9322—National Hispanic Heritage Month, 2015



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# Presidential Documents

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Title 3—

Proclamation 9322 of September 14, 2015

The President

National Hispanic Heritage Month, 2015

By the President of the United States of America

## A Proclamation

Throughout our history, our Nation has been enriched by the storied pasts of all who call the United States of America home. America's Hispanic community has woven unique threads into the diverse fabric of our country and played an important role in shaping our national character as a people of limitless possibility. This month, let us honor their distinct heritage while reaffirming our commitment to enabling them to build a future bright with hope and opportunity for themselves, their families, and the country we love.

Hispanics contribute to our Nation's success in extraordinary ways—they serve in the military and government, attend schools across America, and strengthen the economy. They are the father who works two jobs to give his children a better life, and the mother who ventures out to take a risk and start a business. They are the student—often the first in their family to go to college—who pursues their greatest aspirations through higher education. They are the lawful permanent resident who seeks to naturalize and become a citizen, and the business leader whose loved ones have lived in the United States for generations. Each day, we see the tremendous impact they have on our communities, and they reflect an enduring truth at the heart of our Nation: no matter where you come from or where your roots are, with hard work and perseverance you can make it in America.

My Administration remains committed to ensuring Hispanics have every opportunity to achieve the American dream. Last year, we approved more than 4,000 loans totaling over \$1 billion for Hispanic-owned small businesses, helping create jobs and improve local economies. We have invested resources in education and reformed our schools to provide the opportunities every Hispanic student needs to graduate from high school prepared for the future they will inherit. We have also expanded high-quality preschool and early childhood education for our youngest learners in Latino communities, and provided grants and loans to assist tens of thousands of Hispanic young people and adults on their journey toward earning a college degree. The dropout rate for Hispanic students has been cut by more than half since the year 2000, and college enrollment has risen by 45 percent since 2008. Additionally, since I signed the Affordable Care Act in 2010, the share of Hispanics under 65 without health insurance has fallen by one-third, and in the years ahead I will continue working to address the health disparities that still exist. And we are expanding the cultural, economic, and familial ties that so many Hispanic Americans share with Latin America by entering a new chapter of engagement and cooperation with Cuba.

The United States has a centuries-old tradition of welcoming immigrants, which has given us a tremendous advantage over the rest of the world. Last year, I took action to fix our broken immigration system within the confines of the law. The policies include offering temporary relief to parents of children who are United States citizens or lawful permanent residents so they could come out of the shadows, get right with the law, and further contribute to America's success while also providing for their loved ones—because as a Nation that values families, we must work together to keep

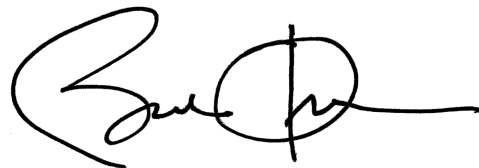
them together. I also took steps to modernize the legal immigration system for families, employers, and workers, and strengthened Federal immigrant integration efforts. I created the White House Task Force on New Americans—a Federal interagency effort focused on strengthening and enhancing our efforts to integrate new Americans and build welcoming communities. And we are working to make sure the millions of individuals who are eligible for citizenship understand the opportunities, rights, and responsibilities that it affords. While these actions make our system better, they are not a permanent fix to our broken immigration system—and that is why I continue to call on the Congress to pass meaningful, comprehensive immigration reform.

As a Nation, we are bound by our shared ideals. America's Hispanic community has the same dreams, values, trials, and triumphs of people in every corner of our country, and they show the same grit and determination that have carried us forward for centuries. During National Hispanic Heritage Month, let us renew our commitment to honoring the invaluable ways Hispanics contribute to our common goals, to celebrating Hispanic culture, and to working toward a stronger, more inclusive, and more prosperous society for all.

To honor the achievements of Hispanics in America, the Congress by Public Law 100-402, as amended, has authorized and requested the President to issue annually a proclamation designating September 15 through October 15 as "National Hispanic Heritage Month."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim September 15 through October 15, 2015, as National Hispanic Heritage Month. I call upon public officials, educators, librarians, and all Americans to observe this month with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of September, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.



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