work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual’s entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the Administrator or the HHS Secretary for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the Administrator or HHS Secretary before that individual enters areas under escort where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual’s entry into where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

(e) The responsible official must ensure and document that individuals are provided the contact information of the USDA Office of Inspector General Hotline and the HHS Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

29. Section § 121.16 is amended as follows:

a. In paragraph (a)(1)(iii), by adding the words “or other storage container” after the word “freezer.”

b. By revising paragraph (a)(1)(v).

c. In paragraph (a)(3)(v), by adding the words “or other storage container” after the word “freezer”.  

d. By removing the word “and” at the end of paragraph (a)(6) and removing the period at the end of paragraph (a)(7) and adding the word “; and” in its place.

e. By adding paragraph (a)(8).

f. By revising paragraphs (b) and (c).

The addition and revisions read as follows:

§ 121.17 Records.

(a) * * *

(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition;  

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity responsible official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;  

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the principal investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the principal investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate and legible, have controlled access, and that their authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocertification certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Done in Washington, DC, this 10th day of January 2017.

Elvis S. Cordova,  
Acting Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2017–00857 Filed 1–18–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981


Almonds Grown in California; Change in Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule implementing a recommendation from the Almond Board of California (Board) that relaxed the quality control requirements prescribed under the California almond marketing order (order). The Board locally administers the order and is comprised of growers and handlers operating within California. The interim rule relaxed incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation decreases California almond handlers’ disposition obligation. This change also allows handlers more flexibility in their operations while continuing to maintain quality control and ensuring compliance with the order’s requirements.


FOR FURTHER INFORMATION CONTACT: Andrea Ricci, Marketing Specialist or Jeffrey Smuthy, Regional Director, California Marketing Field Office,
Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: Andrea.Ricci@ams.usda.gov or Jeffrey.Smutny@ams.usda.gov.

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: http://www.ams.usda.gov/rules-regulations/moa/small-businesses; or by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California, hereinafter referred to as the “order.” The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.”

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

Section 981.442 of the order regulates almond quality, including the percentage of inedible (low quality) kernels required to be disposed of by handlers. Previously, the weight of inedible kernels in excess of 0.50 percent of kernel weight of almonds received by each handler constituted the handler’s disposition obligation. Handlers must satisfy their obligation by disposing of the inedible kernels in Board-accepted, non-human outlets such as animal feed or oil.

In the past several years, total inedible kernel percentages have been trending lower. This is partially due to good agricultural practices used by growers and better technologies in handler facilities. At the same time, the market value of almonds has increased significantly. As a result, some of the Board-accepted outlets have started to clean and repurpose almonds disposed under the obligation causing concern that product is being sold for human consumption without following the order’s outgoing quality requirements. Increasing the inedible kernel tolerance to 2 percent provides handlers more control over low quality product, helping ensure any product destined for human consumption is compliant with the order’s outgoing quality requirements. In an interim rule published in the Federal Register on August 17, 2016, and effective on August 18, 2016, (81 FR 54719, Doc. No. AMS–SC–16–0047, SC16–981–3 IR), § 981.442(a)(4)(i) was amended by changing the disposition obligation from 0.5 percent to 2 percent. This rule continues in effect that action.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 6,800 almond growers in the production area and approximately 100 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

The National Agricultural Statistics Service (NASS) reported in its 2012 Agricultural Census that there were 6,841 almond farms in the production area (California), of which 6,204 had bearing acres. The following computation provides an estimate of the proportion of producers (farms) and agricultural service firms (handlers) that would be considered small under the SBA definitions.

The NASS Census data indicates that out of the 6,204 California farms with bearing acres of almonds, 4,471 (72 percent) have fewer than 100 bearing acres. For the almond industry’s most recently reported crop year (2015), NASS reported an average yield of 2,130 pounds per acre, and a season average grower price of $2.84 per pound. A 100-acre farm with an average yield of 2,130 pounds per acre would produce about 213,000 pounds of almonds. At $2.84 per pound, that farm’s production would be valued at $604,920. Since Census data indicates that the majority of California’s almond farms are smaller than 100 acres, it could be concluded that the majority of growers had annual receipts from the sale of almonds in 2015 of less than $604,920, which is below the SBA threshold of $750,000. Thus, over 70 percent of California’s almond growers would be considered small growers according to SBA’s definition.

According to information supplied by the Board, approximately 30 percent of California’s almond handlers shipped almonds valued under $7,500,000 during the 2014–15 crop year, and would, therefore, be considered small handlers according to the SBA definition.

This rule continues in effect the revision of § 981.442(a)(4)(ii), which relaxed incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation decreases California almond handlers’ disposition obligation, and also allows handlers more flexibility in their operations while continuing to maintain quality control and ensuring compliance with the order’s requirements. Authority for this action is provided in § 981.42(a) of the order.

Regarding the impact of this action on affected entities, increasing the inedible kernel tolerance reduces disposition obligation on handlers and provides handlers with more flexibility and control over the low quality product. This rule is not expected to change handler inspection costs, as handlers currently are required to have all lots inspected to determine the percentage of inedible kernels.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order’s information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 (Vegetable and Specialty Crops.) No changes are necessary in those requirements as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large almond handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Furthermore, the Board’s meeting was widely publicized throughout the almond industry and all interested
persons were invited to attend the meeting and participate in Board deliberations. Like all Board meetings, the April 12, 2016, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue.

Comments on the interim rule were required to be received on or before October 17, 2016. Two comments were received. One commenter stated that this change will allow almond handlers to have more flexibility with their operations. The other commenter stated the increase in tolerance should lead to a decrease in price. Marketing orders do not regulate price. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: https://www.regulations.gov/docket?D=AMS-SC-16-0047.

This action also affirms information contained in the interim rule concerning Executive Orders 12866, 12988, 13175, and 13563; the Paperwork Reduction Act (44 U.S.C. Chapter 35); and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the Federal Register (81 FR 54719) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

PART 981—ALMONDS GROWN IN CALIFORNIA

Accordingly, the interim rule that amended 7 CFR part 981 and that was published 81 FR 54719 on August 17, 2016, is adopted as a final rule, without change.

Dated: January 9, 2017.

Bruce Summers,
Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2017–00589 Filed 1–18–17; 8:45 am]
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