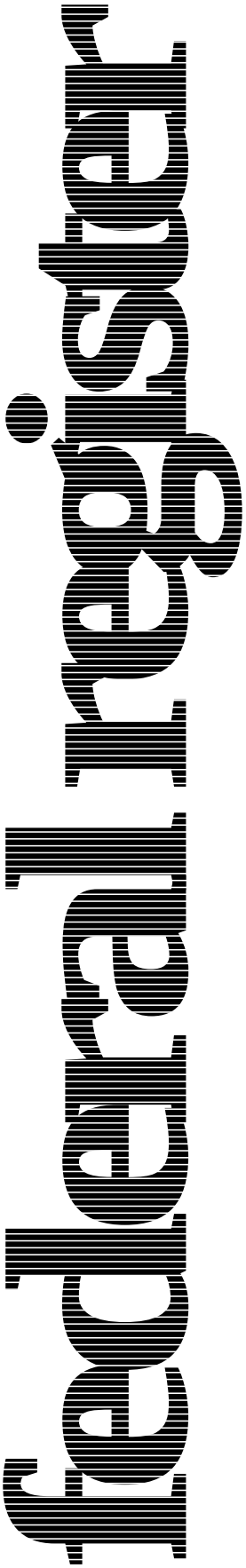
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Friday
February 3, 1995

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

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[INS No. 1435–92: AG Order No. 1946–95]

RIN 1115–AC58

Administrative Naturalization

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule establishes procedures implementing an administrative naturalization process as provided for by recent changes in the immigration laws. The rule streamlines the administrative naturalization process since the courts are now removed from routing decisions approving applicants for naturalization. As a result of this rule, applications for naturalization will be processed to completion within the immigration and Naturalization Service (the Service), with the role of the courts limited to administration of the oath of allegiance in some circumstances, and judicial review of administrative denials.

EFFECTIVE DATE: February 3, 1995.

FOR FURTHER INFORMATION CONTACT: William Tollifson, Adjudications Officer, Naturalization and Special Projects Branch, Adjudications Division, Immigration and Naturalization Service, room 3214, 425 I Street, NW., Washington, DC 20536, telephone: (202) 514–5014.

SUPPLEMENTARTY INFORMATION: This rule finalizes two previous interim rules published by the Immigration and Naturalization Service to implement procedures for administrative naturalization. Title IV of the Immigration Act of 1990 (Pub. L. 101–649) (IMMACT), effective October 1, 1991, transferred jurisdiction over naturalization from the judiciary to the Attorney General, subject to judicial review, and redefined the naturalization process as an administrative proceeding. On October 7, 1991, the Service published in the **Federal Register** an interim rule to implement the procedures governing administrative naturalization. 56 FR 50475. Before a final rule could be drafted, however, Congress enacted the Miscellaneous and Technical Immigration and Naturalization Amendments of 1991 (Pub. L. 102–232) (Technical Amendments), effective January 11, 1992, which significantly changed several statutory provisions relating to administrative naturalization. The Service then published a second interim rule in the **Federal Register** on September 24, 1993, at 58 FR 49905, to implement the changes brought about by the Technical Amendments. That second interim rule also incorporated changes based on public comments received on the first interim rule. This rule adopts as final both the first interim rule (October 7, 1991) and the subsequent changes in the second interim rule (September 24, 1993). This final rule also includes changes based on public comment, and some minor changes resulting from the Service's experience in working with the two interim rules.

As noted above in the two previous interim rules, IMMACT amended the naturalization process so that the judiciary no longer holds exclusive jurisdiction over naturalization applications. It is now the responsibility of the Service not only to receive applications for naturalization and to conduct examinations to determine statutory eligibility for citizenship, but also to render formal determinations on applications for naturalization, to provide for administrative review of such determinations, and to issue naturalization certificates. The judiciary's participation in the naturalization process is limited to administering the oath of allegiance and renunciation for persons whom the Service determines to be admissible to citizenship and to reviewing administrative denials.

The Technical Amendments clarified and revised some changes made by IMMACT in several areas relating to the administrative naturalization process. Most notably, a federal or state court now may elect to exercise exclusive jurisdiction to administer the oath of allegiance to applicants for naturalization under certain circumstances. Also added by the Technical Amendments is the requirement that the Attorney General rather than a court, promptly prepare a naturalization certificate for each person to be administered the oath of allegiance by a court, and then transmit that certificate to the court having jurisdiction to administer the oath. This process reduces administrative costs to the courts while maintaining naturalization as a source of court revenue and also ensures that a certificate of naturalization prepared by the Service can be delivered to the applicant at the time of the administration of the oath, regardless of whether the oath administration ceremony is judicial or administrative. The Technical Amendments also provide a means by which an applicant facing special circumstances may participate in an oath administration ceremony without having to wait until the date of the next public ceremony. The court now has discretion to consider special circumstances in determining whether to administer the oath immediately in a private judicial ceremony, or to refer the person to the Attorney General for immediate administrative naturalization.

Comments on the Interim Rule Published on September 24, 1993

The Service received six comments from the public in response to the September 24, 1993, interim rule. These comments covered 14 specific areas. Only one of the comments addressed issues arising under the Technical Amendments provisions for exclusive jurisdiction of the courts in administering the oath of allegiance. The remaining comments related to issues addressed in both interim rules. The discussion that follows summarizes the issues raised in the comments, provides the Service's position on these issues, and explains the revisions adopted.

Two of the commenters focused on standardized testing of knowledge of the

United States government and history and English literacy, covered in 8 CFR part 312. These two commenters, Educational Testing Services and Comprehensive Adult Student Assessment System, felt that § 312.3(a)(1) as written did not clearly provide that a standardized test of knowledge of United States government and history and English literacy could be taken even after the submission of an application for naturalization, so long as the results were presented as part of the interview process. Both commenters provided suggested language. While the Service agrees that the original language needs clarification, the commenters' suggested language was not accepted because it effectively would restrict the taking of the test to the period before the applicant's first interview. Instead, the Service has modified § 312.3(a)(1) to reflect that the standardized test may be taken and passed up until the date of any examination on the application under 8 CFR part 335, including a retest on the § 312 requirement. The wording in the first sentence also has been changed from ''submits an application'' to ''files an application'' to bring the language into conformity with all other references to receipt of applications by the Service.

One of these commenters also suggested that the Service include specific language in § 312.3(a)(3) to reflect that an applicant's inability to speak English will not be construed as evidence of fraud in the taking of the standardized test. In response to the first interim rule, the Service received a similar request to set forth the exact level of proof required to invalidate test results on the basis of fraud. In this rule, the Service has certified that the inability to speak English may not be used as the sole ground upon which to invalidate test results. However, it should be noted that an applicant's inability to speak English at the interview may provide the officer with a reason to scrutinize more closely the circumstances surrounding the administration of the test. Moreover, while the Service may not invalidate test results as fraudulent solely because an applicant is unable to speak English at the interview, the Service is not precluded from denying an application on the grounds that the applicant is unable to speak English.

The same commenter also requested inclusion of a specific provision stating that persons who have satisfied the educational requirements set forth in section 312 of the Immigration and Nationality Act (the Act) during the legalization program under section 245A of the Act have met the requirements listed in 8 CFR 312.3. The Service points out that such a provision already exists in § 312.3(b). Under that provision, applicants must still demonstrate spoken English skills at the time of the naturalization interview.

One commenter requested clarification of the changes made by the second interim rule to § 312.4. Specifically, the commenter note the requirement that the Service provide an applicant with another interpreter in a timely manner when it disqualifies the applicant's own interpreter. The commenter was concerned that this language could be misconstrued as requiring the Service to obtain an interpreter on the same day as the disqualification. The commenter pointed out that such a requirement would generate a significant cost to the Service and also could lead to violations of the Service's contractual obligations with interpreter firms. The Service has clarified this section to reflect that an interview may be rescheduled within a reasonable time period so long as such rescheduling does not cause undue delay in the adjudication of the application.

The same commenter also noted the removal of the term ''terrorist'' from the definition of ''subversive'' found in § 313.1. As we explained when we published the second interim rule, terrorists are not specifically included among the classes of persons ineligible for naturalization under section 313 of the Act. We note, however, that although section 313 of the Act does not expressly prohibit the naturalization of persons who engage in terrorist activity as defined in section 212(a)(3)(B) of the Act, such persons will be closely scrutinized for lack of good morale character.

Also noted by that commenter were the changes made by the second interim rule in § 316.5(c)(1)(i) regarding the term used to describe the interruption of continuity of residence. The commenter took issue with the use of the phrase ''continuity of residence,'' suggesting that ''continuous residence'' would be a more appropriate term, as the Service uses that term throughout its regulations and particularly in 8 CFR part 245a. It should be noted, however, that § 316.5(c)(l)(i) implements section 316(b) of the Act, which refers to residence as required for admission to citizenship, as opposed to residence in other immigration contexts. Moreover, section 316(b) of the Act uses the term ''continuity of residence.'' Accordingly, § 316.5(c)(1)(i) adheres to the design of the statute by using the Act's terminology and by distinguishing between residence for naturalization purposes and residence as used in other Service regulations.

One commenter asserted that the provision in § 316.10 specifying that a conviction for an aggravated felony be a permanent bar to naturalization only if the conviction occurred after November 29, 1990, contradicts a General Counsel legal opinion dated February 22, 1991 (on file with the Office of General Counsel, INS). The legal opinion discusses when a conviction can be classified as an aggravated felony. However, as the legal opinion also discusses, section 509 of IMMACT, which replaces ''murder'' with ''aggravated felony'' in section 101(f)(8) of the Act, is applicable only to convictions occurring on or after November 29, 1990. Accordingly, an applicant is permanently barred from showing good moral character, and hence from eligibility for naturalization, by a conviction for an aggravated felony only when the conviction occurred on or after that date. As noted in the supplementary information accompanying the second interim rule, however, nothing in the regulations prevents the Service from using a pre-November 29, 1990, aggravated felony conviction as an impediment to establishing good moral character under § 316.10(b) (2) or (3).

One commenter suggested that the provision in § 335.2(a) allowing for the presence of an applicant's attorney or representative at the examination should refer only to § 292.3, rather than to the filing of an appearance in accordance with part 292 generally. However, the broader reference to part 292 was designed to encompass § 292.3 as well as the other guidelines for representation before the Service listed in that part. That commenter also asserted that the Service seems to have expanded the legal representative's participation in the in the naturalization process. As explained in the supplementary information accompanying the second interim rule, prior to the change to administrative naturalization, all applicants were subject to a preliminary investigation, where limited representation was allowed, and to a preliminary examination and final hearing, where full representation was allowed. As applicants are now subject to only one examination, the rights to representation at that examination have been expanded to be consistent with all other adjudications before the Service.

One commenter requested that the Service provide further guidance in § 335.2 to adjudications officers concerning the conduct of naturalization examinations, as

discrepancies sometimes exist in the level of difficulty of questions asked of applicants. Although we recognize the need to provide guidelines for adjudications officers, such guidelines are more properly provided in the Service's Operations Instructions.

That commenter also suggested that the Service amend § 335.6 to allow applicants to make verbal requests for rescheduling of missed interviews at the field office. For reasons of administrative efficiency, the Service must require that all requests be submitted in writing. However, the written request need not take any specific form, but rather may be a brief, informal notation for the adjudications officer to insert in the applicant's file.

One commenter questioned the portion of § 335.7 that allows the Service to deny applications on the merits where applicants fail to explain adequately absences from appearances required after their initial examinations or to provide the Service with additional requested evidence. The commenter suggested that dismissal is more appropriate than denial in cases where the Service does not have sufficient evidence upon which to make a determination. Section 335(e) of the Act provides that, where the applicant fails to prosecute an application, the Service may either decide the application on the merits or dismiss it for lack of prosecution. The Service agrees with the commenter that cases may be more appropriately ''dismissed'' than adjudicated on the merits where no record exists. The Service therefore has made a distinction between cases where the applicant has not appeared for the examination, provided for in § 335.6, and cases where the applicant has already appeared for an examination but the Service requires further testimony or documentary evidence to support the application, provided for in § 335.7. This rule further clarifies the Service's position that when the applicant fails to appear for the examination, leaving the Service without sufficient evidence upon which to render a determination, the case will be dismissed for lack of prosecution after the passage of one year from the date the application was closed. However, when the applicant appears for examination but the Service requests additional testimony or documentation, and the applicant then fails to prosecute the application, the Service will adjudicate the case on the merits, as sufficient evidence should exist to render a decision.

One commenter expressed concern over the process for reviewing completed Forms N–445 prior to the oath administration ceremony, provided for in § 337.2(c). The commenter requested assurance that when further questioning is warranted after review of the completed form, the applicant will be given the opportunity to respond to an officer's questions in a quiet, private setting so as to allow for a meaningful exchange with the officer. The Service believes that completion of the Form N–445 is a necessary part of the naturalization process. Although Service adjudications officers will be provided with guidance on the treatment of applicants whose answers warrant further investigation, such guidelines are provided more properly in the Services Operations Instructions.

That commenter also had concerns that the procedure for requesting expedited administration of the oath of allegiance set forth in § 337.3(c) may cause undue delay, because the Service would be required in some cases to first pass upon the merits of each request and then send a recommendation to the court. The Service has addressed this concern by revising § 337.3(c) to eliminate the recommendation process. The commenter also expressed concern over the requirement that requests for expedition be in writing, and suggested that the Service implement a more flexible approach. While the Service recognizes the need to provide the public with an efficient process, the Service is concerned that many applicants, especially those without legal representation, may have difficulty in communicating with judges or clerks of court to request expedited ceremonies. The Service, therefore, has revised § 337.3(c) to provide that applicants seeking expedited ceremonies may submit their requests to either the court or to the Service.

The same commenter also suggested that the Service attempt to reallocate its resources to rectify discrepancies in waiting times for adjudications. While this regulation is not the proper forum in which to address such concerns, the Service assures the commenter that it is working constantly to improve the efficiency of the administrative naturalization process.

Service Initiated Changes

As a result of working under the interim rules since 1991, the Service discovered some errors or areas where further clarification is needed.

At § 316.2(a)(3), which lists one of the requirements for naturalization, the rule stated only that the applicant must have resided continuously in the United States for 5 years after lawful admission. Section 316(a) of the Act, however, requires that the applicant has resided in the United States for 5 years after lawful admission for permanent residence. In order to bring the regulation into conformity with the statute, the Service has inserted the phrase ''for permanent residence'' at the end of § 316.2(a)(3).

At § 316.5(c)(2), the Service clarified language regarding relinquishment of permanent resident status by aliens who claim nonresident alien status for income tax purposes. The rebuttable presumption of relinquishment of lawful permanent resident status extends not only to persons who ''voluntarily'' claim nonresident alien status for income tax purposes, but also to persons who fail to file income tax returns based on their claims to nonresident alien status.

At § 329.4, the Service had referred erroneously to an inappropriate section of the regulations. This citation has been corrected in § 329.4(b), which formerly referred to ''§ 329.2(a), (c)(1), or (c)(2)'' and now reads ''§ 329.2 (a), (b), or (c)(2).''

At § 339.2, the Service added a provision to clarify the purpose of the courts' submission of monthly reports prepared on Form N–4. As approved in a notice published on October 25, 1993, at 58 FR 55084, 55085, Form N–4, in addition to serving its recordkeeping purpose, will be treated by the Service as a billing document submitted by the courts. Use of Form N–4 in this manner will enable the Service to process more efficiently requests for reimbursement from courts for performance of oath administration ceremonies. The added paragraph also explains that reimbursements for state courts will be determined under the same standards set for the Federal courts.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, § 1(b). The Attorney General has determined that this rule is not a significant regulatory action under Executive Order 12866, § 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 12612

This regulation will not 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. Therefore, in accordance with section 6 of Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12606

The Attorney General has reviewed this rule under Executive Order 12606 and has determined that this rule will not have an impact on family formation, maintenance, or general well-being.

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Archives and records, Authority delegations (Government agencies), Fees, Forms, Freedom of information, Privacy, Reporting and recordkeeping requirements, Surety bonds.

8 CFR Part 292

Administrative practice and procedure, Hearing and appeal procedures, Immigration.

8 CFR Part 299

Citizenship and naturalization, Immigration and Nationality Act, Reporting and recordkeeping requirements.

8 CFR Part 310

Citizenship and naturalization, Courts.

8 CFR Part 312

Citizenship and naturalization, Education.

8 CFR Part 313

Citizenship and naturalization.

8 CFR Part 315

Armed forces, Citizenship and naturalization, Selective service system, Treaties.

8 CFR Part 316

Citizenship and naturalization, International organizations, Reporting and recordkeeping requirements.

8 CFR Part 316a

Citizenship and naturalization, Immigration, Residence.

8 CFR Part 319

Citizenship and naturalization. Reporting and recordkeeping requirements.

8 CFR Part 322

Citizenship and naturalization, Infants and children, Reporting and recordkeeping requirements.

8 CFR Part 324

Citizenship and naturalization, Reporting and recordkeeping requirements, Women.

8 CFR Part 325

Citizenship and naturalization, Reporting and recordkeeping requirements.

8 CFR Part 327

Citizenship and naturalization, Military personnel, Reporting and recordkeeping requirements.

8 CFR Part 328

Citizenship and naturalization, Military personnel, Reporting and recordkeeping requirements.

8 CFR Part 329

Citizenship and naturalization, Military personnel, Reporting and recordkeeping requirements, Veterans.

8 CFR Part 330

Citizenship and naturalization, Reporting and recordkeeping requirements, Seamen.

8 CFR Part 331

Aliens, Citizenship and naturalization.

8 CFR Part 332

Citizenship and naturalization, Education, Reporting and recordkeeping requirements.

8 CFR Part 332a

Citizenship and naturalization, Courts.

8 CFR Part 332b

Citizenship and naturalization, Education.

8 CFR Part 332c

Citizenship and naturalization.

8 CFR Part 332d

Authority delegations (Government agencies), Citizenship and naturalization.

8 CFR Part 333

Citizenship and naturalization.

8 CFR Part 334

Administrative practice and procedure, Citizenship and naturalization, Courts, Reporting and recordkeeping requirements.

8 CFR Part 334a

Citizenship and naturalization, Reporting and recordkeeping requirements.

8 CFR Part 335

Administrative practice and procedure, Authority delegations (Government agencies), Citizenship and naturalization, Reporting and recordkeeping requirements.

8 CFR Part 335a

Citizenship and naturalization.

8 CFR Part 335c

Citizenship and naturalization.

8 CFR Part 336

Citizenship and naturalization, Courts, Hearing and appeal procedures, Reporting and recordkeeping requirements.

8 CFR Part 337

Citizenship and naturalization.

8 CFR Part 338

Citizenship and naturalization, Reporting and recordkeeping requirements.

8 CFR Part 339

Citizenship and naturalization, Courts, Reporting and recordkeeping requirements.

8 CFR Part 340

Citizenship and naturalization, Law enforcement.

8 CFR Part 343b

Citizenship and naturalization, Reporting and recordkeeping requirements.

8 CFR Part 344

Citizenship and naturalization, Courts.

8 CFR Part 499

Citizenship and naturalization, Reporting and Recordkeeping requirements.

Accordingly, the interim rule published at 56 FR 50475 on October 7, 1991, amdnding 8 CFR parts 103, 299, 310, 312, 313, 315, 316, 316a, 319, 322, 324, 325, 327, 328, 329, 330, 331, 332, 332a, 332b, 332c, 332d, 333, 334, 334a 335, 335a, 335c, 336, 337, 338, 339, 340, 343b, 344, and 499, and the interim rule published at 58 FR 49905 on September 24, 1993, amending 8 CFR parts 292, 299, 310, 312, 313, 316, 322, 329, 334, 335, 336, 337, 338, 339, 343b, and 499, are adopted as a final rule with the following changes:

PART 312—EDUCATIONAL REQUIREMENTS FOR NATURALIZATION

1. The authority citation for part 312 continues to read as follows:

Authority: 8 U.S.C. 1103, 1423, 1443, 1447, 1448.

2. Section 312.3 is amended by:

a. Revising paragraph (a)(1); and by

b. Revising paragraph (a)(3), to read as follows:

§ 312.3 Standardized citizenship testing.

(a)(1) An applicant for naturalization may satisfy the reading and writing requirements of § 312.1 and the knowledge requirements of § 312.2 by passing, within one (1) year preceding the date on which he or she files an application for naturalization, or at any time subsequent to filing an application but prior to a final determination on the application, a standardized citizenship test given by an entity authorized by the Service to conduct such a test.

* * * * *

(3) An applicant who passes a standardized citizenship test as provided in paragraph (a)(1) of this section for naturalization shall not be reexamined at the Service naturalization interview on his or her ability to read and write English or on his or her knowledge of the history and form of government of the United States, unless the examining officer has reasonable cause to believe, subsequent to verification of the applicant's test results with the authorized testing entity, that the applicant's test results were obtained English may not be the sole reason for finding that the test results were obtained through fraud or misrepresentation. The Applicant's inability to speak English may not be the sole reason for finding that the test results were botained through fraud or misrepresentation. A written record of the officer's determination shall be made in the record of the application including the response from the testing entity concerning the applicant's test.

* * * * *

3. Section 312.4 is revised to read as follows:

§ 312.4 Selection of interpreter.

An interpreter to be used under § 312.2 may be selected either by the applicant or by the Service. However, the Service reserves the right to disqualify an interpreter provided by the applicant in order to ensure the integrity of the examination. Where the Service disqualifies an interpreter, the Service must provide another interpreter for the applicant in a timely manner. If rescheduling of the interview is required, then a new date shall be set as soon as practicable so as not to delay unduly the adjudication of the application. The officer who disqualifies an interpreter shall make a written record of the reason(s) for disqualification as part of the record of the application.

PART 316—GENERAL REQUIREMENTS FOR NATURALIZATION

4. The authority citation for part 316 continues to read as follows:

Authority: 8 U.S.C. 1103, 1181, 1182, 1443, 1447; 8 CFR 2.1.

5. Section 316.2 is amended by revising paragraph (a)(3) to read as follows:

§ 316.2 Eligibility.

(a) * * *

(3) Has resided continuously within the United States, as defined under § 316.5, for a period of at least five years after having been lawfully admitted for permanent residence;

* * * * *

6. Section 316.5 is amended by revising paragraph (c)(2) to read as follows:

§ 316.5 Residence in the United States.

* * * * *

(c) * * *

(2) *Claim of nonresident alien status for income tax purposes after lawful admission as a permanent resident.* An applicant who is a lawfully admitted permanent resident of the United States, but who voluntarily claims nonresident alien status to qualify for special exemptions from income tax liability, or fails to file either federal or state income tax returns because he or she considers himself or herself to be a nonresident alien, raises a rebuttable presumption that the applicant has relinquished the privileges of permanent resident status in the United States.

* * * * *

PART 329—SPECIAL CLASSES OF PERSONS WHO MAY BE NATURALIZED: NATURALIZATION BASED UPON ACTIVE DUTY SERVICE IN THE UNITED STATES ARMED FORCES DURING SPECIFIED PERIODS OF HOSTILITIES

7. The authority citation for part 329 continues to read as follows:

Authority: 8 U.S.C. 1103, 1440, 1443.

8. Section 329.4 is amended by revising paragraph (b) to read as follows:

§ 329.4 Application and evidence.

* * * * *

(b) *Evidence.* The applicant's eligibility for naturalization under § 329.2(a), (b), or (c)(2) shall be established only by the certification of the executive department under which the applicant served or is serving.

PART 335—EXAMINATION ON APPLICATION FOR NATURALIZATION

9. The authority citation for part 335 continues to read as follows:

Authority: 8 U.S.C. 1103, 1443, 1447.

10. In § 335.6, a new paragraph (c) is added to read as follows:

§ 335.6 Failure to appear for examination.

* * * * *

(c) If the applicant does not request reopening of an administratively closed application within one year from the date the application was closed, the Service will consider that application to have been abandoned, and shall dismiss the application without further notice to the applicant.

11. Section 335.7 is amended by revising the last sentence to read as follows:

§ 335.7 Failure to prosecute application after initial examination.

* * * In the event that the applicant fails to respond within 30 days of the date of notification, the Service shall adjudicate the application on the merits pursuant to § 336.1 of this chapter.

PART 337—OATH OF ALLEGIANCE

12. The authority citation for part 337 continues to read as follows:

Authority: 8 U.S.C. 1103, 1443, 1448.

13. Section 337.3 is amended by revising paragraph (c) to read as follows:

§ 337.3 Expedited administration of oath of allegiance.

* * * * *

(c) All requests for expedited administration of the oath of allegiance shall be made in writing to either the court or the Service. Such requests shall contain sufficient information to substantiate the claim of special circumstances to permit either the court or the Service to properly exercise the discretionary authority to grant the relief sought. The court or the Service may seek verification of the validity of the information provided in the request. If the applicant submits a written request to the Service but is awaiting an oath administration ceremony by a court pursuant to § 337.8, the Service promptly shall provide the court with a copy of the request without reaching a

decision on whether to grant or deny the request.

PART 339—FUNCTIONS AND DUTIES OF CLERKS OF COURT REGARDING NATURALIZATION PROCEEDINGS

14. The authority citation for part 339 continues to read as follows:

Authority: 8 U.S.C. 1103, 1433, 1448.

15. Section 339.2 is amended by adding a new paragraph (e) to read as follows:

§ 339.2 Monthly reports.

* * * * *

(e) *Use of reports for accounting purposes.* Form N–4 shall be used by state and federal courts as a monthly billing document, submitted to the Service for reimbursement in accordance with section 344(f)(1) of the Act. The Service shall use the information submitted on this form to calculate costs incurred by courts in performing their naturalization functions. State and federal courts will be reimbursed pursuant to terms set forth in annual agreements entered into between the Service and the Administrative Office of United States Courts.

Dated: January 26, 1995.

Janet Reno,

Attorney General.

[FR Doc. 95–2645 Filed 2–2–95; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93–CE–41–AD; Amendment 39–9136; AD 95–02–18]

Airworthiness Directives; Beech Aircraft Corporation Models 1900, 1900C, and 1900D Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes Airworthiness Directive (AD) 92–06–09, which currently requires repetitively inspecting the engine trusses for cracks on Beech Aircraft Corporation (Beech) Model 1900 and certain Model 1900C airplanes, repairing or replacing any cracked engine truss, and installing reinforcement doublers. That AD also provides the option of installing an engine truss of improved design as terminating action for the repetitive inspections. Since issuing that AD, the Federal Aviation Administration (FAA) has received several reports of these improved design trusses cracking in Area A (as specified in the service information) of the engine truss. This action retains the currently required repetitive inspections, but shortens the repetitive inspection interval in Area A and eliminates the inspection-terminating replacement option; and also incorporates the Beech Models 1900C and 1900D airplanes that have engine trusses of this same type design installed at manufacture. The actions specified by this AD are intended to prevent failure of the engine truss assembly caused by a cracked engine truss.

DATES: Effective March 25, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 25, 1995.

ADDRESSES: Service information that applies to this AD may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. This information may also be examined at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Steven E. Potter, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4124; facsimile (316) 946–4407.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Beech Model 1900 and certain Model 1900C airplanes was published in the **Federal Register** on December 1, 1993 (58 FR 63305). The action proposed to supersede AD 92–06–09 with a new AD that would (1) retain the repetitive inspection requirements of AD 92–06–09, extend the applicability to include Beech Models 1900C and 1900D airplanes that have a part number 129–910032–79 engine truss installed, and shorten the repetitive inspection interval of Area A (as specified in the service information) of the engine truss to 100 hours TIS; and (2) eliminate the option of terminating the repetitive inspections on the Beech Model 1900 and 1900C airplanes if an improved design engine truss, 129–910032–79, is installed. The inspections were proposed to be accomplished in accordance with Beech Service Bulletin (SB) No. 2255, Revision V, dated October 1993.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the two comments received.

One commenter concurs with the proposal as written.

The other commenter concurs with the actions specified in the proposal, but states that the engine trusses on the Beech Model 1900 airplanes are hard to identify. This commenter states that Beechcraft 1900 Airliner Communique No. 27, dated February 1993, presents information that helps identify the older engine trusses, and recommends that the FAA reference this document in the proposal. The FAA concurs that the Beech Model 1900 airplane engine trusses are hard to identify, and that Beechcraft 1900 Airliner Communique No. 27, dated February 1993, helps identify these trusses. A NOTE has been added in the proposal that references this service communique as a document that could be used in identifying engine trusses.

In addition, Beech has revised SB 2255 to the Revision VI level (dated August 1994). This document revises the inspection schedule for airplanes having engine truss part number 129–910032–79. Implementation of this schedule would be a reduction from that already proposed. The FAA has determined that this SB should be incorporated into the proposal.

After careful review of all available information including the comments referenced above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for the addition of the NOTE, the incorporation of Beech SB No. 2255, Revision VI, dated August 1994, and minor editorial corrections. The FAA has determined that this minor addition, the SB incorporation, and the editorial corrections will not change the meaning of the AD or add any additional burden upon the public than was already proposed.

The FAA estimates that 279 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 16 workhours per airplane to accomplish the required inspection (one-time in all applicable areas), and that the average labor rate is approximately $60 an hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $267,840. The only additional cost impact on U.S. operators by the required action over that which is currently required by AD 92–06–09 is the

required inspections on 77 Beech Models 1900C and 1900D airplanes or $73,920 (16 workhours × $60 × 77 airplanes). These figures are based on the assumption that no affected airplane owner/operator has accomplished the required initial inspection, and do not account for the cost of repetitive inspections. The FAA has no way of determining the number of repetitive inspections each owner/operator would incur.

The regulations adopted herein will not 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 92–06–09, Amendment 39–8189 (57 FR 8060, March 6, 1992), and by adding a new AD to read as follows:

95–02–18 Beech Aircraft Corporation: Amendment 39–9136; Docket No. 93–CE–41–AD. Supersedes AD 92–06–09, Amendment 39–8189.

Applicability: Models 1900, 1900C, and 1900D airplanes (all serial numbers), certificated in any category.

Compliance: Required as indicated in the body of this AD, unless already accomplished.

To prevent failure of the engine truss assembly caused by a cracked engine truss, accomplish the following:

(a) For Models 1900 and 1900C airplanes with either engine truss part number (P/N) 114–910025–1 or P/N 118–910025–1 installed that is not equipped with reinforcement doublers at the engine firewall attachment bosses, upon the accumulation of 1,400 hours TIS or within the next 100 hours TIS after the effective date of this AD, whichever occurs later, install reinforcement doublers in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Beech Service Bulletin (SB) No. 2255, Revision VI, dated August 1994.

(b) For all affected airplanes having engine truss P/N 129–910032–79 installed, initially and repetitively inspect the engine truss for cracks at the weld joints in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Beech SB 2255, Revision VI, dated August 1994, at the times specified in the following chart:

Models	Area specified in figure 1 of Beech SB No. 2255, Rev. VI	Initial inspection	Repetitive inspection
1900 and 1900C	A	Upon accumulating 1,400 hours TIS*	Every 100 hours TIS.
1900 and 1900C	B and C	Upon accumulating 3,200 hours TIS*	Every 100 hours TIS.
1900D	A	Upon accumulating 3,200 hours TIS*	Every 450 hours TIS.
1900D	B and C	Upon accumulating 3,200 hours TIS*	Every 3,000 hours TIS.

*Or within the next 100 hours TIS after the effective date of this AD, whichever occurs later.

(c) For all Models 1900 and 1900C airplanes having engine truss P/N 118–9100–25–37, P/N 118–910025–121, P/N 114–910025–1 or P/N 118–910025–1, initially and repetitively inspect the engine truss for cracks at the weld joints in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Beech Service Bulletin (SB) 2255, Revision VI, dated August 1994, at the times specified in the following chart:

Area specified in figure 1 of Beech SB N. 2255, Rev. VI	Initial inspection	Repetitive inspection
A	Upon accumulating 1,400 hours TIS*.	Every 100 hours TIS.
B	Upon accumulating 1,400 hours TIS*.	Every 600 hours TIS.
C	Upon accumulating 1,400 hours TIS*.	Every 3,000 hours TIS.

*Or within the next 100 hours TIS after the effective date of this AD, whichever occurs later.

Note 1: Beechcraft 1900 Airliner Communique No. 27, dated February 1993, provides information for identifying engine trusses on Beech Model 1900 airplanes. Copies of this document may be obtained from the Wichita Aircraft Certification Office (ACO) at the address specified in paragraph (f) of this AD.

(d) If any cracks are found during the inspections required by paragraphs (b) and (c) of this AD, prior to further flight, repair the crack or replace the engine truss with one of the applicable truss part numbers specified in the following table, and reinspect the truss at the times previously specified:

Truss part No.	Models	Instructions
118–910025–37 (serviceable truss).	1900 and 1900C.	Applicable Maintenance Manual.
118–910025–121 (serviceable truss).	1900 and 1900C.	Applicable Maintenance Manual.
129–910032–79.	1900, 1900C and 1900D.	Beech Kit 114–9036–1 or 114–9036–3.

Note 2: Installation of an improved design engine truss, P/N 129–910032–79, on any of the affected airplanes does not eliminate the repetitive inspection requirement of this AD.

Note 3: Compliance with a previous revision level of the service bulletin referenced in this AD fulfills the applicable requirements of this AD and is considered ''unless already accomplished''.

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Wichita ACO, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(g) The inspections and replacement (if necessary) required by this AD shall be done in accordance with Beech Service Bulletin No. 2255, Revision VI, dated August 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(h) This amendment (39–9136) supersedes AD 92–06–09, Amendment 39–8189.

(i) This amendment (39–9136) becomes effective on March 25, 1995.

Issued in Kansas City, Missouri, on January 26, 1995.

Michael K. Dahl,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–2403 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 94–ANE–40; Amendment 39–9135; AD 95–02–16]

Airworthiness Directives; Pratt & Whitney JT8D Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Pratt & Whitney (PW) JT8D series turbofan engines, that currently requires initial and repetitive inspections of the Number 7 fuel nozzle and support assembly, replacement of the Number 7 fuel nozzle and support assembly with a more leak-resistant configuration, and replacement of aluminum oil pressure and scavenge tube fittings with steel fittings. This amendment adds a requirement incorporated in a new revision of a PW Alert Service Bulletin (ASB) that was omitted from the existing AD to replace an additional aluminum oil scavenge line bolt with a steel bolt. This amendment also makes a correction to a note in the compliance section to apply only to PW JT8D–200 series engines. This amendment is prompted by the need to make these corrections. The actions specified by this AD are intended to prevent fuel leakage from the Number 7 fuel nozzle and support assembly, ignition of that leaking fuel, and liberation of oil from melted oil line fittings, which can result in an uncontained engine fire and damage to the aircraft.

DATES: Effective February 21, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 21, 1995.

Comments for inclusion in the Rules Docket must be received on or before April 4, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 94–ANE–40, 12 New England Executive Park, Burlington, MA 01803–5299.

The service information referenced in this AD may be obtained from Pratt & Whitney, Technical Publications Department, M/S 132–30, 400 Main Street, East Hartford, CT 06108. This information may be examined at the FAA, New England Region, Office of the Assistant Chief Counsel, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mark A. Rumizen, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (617) 238–7137, fax (617) 238–7199.

SUPPLEMENTARY INFORMATION: On June 29, 1994, the Federal Aviation Administration (FAA) issued airworthiness directive (AD) 94–14–16, Amendment 39–8964 (59 FR 35238, July 11, 1994), applicable to Pratt & Whitney (PW) JT8D series turbofan engines, to require inspection of the Number 7 fuel nozzle and support assembly for evidence of fuel leakage and burning until replacement of the Number 7 fuel nozzle and support assembly with an improved sealing configuration. That AD also requires replacement of the aluminum oil tube fittings with steel fittings. That action was prompted by two reports of uncontained engine fires on Pratt & Whitney (PW) JT8D series engines due to fuel leakage from the Number 7 fuel nozzle and support assembly, ignition of that fuel, melting of aluminum oil pressure and scavenge tube fittings that are in the proximity of the Number 7 nozzle, and augmentation of that fire with the liberated oil. The resulting fire burned through the engine diffuser case and fan ducts, causing an aircraft engine cowl fire. That condition, if not corrected, could result in fuel leakage from the Number 7 fuel nozzle and support assembly, ignition of that leaking fuel, and liberation of oil from melted oil line fittings, which can result in an uncontained engine fire and damage to the aircraft.

Since the issuance of that AD, the FAA noted the omission of the requirement to replace an additional aluminum oil scavenge line bolt with a steel bolt. This additional requirement is incorporated in Revision 2 to PW Alert Service Bulletin (ASB) No. A6170, dated October 20, 1994. Also, the FAA was alerted of an error in the compliance section where the incorrect engine series was specified. In paragraph (b)(2)(iv), the reference to ''all other JT8D engines'' should read ''JT8D–200 series engines.'' In addition, PW has issued Revision 2 to ASB No. A6169, dated October 26, 1994, which differs from Revision 1, cited in the current AD, only by minor, non-substantive changes.

The FAA has reviewed and approved the technical contents of PW ASB No. A6153, Revision 1, dated June 8, 1994, that describes procedures for initial and repetitive borescope inspections of the Number 7 fuel nozzle and support assembly; and PW ASB A6170, Revision 2, dated October 20, 1994, and ASB No. A6169, Revision 2, dated October 26, 1994, that describe procedures for replacement of the Number 7 fuel nozzle and support assembly with a more leak-resistant configuration and replacement of the aluminum oil tube fittings with steel fittings, respectively.

Since an unsafe condition has been identified that is likely to exist or develop on other engines of this same type design, this AD supersedes AD 94–14–16 to continue to require inspection

of the Number 7 fuel nozzle and support assembly for evidence of fuel leakage and burning until replacement of the Number 7 fuel nozzle and support assembly with an improved sealing configuration. This AD also requires replacement of the aluminum oil tube fittings with steel fittings. In addition, this AD adds a requirement incorporated in PW ASB No. 6170, Revision 2, dated October 20, 1994, that was omitted from AD 94–14–16 to replace an additional aluminum oil scavenge line bolt with a steel bolt, and makes a correction to paragraph (b)(2)(iv). The actions are required to be accomplished in accordance with the alert service bulletins described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 94–ANE–40.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866.

It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–8964, (59 FR 35238, July 11, 1994), and by adding a new airworthiness directive, Amendment 39–9135, to read as follows:

95–02–16 Pratt & Whitney: Amendment 39–9135. Docket 94–ANE–40. Supersedes AD 94–14–16, Amendment 39–8964.

Applicability: Pratt & Whitney (PW) Model JT8D–209, –217, –217A, –217C, –219 turbofan engines; and JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines incorporating the original issue or any revision of Pratt & Whitney Service Bulletin No. 5650; and any PW Model JT8D engine with low emissions fuel nozzles, Part Numbers 775485, 809137–01, 802965, and 5004308–02 installed. These engines are installed on but not limited to Boeing 727 and 737 series, and McDonnell Douglas DC–9 and MD–80 series aircraft.

Compliance: Required as indicated, unless accomplished previously.

To prevent fuel leakage from the Number 7 fuel nozzle and support assembly and melting of the oil pressure and scavenge tube fittings, which can result in an uncontained engine fire and damage to the aircraft, accomplish the following:

(a) Inspect Number 7 fuel nozzle and support assemblies in accordance with PW Alert Service Bulletin (ASB) No. A6153, Revision 1, dated June 8, 1994, as follows:

(1) For Number 7 fuel nozzle and support assemblies that have accumulated more than 2,500 hours time in service (TIS) since last fuel nozzle and support assembly overhaul on the effective date of this airworthiness directive (AD), initially inspect for fuel leakage within 700 hours TIS after the effective date of this AD.

(2) For engines with Number 7 fuel nozzle and support assemblies with 2,500 or less hours TIS since fuel nozzle and support assembly overhaul on the effective date of this AD, initially inspect prior to accumulating 3,200 hours TIS since overhaul.

(3) Thereafter, inspect for fuel leakage in accordance with PW ASB A6153, Revision 1, dated June 8, 1994, at intervals not to exceed 700 hours TIS since last inspection.

(4) Remove from service Number 7 fuel nozzle and support assemblies that exhibit evidence of fuel leakage as described in PW ASB No. A6153, Revision 1, dated June 8, 1994, and replace with the improved sealing configuration nozzle in accordance with paragraph (b) of this AD, as follows:

(i) Within 25 hours TIS, or 25 cycles in service (CIS), whichever occurs first, after the inspection performed in paragraph (a)(1), (a)(2), or (a)(3) for aircraft with only one engine exhibiting Number 7 fuel nozzle and support assembly leakage.

(ii) Prior to further flight, on aircraft with two engines exhibiting Number 7 fuel nozzle and support assembly leakage, remove and replace at least one of the leaking Number 7 fuel nozzle and support assemblies. The remaining Number 7 fuel nozzle and support assembly that exhibits leakage shall be removed and replaced in accordance with paragraph (a)(4)(i) of this AD.

(iii) Prior to further flight, on Boeing 727 aircraft, with three engines exhibiting Number 7 fuel nozzle and support assembly leakage, remove and replace at least two of the leaking Number 7 fuel nozzle and support assemblies. The remaining Number 7 fuel nozzle and support assembly that

exhibits leakage shall be removed and replaced in accordance with paragraph (a)(4)(i) of this AD.

Note: Fuel nozzles and support assemblies that have not undergone overhaul do not require inspection in accordance with paragraph (a) of this AD.

(b) At the next accessibility of the diffuser build group after the effective date of this AD, but no later than July 31, 1999, accomplish the following:

(1) Replace the Number 7 fuel nozzle and support assembly with the improved sealing configuration in accordance with Part 1 of PW ASB No. A6169, Revision 2, dated October 26, 1994.

(2) Replace the aluminum pressure and scavenge oil tube fittings with steel fittings in accordance with PW ASB No. A6170, Revision 2, dated October 20, 1994.

Note: Replacement of the following oil tubes with corresponding oil tubes that incorporate steel fittings constitutes compliance with paragraph (b)(2) of this AD:

(i) Outer internal Number 4 and 5 bearing pressure tube assembly for PW JT8D–200 series engines.

(ii) Outer internal main bearing pressure tube assembly for PW JT8D–200 series engines.

(iii) Main bearing pressure manifold assembly for PW JT8D–200 series engines.

(iv) Front Number 4½ and 6 bearing pressure tube assembly for JT8D–200 series engines.

(v) Number 4 bearing oil scavenge tube assembly for all other JT8D engines.

(vi) Number 4 bearing oil pressure tube assembly for all other JT8D engines.

(vii) Main bearing pressure manifold assembly for all other JT8D engines.

(c) Incorporation of the hardware required by paragraph (b)(1) of this AD, constitutes terminating action for the inspections required by paragraph (a) of this AD.

(d) For the purpose of this AD, accessibility of the diffuser build group is defined as engine maintenance that entails flange separation of the diffuser case from the combustion chamber outer case.

(e) For the purpose of this AD, fuel nozzle and support assembly overhaul is defined as disassembly of the fuel nozzle from the support assembly that entails removal of the fuel nozzle nut.

(f) For any Number 7 fuel nozzle and support assembly that is removed for evidence of leakage in accordance with paragraph (a) of this AD, submit the following information within 60 days after the removal, to the Manager, Engine Certification Office, Engine and Propeller Directorate, Aircraft Certification Service, FAA, 12 New England Executive Park, Burlington, Massachusetts, 01803–5299; fax (617) 238–7199:

(1) Fuel nozzle and support assembly part number and serial number.

(2) Fuel nozzle and support assembly time and cycles since overhaul.

(3) Description of fuel nozzle and support assembly distress.

(4) Position of distressed fuel nozzle and support assembly.

(5) Description of any other resultant engine damage.

(6) Engine serial number.

(7) Engine time and cycles since overhaul.

The reporting requirements of this AD terminate after compliance with paragraph (b)(1) of this AD. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provision of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520) and have been assigned OMB Control Number 2120–0056.

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. The request should be forwarded through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(h) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

(i) The inspections and modifications shall be done in accordance with the following service documents:

Document No.	Pages	Revision	Date
PW ASB No. A6153	1–4	1	June 8, 1994.
	5	Original	Feb. 4, 1994.
	6–8	1	June 8, 1994.
	9–12	Original	Feb. 4, 1994.
Total pages: 12.			
PW ASB No. A6169	1	2	Oct. 26, 1994.
	2–6	1	June 15, 1993.
	7	Original	Apr. 29, 1993.
	8	2	Oct. 26, 1994.
	9–16	Original	Apr. 29, 1993.
	17	1	June 15, 1994.
	18–29	Original	Apr. 29, 1993.
	30–31	2	Oct. 26, 1994.
Total pages: 31.			
PW ASB No. A6170	1	2	Oct. 20, 1994.
	2–3	1	Sept. 9, 1994.
	4–5	2	Oct. 20, 1994.
	6–7	1	Sept. 9, 1994.
	8	2	Oct. 20, 1994.
	9	Original	May 13, 1994.
	10	2	Oct. 20, 1994.
	11–13	Original	May 13, 1994.
	14	2	Oct. 20, 1994.
	15–18	1	Sept. 9, 1994.
	19–21	2	Oct. 20, 1994.
	22	1	Sept. 9, 1994.
Total pages: 22.			

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney, Technical Publications Department, M/S 132–30, 400 Main Street, East Hartford, CT 06108. Copies may be inspected at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(j) This amendment becomes effective on February 21, 1995.

Issued in Burlington, Massachusetts, on January 24, 1995.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 95–2405 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 71

[Airspace Docket No. 94–ANM–50]

Establishment of Class E Airspace; Saratoga, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes the Saratoga, Wyoming, Class E airspace. This action is necessary to accommodate a new instrument approach procedure at Shively Field Airport, Saratoga, Wyoming.

EFFECTIVE DATE: 0901 UTC, March 30, 1995.

FOR FURTHER INFORMATION CONTACT: James Riley, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–AMN–50, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone number: (206) 227–2537.

SUPPLEMENTARY INFORMATION:

History

On October 28, 1994, the FAA proposed to amend part 71 of Federal Aviation Regulations (14 CFR part 71) to establish the Saratoga, Wyoming, Class E airspace area (59 FR 54138). This action is necessary to accommodate a new instrument approach procedure at Shively Field Airport, Saratoga, Wyoming. The area will be depicted on aeronautical charts for pilot reference.

Interested parties were invited to participate in the rulemaking proceeding by submitting written comments on the proposal. No comments were received. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of Federal Aviation Regulations amends Class E airspace at Saratoga, Wyoming. The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the FAA amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ANM WY E5 Saratoga, WY [New]

Saratoga, Shively Field, WY
(Lat. 41°26′41″ N, long. 106°49′25″ W)
Saratoga NDB
(Lat. 41°26′42″ N, long. 106°49′56″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of the Shively Field Airport and within 3.1 miles each side of the 342° bearing from the Saratoga NDB extending from the 6.9-mile radius to 10 miles northwest of the NDB; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at: lat. 41°54′45″ N, long. 106°47′15″ W; to lat. 41°17′00″ N, long. 106°32′30″ W; to lat. 41°10′00″ N, long. 107°03′45″ W; to lat. 41°47′30″ N, long. 107°19′00″ W; to the point of beginning, excluding that portion within the Rawlins Municipal Airport, WY, Class E airspace area.

* * * * *

Issued in Seattle, Washington on January 18, 1995.

Richard E. Prang,

Acting Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 95–2734 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 157

[Docket No. RM81–19–000]

Project Cost and Annual Limits

Issued: January 31, 1995

AGENCY : Federal Energy Regulatory Commission.

ACTION : Final rule.

SUMMARY: Pursuant to the authority delegated by 18 CFR 375.307(e)(1), the Director of the Office of Pipeline Regulation computes and publishes the project cost and annual limits specified in Table I of § 157.208(d) and Table II of § 157.215(a) for each calendar year.

EFFECTIVE DATE: January 1, 1995.

FOR FURTHER INFORMATION CONTACT: Martin A. Burless, Jr., Chief, Branch I, Division of Pipeline Certificates, OPR (202) 208–0581.

SUPPLEMENTARY INFORMATION:

Publication of Project Cost Limits Under Blanket Certificates

Order of the Director, OPR

Section 157.208(d) of the Commission's Regulations provides for project cost limits applicable to construction, acquisition, operation and miscellaneous rearrangement of facilities (Table I) authorized under the blanket certificate procedure (Order No. 234, 19 FERC ¶61,216). Section 157.215(a) specifies the calendar year dollar limit which may be expended on underground storage testing and development (Table II) authorized under the blanket certificate. Section 157.208(d) requires that the ''limits specified in Tables I and II shall be adjusted each calendar year to reflect the 'GNP implicit price deflator' published by the Department of Commerce for the previous calendar year.''

Pursuant to § 375.307(e)(1) of the Commission's Regulations, the authority for the publication of such cost limits, as adjusted for inflation, is delegated to

the Director of the Office of Pipeline Regulation. The cost limits for calendar years 1982 through 1995, as published in Table I of § 157.208(d) and Table II of § 157.215(a), are hereby issued.

Note that these inflation adjustments are based on the Gross Domestic Product (GDP) Implicit Price Deflator rather than the Gross National Product (GNP) Implicit Price Deflator, which is not yet available for 1994. The Commerce Department advises that in recent years the annual change has been virtually the same for both indices. Further adjustments will be made, if necessary.

List of Subjects in 18 CFR Part 157

Natural gas.

Robert J. Cupina,

Deputy Director, Office of Pipeline Regulation.

Accordingly, 18 CFR Part 157 is amended as follows:

PART 157—[AMENDED]

1. The authority citation for Part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

§ 157.208 [Amended]

2. Table I in § 157.208(d) is revised to read as follows:

§ 157.208 Construction, acquisition, operation, and miscellaneous rearrangement of facilities.

* * * * *

(d) * * *

TABLE I

Year	Limit	
	Automobile projected cost limit (col. 1)	Prior notice projected cost limit (col. 2)
1982	$4,200,000	$12,000,000
1983	4,500,000	12,800,000
1984	4,700,000	13,300,000
1985	4,900,000	13,800,000
1986	5,100,000	14,300,000
1987	5,200,000	14,700,000
1988	5,400,000	15,100,000
1989	5,600,000	15,600,000
1990	5,800,000	16,000,000
1991	6,000,000	16,700,000
1992	6,200,000	17,300,000
1993	6,400,000	17,700,000
1994	6,600,000	18,100,000
1995	6,700,000	18,400,000

* * * * *

§ 157.215 [Amended]

3. Table II in § 157.215(a) is revised to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

TABLE II

Year	Limit
1982	$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000

* * * * *

[FR Doc. 95–2707 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 825

RIN 1215–AA85

The Family and Medical Leave Act of 1993; Deferral of Effective Date of Regulations

AGENCY: Wage and Hour Division, Labor.

ACTION: Deferral of effective date of regulations.

SUMMARY: This document defers the effective date, from February 6, 1995, to April 6, 1995, of Labor Department regulations implementing the Family and Medical Leave Act of 1993, 29 CFR Part 825, which were published in the **Federal Register** Friday, January 6, 1995 (60 FR 2180). This action is taken in order to provide the public additional time to implement the final regulations, including, where appropriate, to revise policies and procedures.

EFFECTIVE DATE: This document is effective February 3, 1995. The effective date of the final Family and Medical Leave Act regulations published in the **Federal Register** on January 6, 1995 (60 FR 2180), is hereby deferred until April 6, 1995.

FOR FURTHER INFORMATION CONTACT: J. Dean Speer, Division of Policy and Analysis, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3506, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 219–8412. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Final regulations implementing the Family and Medical Leave Act of 1993 (FMLA), 29 U.S.C. 2601 *et seq.*, were published in the **Federal Register** on January 6, 1995, with an effective date of February 6, 1995 (see 60 FR 2180). In response to requests that the Department of Labor provide additional time to enable employers and other members of the public to comply with their new responsibilities and to implement revised policies and procedures consistent with the final regulations, the Department is deferring, from February 6, 1995, until April 6, 1995, the effective date of the final Family and Medical Leave Act regulations published on January 6, 1995.

Because these rules are scheduled to become effective very shortly, notice and public comment on this change of effective date is impracticable, unnecessary and contrary to the public interest, and good cause exists for making this deferral effective immediately.

List of Subjects in 29 CFR Part 825

Employee benefit plans, Health, Health insurance, Labor management relations, Maternal and child health, Teachers.

Authority: The statutory authority for this action is as follows: 29 U.S.C. 2654; Secretary's Order 1–93 (58 FR 21190).

Signed in Washington, DC, this 31st day of January, 1995.

Maria Echaveste,

Administrator, Wage and Hour Division.

[FR Doc. 95–2702 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–93–086]

RIN 2115–AE47

Drawbridge Operation Regulations; Gulf Intracoastal Waterway, Sarasota, FL

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the Sarasota/Manatee Metropolitan Planning Organization (MPO) and the Florida Department of Transportation (FDOT), the (bridge owner), the Coast Guard is changing the regulations governing the Siesta Key Drawbridge on SR758, Gulf Intracoastal Waterway mile 71.6, across Roberts Bay at Sarasota, Sarasota

County, Florida. This change is intended to relieve highway congestion while still meeting the reasonable needs of navigation.

EFFECTIVE DATE: March 6, 1995.

FOR FURTHER INFORMATION CONTACT: Ian L MacCartney, Project Manager, Bridge Section, at (305) 536–6546.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Ian L. MacCartney, Project Manager, and LT. J. M. Losego, Project Counsel.

Regulatory History

On September 16, 1994, the Coast Guard published a notice of proposed rulemaking entitled Drawbridge Operation Regulations; Gulf Intracoastal Waterway, Sarasota, FL in the **Federal Register** (59 FR 47577). The Coast Guard received five letters commenting on the proposal. A public hearing was not requested and one was not held.

Background and Purpose

This drawbridge presently opens on signal except that from 11 a.m. to 6 p.m., on weekend and holidays, the draw need open only on the hour, quarter hour, half hour, and three quarter hour. The MPO and FDOT requested that the bridge open only on the hour and half hour during certain periods of each day to help reduce traffic delays, particularly during morning and afternoon commuter hours and on busy weekends. A comparison of highway traffic volumes between 1985 and 1993 indicated there has been an overall increase in traffic volume with current levels exceeding highway capacity on weekday afternoons during the winter season without any bridge openings.

The number of bridge openings continue to average less than two per hour with a maximum of 4 openings per hour being experienced periodically during the winter season. Based on analysis of the highway traffic and bridge opening data provided by FDOT on June 28, 1993, the Coast Guard determined that most of the weekday delays were caused by back to back bridge openings which did not allow accumulated vehicle traffic to clear before the next opening. The Coast Guard concluded that a 30 minute opening schedule was not warranted, but as a compromise, tested a 20 minute opening schedule which would limit openings to 3 times per hour daily, year around. This test was conducted from January 1, 1994, to February 23, 1994. The results demonstrated that strong cross winds, heavy currents and shallow water adjacent to the channel near the bridge create holding conditions for northbound vessels that could become unsafe for navigation if the opening schedule is extended to 30 minutes. A daily 20 minute schedule would help reduce traffic delays without significantly increasing the danger to vessels caused by the potentially unsafe holding conditions.

Discussion of Comments and Changes

Two commenters were in favor of the year round 20 minute opening schedule. One commenter opposed any increase in vessel delays due to unsafe holding conditions near the bridge. He suggested extending the existing 15 minute schedule to include peak weekday traffic periods and recommended improving local traffic light coordination with the bridge openings. One commenter recommended openings on the hour and half hour similar to the nearby Ringling Causeway Drawbridge. Another commenter recommended sailboats be required to operate offshore and pay a fee for each bridge opening to minimize impacts on highway traffic. The Coast Guard has carefully considered these comments and has concluded the 20 minute schedule will reduce bridge openings without creating unsafe holding conditions for waiting vessels. FDOT will be encouraged to install traffic light preemption programs which should help reduce cross traffic delays and improve vehicular dispersal after each bridge opening.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT (44 FR 11040; February 26, 1979) is unnecessary. We conclude this because the rule exempts tugs with tows.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal, if adopted, will have a significant economic impact on a substantial number of small entities. ''Small entities'' include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632). Because it expects the impact of this proposal to be minimal, the Coast Guard certifies under section 605(b) that this proposal, if adopted, will not have a significant impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612, and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this proposal and concluded that, under section 2.B.2.g.(5) of Commandant Instruction M16475.1B, promulgation of operating requirements or procedures for drawbridges is categorically excluded from further environmental documentation. A Categorical Exclusion Determination is available for inspection or copying at the above address.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. In § 117.287, paragraph (b–1) is revised to read as follows:

§ 117.287 Gulf Intracoastal Waterway.

* * * * *

(b–1) The draw of the Siesta Key bridge, mile 71.6 at Sarasota, shall open on signal, except that, from 11 a.m. to 6 p.m. daily, the draw need open only on the hour, 20 minutes past the hour, and 40 minutes past the hour.

* * * * *

Dated: January 18, 1995.

W.P. Leahy,

Rear Admiral, U.S. Coast Guard Commander, Seventh Coast Guard District.

[FR Doc. 95–2650 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF EDUCATION

34 CFR Parts 74 and 75

Administration of Grants and Agreements With Institutions of Higher Education, Hospitals, and other Non-Profit Organizations; Direct Grant Programs

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends 34 CFR parts 74 and 75 to add the Office of Management and Budget (OMB) control numbers to certain sections of the regulations. Those sections contain information collection requirements approved by OMB. The Secretary takes this action to inform the public that these requirements have been approved.

EFFECTIVE DATE: These regulations are effective on February 3, 1995.

FOR FURTHER INFORMATION CONTACT: Greg Vick, U. S. Department of Education, 600 Independence Avenue, S.W., Room 3636, Regional Office Building 3, Washington, D.C. 20202. Telephone (202) 708–8199. Individuals who use a telecommunications device 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 time, Monday through Friday.

SUPPLEMENTARY INFORMATION: On June 10, 1994, final regulations for Direct Grant Programs (part 75) were published in the **Federal Register** at 59 FR 30258, and on July 6, 1994, final regulations for the Administration of Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-Profit Organizations (part 74) were published in the **Federal Register** at 59 FR 34722. Compliance with information collection requirements in 34 CFR 74.12, 74.21, 74.25, 74.34, 74.44, 74.45, 74.46, 74.47, 74.51, 74.52, 74.53, 74.71, 74.72, 75.118 and 75.590 was delayed until those requirements were approved by OMB under the Paperwork Reduction Act of 1980. OMB approved the information collection requirements in the regulations for part 75 on June 3, 1994 and for part 74 on July 12, 1994.

Waiver of Proposed Rulemaking

In accordance with the Administrative Procedure Act (5 U.S.C. 553), it is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations. However, the publication of OMB control numbers is purely technical and does not establish substantive policy. Therefore, the Secretary has determined under 5 U.S.C. 553(b)(B), that proposed rulemaking is unnecessary and contrary to the public interest and that a delayed effective date is not required under 5 U.S.C. 553(d)(3).

List of Subjects

34 CFR Part 74

Administrative practice and procedure, Education Department, Grant programs-education, Grant administration, Hospitals, Institutions of higher education, Non-profit organizations, Reporting and recordkeeping requirements.

34 CFR Part 75

Education Department, Discretionary grant programs, Continuation funding, Grant administration, Reporting and recordkeeping requirements, Performance reports, Unobligated funds.

Dated: January 27, 1995.

Donald R. Wurtz,

Chief Financial Officer.

The Secretary amends Parts 74 and 75 of Title 34 of the Code of Federal Regulations as follows:

PART 74—ADMINISTRATION OF GRANTS AND AGREEMENTS WITH INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NON-PROFIT ORGANIZATIONS

1. The authority citation for part 74 continues to read as follows:

Authority: 20 U.S.C. 1221e–3(a)(1) and 3474; OMB Circular A–110, unless otherwise noted.

2. Sections 74.12, 74.21, 74.25, 74.34, 74.44, 74.45, 74.46, 74.47, 74.51, 74.52, 74.53, 74.71, and 74.72 are amended by adding the OMB control number at the end of these sections to read as follows: ''(Approved by the Office of Management and Budget under control number 1880–0513)''

PART 75—DIRECT GRANT PROGRAMS

3. The authority citation for part 75 continues to read as follows:

Authority: 20 US.C. 1221e-3(a)(1) and 3474, unless otherwise noted.

§ 75.118 [Amended]

§ 75.599 [Amended]

4. Sections 75.118 and 75.590 are amended by adding the OMB control number at the end of these sections to read as follows: ''(Approved by the Office of Management and Budget under control number 1875–0102)''

[FR Doc. 95–2659 Filed 2–2–95; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH35

Compensation for Certain Undiagnosed Illnesses

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations to authorize compensation for disabilities resulting from the undiagnosed illnesses of Persian Gulf veterans. This amendment provides the necessary regulatory framework to allow the Secretary to pay compensation under the authority granted by the Persian Gulf War Veterans' Benefits Act.

EFFECTIVE DATE: November 2, 1994, the effective date of Title I of Public Law 103–446.

FOR FURTHER INFORMATION CONTACT: Steven Thornberry, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: ''The Persian Gulf War Veterans' Benefits Act,'' Title I of Public Law 103–446, authorizes the Secretary of Veterans Affairs to compensate any Persian Gulf veteran suffering from a chronic disability resulting from an undiagnosed illness or combination of undiagnosed illnesses that became manifest either during active duty in the Southwest Asia theater of operations during the Persian Gulf War or to a degree of 10 percent or more within a presumptive period following such service, as determined by the Secretary. On December 8, 1994, VA published a proposed rule to implement the statute (59 FR 63283–85). We requested that comments to the proposed rule be submitted on or before January 9, 1995. We received 10 comments.

We had proposed that, for the purposes of § 3.317, a disability resulting from an undiagnosed illness would be considered chronic if it had existed for 6 months or more. One commenter recommended that VA consider disabilities subject to

intermittent periods of improvement and worsening over a 6-month period as chronic.

VA agrees that including this concept in the rule will promote clarity and ensure that the criteria for chronicity are consistently applied. Therefore, we have revised § 3.317(a) as the commenter suggested.

Another commenter recommended that the rule specify the point from which VA would measure chronicity, i.e., forward from the date symptoms were first reported or backward from date of claim.

The 6-month period of chronicity will be measured from the earliest date the symptoms of the disability became manifest, whether as reported and documented during the course of a medical examination or as established by other, non-medical evidence. In order to ensure proper understanding, we have revised § 3.317(a) to clarify this issue.

Another commenter objected to defining a chronic disease as one which has existed for at least 6 months and suggested that chronicity be determined on the basis of clinical and laboratory findings and application of the criteria for a showing of chronic diseases in 38 CFR 3.303(b).

VA does not agree. The criteria of § 3.303(b) require a combination of manifestations sufficient to identify the disease entity and sufficient observation to establish chronicity at the time. So long as we are dealing with a known disease whose clinical course is familiar, those criteria are appropriate. In our judgment, however, they are not appropriate for dealing with an undiagnosed illness, which cannot be associated with a known disease process and the clinical course of which cannot be predicted. In these cases, it is essential to establish an objective indicator of chronicity to ensure that the same standard will be applied in every case. Therefore, we have adopted 6 months, a period commonly accepted within the medical community for that purpose, as the standard for determining chronicity.

One commenter recommended that the regulation include a statement that objective indications of disability mean both ''signs'' in the medical sense and non-medical indicators capable of independent verification, as VA stated in the preamble to the proposed rule.

We agree with the commenter's recommendation and have amended § 3.317(a) accordingly.

Another commenter suggested that the regulation explicitly state how many ''signs or symptoms'' of undiagnosed illness must be present for a veteran to be eligible for compensation under § 3.317. The commenter stated that it appears that VA would accept even a single symptom as sufficient to qualify.

The commenter is correct in assuming that a single symptom or sign may be sufficient to establish entitlement under § 3.317, provided it is determined to be the result of an undiagnosed illness. This was intended by our proposed § 3.317(a)(1): ''* * * objective indications of chronic disability * * * manifested by *one or more* signs and symptoms * * *'' (emphasis added). However, as further clarification, we have amended the words ''signs and symptoms'' to read ''signs or symptoms.''

The proposed regulation, as required by the statute, contained a list of 13 categories of signs and symptoms which might be manifestations of undiagnosed illnesses. One commenter said that it was not clear why VA considered some of the 13 signs and symptoms listed at § 3.317(b) undiagnosable. As an example, the commenter referred to fatigue lasting longer than 6 months as having a known diagnosis, already recognized by VA, of chronic fatigue syndrome (CFS).

The signs and symptoms listed at § 3.317(b) represent possible manifestations of undiagnosed illnesses. However, the commenter's implication that a medically verifiable sign of an illness constitutes a diagnosis of a specific disease is not correct. A ''disease'' is manifested by a characteristic set of symptoms and signs (*Dorland's Illustrated Medical Dictionary*, 27th ed.). A single sign or symptom may be among the characteristic signs and symptoms of more than one disease, depending on any other signs and symptoms with which it appears. Many Persian Gulf veterans, however, have come forward with signs and symptoms which are not characteristic of any known disease.

The commenter's assertion that fatigue lasting longer than 6 months by itself equates to CFS is also incorrect. VA has adopted criteria for CFS similar to those contained in guidelines published by the U.S. Department of Health and Human Services (HHS), which require a combination of several major and minor criteria to establish a diagnosis of CFS (see the **Federal Register** of November 29, 1994, 59 FR 60901). The major criteria include fatigue so severe as to reduce daily activities below 50 percent of the usual, pre-illness level for at least 6 months. Fatigue of a lesser severity, which does not last for 6 months, or which is not accompanied by the major or minor criteria recognized by VA, would not support a diagnosis of CFS. If that fatigue does not fall among the characteristic signs and symptoms of another disease, it certainly might indicate the presence of an undiagnosed illness.

This same commenter stated that VA has a working definition of ''Persian Gulf Syndrome'' that lists many of the 13 signs and symptoms listed at § 3.317(b) and wondered why this ''syndrome'' is not cited in that paragraph.

''Persian Gulf Syndrome'' is not a disease entity currently recognized by VA or commonly accepted within the medical community. VA has, in fact, been unable to establish a single ''working definition,'' and any working definition, by its very nature, would not find a firm basis in the current scientific and medical evidence and, in our judgment, should not be used to establish entitlement under the provisions of this rule. The purpose of this rule making is not to define by regulation what the medical community has yet to identify or define, but rather to establish criteria for paying compensation to Persian Gulf veterans suffering from chronic disabilities resulting from undiagnosed illnesses.

One commenter recommended that § 3.317(b) specify that other signs and symptoms might qualify as possible manifestations of undiagnosed illness.

The list at § 3.317(b) is simply a guideline presenting the symptoms and signs which have been encountered in over 17,000 completed and analyzed examinations of participants in VA's Persian Gulf Health Registry. The categories are broad and encompass a wide range of conditions and complaints. Section 3.317(b) itself clearly indicates that this list is not exclusive, and we do not believe that revising the language would make the point any clearer.

Another commenter stated that many Persian Gulf veterans also complained of hair loss and memory loss and requested that VA clarify whether these conditions are encompassed by the 13 listed categories.

Hair loss is included within the category ''signs and symptoms involving skin'' (§ 3.317(b)(2)), and memory loss is included within the category ''neuropsychological signs or symptoms'' (§ 3.317(b)(7)). This is consistent with current VA rating procedures, and we see no need to make the list more specific, since any attempts to expand the list and make it exclusive might inadvertently omit conditions that could be manifestations of undiagnosed illnesses.

One commenter recommended that VA alter the wording of proposed § 3.317(a)(3) (§ 3.317(a)(4) in the final rule), which provides that VA will evaluate chronic disabilities of undiagnosed illnesses using the criteria of VA's Rating Schedule for a disease or injury in which ''the functions affected, anatomical localization, and symptomatology are similar,'' to read ''the functions affected, anatomical localization, *or* symptomatology.''

Since we intend to allow rating specialists enough flexibility to rate as accurately and fairly as possible, we have amended the language as the commenter suggested.

This same commenter also recommended that VA develop full rating criteria specific to the undiagnosed illnesses of Persian Gulf veterans, and covering the full range of physiological and psychological disabilities being reported.

Although Persian Gulf veterans have reported that they are suffering from a variety of signs and symptoms, the scientific and medical communities have been unable to identify a single disease process and, in fact, have suggested that more than one disease category may be involved. Our purpose in this rule making is to authorize compensation for the *disabilities* resulting from the undiagnosed illnesses, and, in our judgment, the criteria in the Rating Schedule are adequate to evaluate any disabilities which may arise.

One commenter recommended that VA revise § 3.317 to specify that service connection may be recognized for aggravation of a preexisting undiagnosed illness during service in the Southwest Asia theater of operations or during the presumptive period.

VA does not agree. In enacting Public Law 103–446, Congress authorized VA to compensate Persian Gulf veterans who suffer chronic disabilities resulting from undiagnosed illnesses that became manifest during active service in the Southwest Asia theater of operations or within a presumptive period thereafter, as determined by the Secretary. It would exceed the Secretary's statutory authority to compensate for aggravation of disabilities resulting from preexisting undiagnosed illnesses. Furthermore, since the course of an undiagnosed illness cannot be predicted, it would be impossible to determine whether an increase in disability was due to the natural progress of the illness or to aggravation during service.

The proposed regulation contained provisions prohibiting payment of compensation where affirmative evidence establishes that an undiagnosed illness was not incurred during active service in the Persian Gulf (§ 3.317(c)(1)), and where affirmative evidence establishes that an undiagnosed illness is the result of a supervening condition or event that occurred following the veteran's most recent departure from the Southwest Asia theater of operations and the onset of the illness (§ 3.317(c)(2)). One commenter stated that § 3.317(c)(1) was redundant and unnecessary in light of § 3.317(c)(2).

VA does not agree. The prohibition contained in § 3.317(c)(2) applies whether the illness was alleged to have occurred during service in the Southwest Asia theater of operations or during the presumptive period thereafter. However, since Public Law 103–446 did not contemplate eligibility by reason of aggravation of a pre-existing undiagnosed illness, the provisions of § 3.317(c)(1) are necessary to ensure that entitlement to compensation is properly established.

One commenter stated that the ''affirmative evidence'' standard for determining that an undiagnosed illness was the result of a supervening condition or event does not equate to any standard known in law but is rather an arbitrary standard established by VA. The commenter suggested substituting the recognized legal standard of ''clear and convincing evidence.''

VA does not agree. In fact, the standard of ''affirmative evidence'' is long established in the statutes and regulations governing VA benefits. It is used in 38 U.S.C. 1113 to define the type of evidence sufficient to rebut a presumption of service connection. Congress again adopted the term at 38 U.S.C. 1116(a)(3), which provides that a veteran who served in the Republic of Vietnam during the Vietnam era and has one of the presumptive diseases related to herbicide exposure will be presumed to have been exposed to herbicides ''unless there is affirmative evidence'' to the contrary. Under 38 CFR 3.307(d), affirmative evidence accepted to rebut a presumption of service connection, although not requiring a conclusive showing, must, nonetheless, be competent to indicate the time of existence or inception of a disease and must support a conclusion that a disease was not incurred in service. We believe that this standard is both reasonable for determining whether a claimed undiagnosed illness is the result of a supervening condition and consistent with standards that VA applies to presumption for diagnosed conditions.

One commenter recommended that the regulation define the term ''known clinical diagnosis'' in order to specify the criteria to be applied in determining whether a condition qualifies as an undiagnosed illness.

VA does not agree. The concept of what constitutes a ''known clinical diagnosis'' is not such a matter of uncertainty within the medical community as the commenter has implied. Examining physicians routinely determine whether or not an illness is part of a disease process that follows a particular clinical course which can be generally predicted. If the physician is unable to attribute a disability to such a known clinical diagnosis, he or she would routinely include a statement to that effect on the examination report. In the event of conflicting findings, it would be incumbent upon VA to resolve the issue on the basis of all medical evidence of record.

Another commenter believed that the requirement for a finding of undiagnosed illness is outside currently accepted standards of medical practice and that physicians should not be required to make a diagnosis of an ''undefined non-disease.''

The regulation does not require that physicians make such a diagnosis. Physicians should simply record all noted signs and reported symptoms, document all clinical findings, and provide a diagnosis where possible. If the signs and symptoms are not characteristic of a known clinical diagnosis, the physician should so indicate. This conforms with the usual standards of medical practice.

The proposed regulation provided that VA shall pay compensation to a Persian Gulf veteran who exhibits objective indications of chronic disability resulting from an undiagnosed illness or combination of illnesses as manifested by one of the 13 signs and symptoms listed at § 3.317(b). One commenter stated that objective verification of symptoms by an examining physician would be impossible, since most of the 13 signs and symptoms are subjective. He predicted that many veterans would not present with objective signs perceptible to examining physicians and that, therefore, examinations would be judged inadequate or claims would be denied for a lack of objective evidence. Another commenter recommended that VA omit the word ''objective.''

VA does not agree. Some veterans may present with purely subjective symptoms, which, nonetheless, establish the basis for a valid claim under the provisions of this rule. We believe, however, that it is not only fair but also in keeping with Congressional intent to require some objective

indication of the presence of a chronic *disability* attributable to an undiagnosed illness before awarding compensation. In the House of Representatives report on H.R. 4386, an earlier version of Persian Gulf legislation, the Committee on Veterans' Affairs stated its intention ''that there must be some objective indication or showing of the disability which is observable by a person other than the veteran, or for which medical treatment has been sought.'' (House Report # 103–669, p. 7.) Similarly, at a September 14, 1994, hearing on the Senate Committee on Veterans' Affairs, Senator Rockefeller, then Chairman of the Committee, stated that in introducing S. 2330, an earlier Senate version of the legislation, it was his intention that compensation be paid in situations where a veteran ''has symptoms that can be verified by objective tests that show that the [veteran] is not well.'' (S. Hrg. 103–829, p. 3.)

Ordinarily, an objective indication is established through medical findings, i.e., ''signs'' in the medical sense of evidence perceptible to an examining physician. However, we also will consider non-medical indications which can be independently observed or verified, such as time lost from work, evidence that a veteran has sought medical treatment for his or her symptoms, evidence affirming changes in the veteran's appearance, physical abilities, and mental or emotional attitude, etc. Lay statements from individuals who establish that they are able from personal experience to make their observations or statements will be considered as evidence when VA determines whether the veteran is suffering from an undiagnosed illness.

Two commenters suggested that where the previously undiagnosed illness of a veteran is subsequently diagnosed, compensation under § 3.317 should continue until a decision on eligibility under other statutory or regulatory provisions has been reached.

Once the illness in a particular case has been diagnosed and a veteran is no longer entitled to compensation under the provisions of § 3.317, the provisions of § 3.500(y) require termination of compensation as of the last day of the month in which 60 days following the final rating decision expires. However, VA will simultaneously begin consideration of potential entitlement under other statutory and regulatory provisions and will initiate any required development for additional evidence. Although the 60-day period of § 3.500(y) is fixed in accordance with the requirements of 38 CFR 3.105(d) and (e), those sections of the regulations also provide for a 60-day predetermination period prior to final rating action in order to safeguard a veteran's due process rights. We believe that a decision on entitlement under other provisions can be made prior to termination or reduction under § 3.500(y).

While the possibility remains that some awards under § 3.317 might be terminated prior to a final determination of entitlement under other provisions, we have no authority to pay compensation in the absence of an actual determination of entitlement. However, if payment is terminated but entitlement is subsequently established on another basis, payments may be made retroactive to the date compensation under the provisions of § 3.317 was terminated.

One commenter recommended that this regulation state that if scientific research eventually establishes that the signs and symptoms of Persian Gulf veterans with undiagnosed illnesses constitute a syndrome which can be attributed to service in the Persian Gulf, the provisions of 38 CFR 3.303(d) will provide a basis for establishing service connection for this syndrome.

VA does not agree. Section 3.303(d) provides that, notwithstanding statutory presumptive periods, service connection may be granted for a disease first diagnosed after discharge from service when all pertinent evidence establishes that the disease was incurred in service. However, so long as medical and scientific research has not established that some or all Persian Gulf veterans with undiagnosed illnesses are in fact suffering from a recognizable disease process attributable to service in the Gulf, any regulatory assumption that research will, in fact, eventually support such a finding would be conjectural and premature.

One commenter remarked that VA, in establishing a presumptive period, seems not to have taken into account either credible scientific and medical evidence or pertinent circumstances regarding the experiences of Persian Gulf veterans and, thus, failed to meet statutory requirements of Public Law 103–446.

VA does not agree. Public Law 103–446 required VA to determine an appropriate presumptive period following a review of the credible scientific and medical evidence and the historical treatment afforded disabilities for which manifestation periods have been established, and taking into account other pertinent circumstances regarding the experiences of veterans of the Persian Gulf War. Although many veterans began to develop unexplained signs and symptoms of illness shortly after their return from the Persian Gulf, there is as yet little or no medical or scientific evidence definitively linking the illnesses with service in the Gulf, and the credible evidence available supports no conclusions regarding etiology or definition of these illnesses. The National Institutes of Health (NIH)-sponsored Technology Assessment Workshop on the Persian Gulf Experience and Health, held in April 1994, concluded that it was not possible to establish a single case definition for the illnesses of Persian Gulf veterans and that, in fact, more than one disease category might be present, with overlapping symptoms and causes. More recently, a report of the Medical Follow-up Agency of the Institute of Medicine (IOM), published in January of this year, endorsed the report of the NIH panel comprized of non-government experts and stated that ''[t]he Gulf War illness phenomenon may prove to be a mixture of several illnesses, or may prove not to be associated with a specific exposure or disease.'' The IOM report further concluded that establishment of a case definition was ''handicapped by the lack of any generally recognized pathognomonic physical signs or laboratory findings, and by uncertainty about whether a specific syndrome exists and, if it does exist, its prevalence among Gulf War veterans. The subjectivity of many of the complaints associated with the Gulf War illness creates serious problems for those seeking to investigate the validity and origins of the illness.'' (Health Consequences of Service During the Persian Gulf War: Initial Findings and Recommendations for Immediate Action, National Academy Press, 1995, p. 26.) Given this uncertainty of available scientific and medical evidence, we felt that a presumptive period could not be established on this basis, and we looked to the other 2 factors, historical treatment and pertinent circumstances, to determine an appropriate period.

For many years Congress has authorized a one-year presumptive period for various chronic diseases, many of which present signs and symptoms similar to those of the undiagnosed illnesses of Persian Gulf veterans (see 38 U.S.C. 1101(3) and 1112(a)). This historical treatment of chronic diseases might indicate that a one-year presumptive period would be warranted for the undiagnosed illnesses of Persian Gulf veterans. We felt, however, that a one-year presumptive period would not meet the particular needs of these veterans, because it was

not immediately apparent when most of them left the Southwest Asia theater of operations that their signs and symptoms, which some believed resulted from exposure to environmental hazards, would present the problems of diagnosis and etiology that remain unresolved today. We believe that two years following service in the Gulf provides an adequate period of time in which all veterans of the hostilities would have become aware of the potential significance of their symptoms and have had an opportunity to present and document health concerns that arose soon after their departure from the Gulf. Certainly by the end of the first 2 years following their return, there were great public awareness of and concern for Persian Gulf veterans with unexplained illnesses that defied diagnosis but seemed to be in some way linked to service in the Persian Gulf.

An additional reason for establishing a 2-year presumptive period rather than a one-year period is that VA did not begin full-scale operation of its Persian Gulf Health Registry until November 1992. Because many Persian Gulf veterans first presented their health concerns in connection with VA's Persian Gulf Health Registry examination, veterans of the actual hostilities, who began to return from the Gulf by mid-1991, did not have this resource available to them within their first year after leaving the Gulf. Within 2 years, however, all veterans of the hostilities would have had this opportunity to document their illnesses. Therefore, we established a 2-year presumptive period running from the date of a veteran's last service in the Southwest Asia theater of operations.

Two commenters recommended that in establishing a presumptive period VA take into account the bases for the longer presumptive periods established for certain diseases associated with radiation and herbicide exposure. One of these same commenters specifically recommended establishing a presumptive period based on the onset of symptoms of ''slow viruses,'' which may take up to 8 years to become manifest.

VA does not agree. Where scientific and medical evidence has concluded that manifestation of a disease may be delayed following exposure to specific substances, such as herbicides or radiation, that evidence might justify establishment of an appropriate presumptive period. However, medical and scientific evidence addressing the latency periods of known diseases cannot form a basis for determining a latency period for undiagnosed illnesses. Longer or open-ended presumptive periods for certain diseases, such as those associated with exposure to radiation or herbicides, were established only following many years of extensive research. For example, to assist in determining what diseases may be associated with exposure to herbicides used in the Republic of Vietnam during the Vietnam era, VA contracted with the National Academy of Sciences (NAS) to do a review of the available scientific and medical literature. The NAS subsequently reviewed 6,420 abstracts of scientific or medical studies and approximately 230 epidemiological studies prior to submitting recommendations. A similar body of medical and scientific evidence addressing the undiagnosed illnesses of Persian Gulf veterans simply does not exist at this time, and what evidence is available supports no conclusions regarding etiology or identification. There is no basis, other than conjecture, for comparing the undiagnosed illnesses of Persian Gulf veterans to the symptoms of slow viruses or to diseases associated with exposure to radiation or herbicides.

Several commenters believed that a 2-year presumptive period was either arbitrary, premature, or too restrictive and, citing the current uncertainty of medical and scientific evidence, recommended presumptive periods ranging from 5 years to open-ended.

Although medical and scientific evidence is accumulating about the various signs and symptoms of Persian Gulf veterans with undiagnosed illnesses, there is little or no evidence definitively linking the illnesses with service in the Gulf, and the credible evidence available supports no conclusions regarding etiology, definition of the undiagnosed illnesses, or latency period, which would justify adopting a longer presumptive period. The commenters offered no other reasonable basis to justify a presumptive period longer than 2 years, and we have not adopted their recommendations.

Six commenters believe that the 2-year presumptive period is inadequate because Persian Gulf veterans were unaware that they would need to document their undiagnosed illnesses. They stated that associating the presumptive period with establishment of the Persian Gulf Health Registry did not give all veterans of the hostilities an adequate opportunity to document their illnesses because availability of the Registry examination was not widely known until mid-1993, nearly 2 years after the first U.S. servicemembers began returning from the Persian Gulf.

The Persian Gulf Registry examination is not the only acceptable means of documenting the presence of an undiagnosed illness. Other types of medical evidence may be used, such as routine VA medical reports, military medical records, and reports from private physicians. We believe that where the illness of a veteran manifested itself to a compensable degree (10 percent or greater), it is very likely either that the veteran would have sought medical treatment or that other, non-medical evidence is available which would document the veteran's signs or symptoms. For example, lay statements from individuals who establish that they are able from personal experience to make their observations or statements concerning the appearance of the signs or symptoms of a veteran's illness may be used to establish entitlement. In fact, many veterans did file claims for compensation within 2 years of leaving the Gulf based on disabilities that they felt may have resulted from exposure to environmental hazards. VA examinations and other medical evidence reflecting complaints of or treatment for these disabilities should provide adequate documentation for the purposes of this regulation. The 2-year presumptive period is not intended to limit the presumption of service connection under § 3.317 to illnesses documented within that time frame. Documentation of the signs and symptoms first made shortly after the presumptive period might establish entitlement if it reasonably supports a conclusion that the illness existed during the 2-year period following a veteran's last service in the Persian Gulf region.

These commenters also stated that many who remained on active duty after service in the Persian Gulf were hesitant to report their ailments for fear of jeopardizing their military careers.

In our judgment, remaining on active duty following service in the Persian Gulf does not necessarily preclude the likelihood that alternative documentation acceptable to VA can be obtained. Although many of these individuals might have been unwilling to seek treatment for their illnesses from military physicians, documentation of treatment from civilian physicians might exist for some. In the event that others chose not to obtain medical treatment of any kind, lay statements, such as those mentioned earlier, may be used to establish entitlement.

These commenters also stated that since many VA and Department of Defense (DOD) physicians have been unwilling to acknowledge that their

illnesses could be related to Persian Gulf service, it is possible that complaints that have been made have gone unreported to VA regional offices in connection with claims for compensation.

When a veteran files a claim for compensation, the regional office of jurisdiction obtains all pertinent VA, military, and private medical records. Whether or not an examining physician agreed with the veteran's belief that his or her illness was the result of service in the Persian Gulf, it is likely that documentation of the complaint exists, since the physician would have been obligated to record it. If the complaint was made within the 2-year presumptive period, that record will serve as documentation to establish potential entitlement to compensation.

Three commenters recommended that VA measure the presumptive period from a date other than the date of a veteran's last service in the Southwest Asia theater of operations. They separately recommended that the presumptive period run from the effective date of Public Law 103–446, the date VA's Persian Gulf Health registry was established, or the date of a veteran's separation from service.

VA does not agree. Since the statute presumes that these health concerns are related to Persian Gulf service, it is reasonable that the presumptive period be measured from the date service in the Gulf ended, and the statute itself specifically indicates that the presumptive period will be so measured. Furthermore, measuring the presumptive period from the last date of Gulf service is consistent with other presumptive periods, such as those for diseases related to radiation or herbicide exposure, which are measured from the last date on which exposure could have occurred. Finally, if the presumptive period were to be measured from the date a veteran was separated from service, veterans who remained on active duty for several years after they left the Persian Gulf would be unfairly advantaged.

Another commenter felt that, where the undiagnosed illnesses of Persian Gulf veterans are eventually diagnosed, the regulation should also allow a 2-year presumptive period for the diagnosed conditions.

VA does not agree. The undiagnosed illness provisions of Public Law 103–446, as implemented by § 3.317, were specifically intended to relieve the unique situation in which certain Persian Gulf War veterans found themselves unable to establish entitlement to VA compensation because their illnesses currently cannot be diagnosed. There is already a well-established statutory and regulatory framework for compensating disabilities resulting from diagnosed diseases, which Congress could have revised if it had chosen to do so. Compensation may be awarded when the evidence establishes that a disease was incurred directly during active duty or that a preexisting disease was aggravated by active duty, so long as any increase in severity was not due to the natural progress of the disease. Compensation may also be paid on a presumptive basis for certain chronic diseases that appear within a statutory presumptive period, generally one year. If the undiagnosed illnesses of Persian Gulf veterans are eventually identified and this current legal framework for compensation proves to be inadequate, that will be an issue for VA and the Congress to consider at that time.

VA wishes to thank the commenters for their thoughtful remarks. The rule is hereby adopted as proposed with the revisions to § 3.317(a) mentioned in the preamble.

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. This final rule would not directly affect small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of §§ 603 and 604.

This final rule has been reviewed by the Office of Management and Budget under the provisions of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

(The Catalog of Federal Domestic Assistance program numbers are 64.109 and 64.110.)

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Health care, Individuals with disabilities, Pensions, Veterans.

Approved: January 25, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR Part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Section 3.317 is added to read as follows:

§ 3.317 Compensation for certain disabilities due to undiagnosed illnesses.

(a)(1) Except as provided in paragraph (c) of this section, VA shall pay compensation in accordance with chapter 11 of title 38, United States Code, to a Persian Gulf veteran who exhibits objective indications of chronic disability resulting from an illness or combination of illnesses manifested by one or more signs or symptoms such as those listed in paragraph (b) of this section, provided that such disability:

(i) became manifest either during active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War, or to a degree of 10 percent or more not later than two years after the date on which the veteran last performed active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War; and

(ii) by history, physical examination, and laboratory tests cannot be attributed to any known clinical diagnosis.

(2) For purposes of this section, ''objective indications of chronic disability'' include both ''signs,'' in the medical sense of objective evidence perceptible to an examining physician, and other, non-medical indicators that are capable of independent verification.

(3) For purposes of this section, disabilities that have existed for 6 months or more and disabilities that exhibit intermittent episodes of improvement and worsening over a 6-month period will be considered chronic. The 6-month period of chronicity will be measured from the earliest date on which the pertinent evidence establishes that the signs or symptoms of the disability first became manifest.

(4) A chronic disability resulting from an undiagnosed illness referred to in this section shall be rated using evaluation criteria from part 4 of this chapter for a disease or injury in which the functions affected, anatomical localization, or symptomatology are similar.

(5) A disability referred to in this section shall be considered service connected for purposes of all laws of the United States.

(b) For the purposes of paragraph (a)(1) of this section, signs or symptoms which may be manifestations of undiagnosed illness include, but are not limited to:

(1) fatigue

(2) signs or symptoms involving skin

(3) headache
(4) muscle pain
(5) joint pain
(6) neurologic signs or symptoms
(7) neuropsychological signs or symptoms
(8) signs or symptoms involving the respiratory system (upper or lower)
(9) sleep disturbances
(10) gastrointestinal signs or symptoms
(11) cardiovascular signs or symptoms
(12) abnormal weight loss
(13) menstrual disorders.

(c) Compensation shall not be paid under this section:

(1) if there is affirmative evidence that an undiagnosed illness was not incurred during active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War; or

(2) if there is affirmative evidence that an undiagnosed illness was caused by a supervening condition or event that occurred between the veteran's most recent departure from active duty in the Southwest Asia theater of operations during the Persian Gulf War and the onset of the illness; or

(3) if there is affirmative evidence that the illness is the result of the veteran's own willful misconduct or the abuse of alcohol or drugs.

(d) For purposes of this section:

(1) the term ''Persian Gulf veteran'' means a veteran who served on active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War.

(2) the Southwest Asia theater of operations includes Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations.

(Authority: Title I, Pub. L. 103–446; 38 U.S.C. 501(a))

3. Section 3.500 is amended by adding paragraph (y) to read as follows:

§ 3.500 General.

* * * * *

(y) *Compensation for certain disabilities due to undiagnosed illnesses (§§ 3.105; 3.317).* Last day of the month in which the 60-day period following notice to the payee of the final rating action expires. This applies to both reduced evaluations and severance of service connection. (Authority: Pub. L. 103–446; 38 U.S.C. 501(a))

[FR Doc. 95–2764 Filed 2–1–95; 9:07 am]
BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 270

[FRL–5149–1]

Determination of Point at Which RCRA Subtitle C Jurisdiction Begins for Municipal Waste Combustion Ash at Waste-to-Energy Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of statutory interpretation.

SUMMARY: On May 2, 1994, the Supreme Court issued its decision in *City of Chicago* v. *Environmental Defense Fund, Inc.* 114 S.Ct. 1588 (1994). In so doing, the Court held that, although municipal waste-to-energy (WTE) facilities that burn household wastes alone, or in combination with nonhazardous wastes from industrial and commercial sources, are exempt from regulation as a hazardous waste treatment, storage, or disposal facility under Subtitle C of the Resource Conservation and Recovery Act (RCRA), the ash that they generate is not exempt. The Court, however, did not specify the point at which the ash generated by the WTE facility becomes subject to Subtitle C of RCRA. EPA is responding to numerous requests for resolution of this issue by announcing today that it interprets § 3001(i) of RCRA to first subject the ash generated by a WTE facility to RCRA Subtitle C when it exits the combustion building following the combustion and air pollution control processes.

EFFECTIVE DATE: February 3, 1995.

ADDRESSES: Docket Clerk, OSW (OS–305), Docket No. *95–XA2N–FFFFF,* U.S. Environmental Protection Agency Headquarters, 401 M Street, SW., Washington, DC 20460. The public docket is located in M2616 at EPA Headquarters and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. Appointments may be made by calling (202) 260–9327. Copies cost $0.15/page. Charges under $25.00 are waived.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/Superfund Hotline, Office of Solid Waste, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460, (800) 424–9346, TDD (800) 553–7672 (hearing impaired); in the Washington, DC metropolitan area the number is (703) 920–9810, TDD (703) 486–3323.

For more detailed information on specific aspects of this Notice, contact Andrew L. Teplitzky (703–308–7275) or Allen J. Geswein (703–308–7261), Office of Solid Waste (5306W), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Authority
II. Background
A. Nature of Ash From Waste-To-Energy Facilities
B. Regulatory History of Waste-to-Energy Ash
C. Initial Agency Reaction to the Supreme Court Decision
III. The Point of Subtitle C Jurisdiction
A. EPA's Interpretation
1. Legal Analysis
2. Illustrative Examples
B. Other Interpretations Considered
1. Facility Property Boundary
2. Inside the Combustion Building
C. Additional Policy Considerations
IV. Conclusion

I. Authority

This action interpreting RCRA Section 3001(i) and the hazardous waste regulations in 40 CFR Parts 260–271 is being taken under the authority of sections 2002 and 3001 of the Solid Waste Disposal Act of 1970 as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6912 and 6921).

II. Background

A. Nature of Ash From Waste-to-Energy Facilities

Combustion of municipal solid waste, particularly through WTE facilities, can be an important component of a local government's waste management practices. As of 1993, approximately 207 million tons of municipal solid waste were generated annually in the U.S., 16 percent of which (33 million tons) was combusted. There are approximately 150 municipal waste combustors in the U.S., 80 percent of which are WTE facilities. The remaining 20 percent incinerate waste without recovering energy.

Approximately 25 percent (dry weight) of the waste that is combusted remains as ash, amounting to around eight million tons of municipal waste combustor (MWC) ash generated annually. While the ash may be collected at a number of locations within a WTE facility, it typically is characterized as either ''bottom ash'' or ''fly ash.'' Bottom ash collects at the bottom of the combustion unit and comprises approximately 75–80% of the total ash by weight. Fly ash collects in the air pollution control devices that ''clean'' the gases produced during the combustion of the waste and comprises

around 20–25% of the total by weight. The fly ash from a WTE facility's different air pollution control devices typically is consolidated and then combined with the bottom ash via enclosed conveyors at the bottom of the MWC where it is cooled and conveyed to a storage area. EPA estimates that nearly 80% of WTE facilities routinely combine their ash.

The regulation of WTE ash has been the subject of controversy and debate ever since the inception of the hazardous waste management program under Subtitle C of RCRA. EPA's notice of June 7, 1994 (59 Fed. Reg. 29372) provides a discussion of the regulatory history of ash from WTE facilities. The following section summarizes that discussion.

B. Regulatory History of Waste-to-Energy Ash

In 1980, EPA promulgated a rule exempting household wastes from all RCRA requirements for hazardous wastes (40 CFR 261.4(b)(1)). EPA interpreted this exemption to extend to the residuals from the treatment of household wastes, including ash from the combustion of household wastes. The exemption, however, did not address ash from the combustion of household wastes combined with nonhazardous commercial and industrial wastes.

In 1984, Congress added to RCRA a new Section 3001(i). This provision addressed WTE facilities burning exempt household hazardous wastes and nonhazardous commercial and industrial wastes to produce energy. In July 1985, EPA promulgated a rule that codified this provision. In the preamble accompanying this rule, EPA announced that it interpreted the statute to exempt the combustion of waste, but not the management of ash, from Subtitle C (50 Fed. Reg. 28702, 28725–26 (July 15, 1985)). Since 1985, the Agency's interpretation of § 3001(i) of RCRA has been a subject of much debate.

In September 1992, EPA Administrator William Reilly signed a memorandum announcing that the Agency interpreted Section 3001(i) to exempt from all Subtitle C requirements ash from WTE facilities burning household wastes and nonhazardous wastes. On May 2, 1994, the Supreme Court issued an opinion interpreting Section 3001(i) of RCRA, 42 U.S.C. 6921(i). *City of Chicago* v. *EDF*, 114 S.Ct. 1588 (1994). The Court held that this provision does not exempt ash generated at WTE facilities burning household wastes and nonhazardous commercial wastes from the hazardous waste requirements of Subtitle C of RCRA.

As a result of this decision, persons generating ash from WTE facilities must determine whether the ash is hazardous. Studies show that ash sometimes is a hazardous waste under RCRA because it exhibits EPA's toxicity characteristic (TC). Generally, this determination is made by either testing using the Toxicity Characteristic Leaching Procedure (TCLP) (see 40 CFR § 261.24) or by using knowledge of the combustion process to determine whether the ash would exhibit the TC. Typically, ash that ''fails'' the TC leaches lead or cadmium above levels of concern. Existing studies also show that fly ash contains the highest concentrations of inorganic chemical constituents. It is more likely to exhibit the TC than either bottom ash or combinations of bottom ash and fly ash. Ash that is determined to be a hazardous waste must be handled in compliance with EPA regulations for hazardous waste management. Ash that is determined not to be a hazardous waste may be disposed in a non-hazardous waste facility.

C. Initial Agency Reaction to the Supreme Court Decision

While the Supreme Court decision ended nearly a decade of controversy over the general regulatory status of ash, it also raised some new legal and policy issues. To provide some immediate interim guidance, the Agency issued several documents shortly after the Supreme Court decision.

First, on May 24, 1994, the Agency released for immediate use a draft guidance manual for ''Sampling and Analysis of Municipal Refuse Incinerator Ash.'' The purpose of the manual was to assist owners and operators of MWCs in designing a plan for testing ash to determine whether it is hazardous. On June 23, 1994, EPA formally requested public comment on the draft guidance (59 Fed. Reg. 32427). The comment period ended on September 21, 1994. The Agency intends to issue a final guidance manual in the Spring of 1995.

Second, on May 27, 1994, EPA issued a memorandum outlining an implementation strategy to assist affected parties in achieving compliance with the Court's decision. The strategy identified the Agency's priorities for pursuing enforcement actions concerning the management of MWC ash. The Agency intends to issue a revised implementation strategy shortly.

Third, on June 7, 1994, the Agency published a notice addressing two issues of statutory and regulatory interpretation related to the management of WTE ash that is hazardous (59 Fed. Reg. 29372). First, the notice extended the deadline within which owners/operators of facilities that treat, store, or dispose of hazardous ash must file a hazardous waste permit application. This action gave owners and operators of facilities that manage hazardous ash six months to apply for ''interim status'' under the RCRA hazardous waste regulatory program. Without interim status, the facility would be out of compliance with RCRA's permit requirements and face potentially significant civil and criminal penalties.

The second issue discussed in this notice was the Agency's interpretation that ash from WTE facilities be classified as a ''newly identified waste'' for the purposes of the RCRA land disposal restrictions (LDRs), meaning that the current land disposal restrictions do not apply. When the restrictions apply, hazardous ash will have to meet specified treatment standards prior to land disposal. EPA currently takes the position that if a waste exhibits a hazardous waste characteristic at its point of generation, it must meet LDR standards even if it ceases to exhibit the characteristic prior to land disposal.

III. The Point of Subtitle C Jurisdiction

A. EPA's Interpretation

1. Legal Analysis

Neither the Supreme Court's decision on ash nor any of EPA's previous policy statements on ash address the point at which the ash generated by a WTE facility becomes subject to Subtitle C of RCRA—in other words, at which point or points in the facility the owner/operator must determine whether the ash exhibits the toxicity characteristic of a hazardous waste (and, in the future, the point at which LDR restrictions will begin to apply).

Section 3001(i) provides that ''[a] resource recovery facility recovering energy from the mass burning of municipal solid waste shall not be deemed to be treating, storing, disposing of, or otherwise managing hazardous waste * * *.'' if certain conditions regarding waste receipt are met. In the *City of Chicago* case, the Supreme Court issued a narrowly focused opinion addressing the issue of whether this language created an exemption for ash generated by resource recovery facilities. Noting that the provision fails to mention ash and fails to include ''generation'' in the list of exempted activities, the Court found that no exemption for ash was intended. 114 S.

Ct. at 1591–92. In fact, the Court found the statute to be so free from ambiguity on this issue that there was no need to consult legislative history and no occasion to defer, under the principles of *Chevron, U.S.A.* v. *NRDC*, 467 U.S. 837 (1984), to the interpretation preferred by the Agency. *Id.* at 1594.

The Court, however, failed to reach the issue of the precise point at which regulation of ash must begin, and section 3001(i) does not expressly address the issue. For the reasons set out below, EPA believes it is reasonable to interpret Section 3001(i) to first impose hazardous waste regulation at the point that the ash leaves the ''resource recovery facility,'' defined as the combustion building (including connected air pollution equipment). Consequently, the point at which an ash hazardous waste determination should be made (and, in the future, at which the LDRs will begin to apply) is the point at which ash exits the combustion building following the combustion and air pollution control processes.

Section 3001(i) does not define the term ''resource recovery facility.'' EPA believes that it is reasonable to conclude that Congress intended to refer to the building that houses the combustion device. This is the common sense reading of the term, and it strikes a better balance between the objectives of section 3001(i) and the rest of Subtitle C than either of the alternative readings described below. Further, EPA believes that it is reasonable to conclude that Congress intended to exempt all handling of any hazardous waste within the building, including the handling of hazardous ash. Subjecting ash within the building to hazardous waste regulation could, for example, require operators to collect samples of ash for waste determination purposes. It also could affect the number of hazardous ash waste streams that would become subject to LDR treatment standards. ''Collection'' and ''treatment'' are among the activities included in the definition of ''management'' in section 1004(7) of RCRA. Section 3001(i) expressly exempts treatment, storage, disposal and management of hazardous waste at resource recovery facilities. *See City of Chicago*, 114 S. Ct. at 1592.

This interpretation is not only a reasonable reading of the statutory language, it also serves Congress' intent to ''encourage commercially viable resource recovery facilities and to *remove impediments to their operation*.'' (Emphasis added.) S. Rep. 98–284, 98th Cong., 2d Sess. at 61. Regulating ash only at the point it exits the combustion building removes some potentially significant impediments. If the statute allowed regulation of ash inside the building, the facility owner/operator might need to sample and analyze ash at multiple points. This approach could require owners and operators to deal with major logistical problems associated with shutting down individual boilers and retrofitting/reconfiguring the combustor to accommodate installation of multiple handling and storage systems to separately convey the ash streams to different load out areas and ash conditioning systems. Some facilities may not currently have the space to accommodate the additional equipment required and could be forced to either close or temporarily shut down until additional space could be procured. Retrofitting a facility in this manner could be costly. Some state and industry representatives, in fact, have projected costs in excess of several million dollars per facility. Hence, this interpretation could conflict with Congressional intent by serving as an ''impediment'' to resource recovery facilities. S. Rep. 98–284 at 61. In addition, the cost of sampling and analysis alone probably would at least double considering collection and analysis of at least two different ash streams—bottom ash and fly ash—instead of a single combined ash stream. (Although owners and operators may legally use knowledge in lieu of testing, due to the variable nature of ash, virtually all owners and operators conduct TCLP testing.) These costs would contribute to the total burden imposed on the WTE facility.

Finally, in selecting an interpretation of section 3001(i), EPA also must consider Subtitle C's general goal of protecting human health and the environment from the threats posed by hazardous waste. As explained in greater detail in section C below, EPA does not believe that this interpretation would have any significant impact on the level of environmental protection for ash.

EPA also believes that today's interpretation is consistent with the Supreme Court's 1994 decision construing RCRA § 3001(i). In *City of Chicago* v. *EDF*, 114 S. Ct. 1588 (1994), the Court held that Congress intended to exempt ''resource recovery facilities,'' but did not define the term. *See, e.g.*, 114 S. Ct. at 1591–92. While the Court clearly stated that the statute did not exempt facility owners from regulation as hazardous waste generators, *id.* at 1592, determining that ash is not subject to regulation until it exits the combustion building does not exempt the facility owner from regulation as a generator. Rather, it defines the point at which the owner must begin to perform the generator's duties. Further, today's interpretation does not create the type of total exemption for ash that the Supreme Court rejected in *City of Chicago*. Operators of MWC facilities still must comply with the generator's duty to make a hazardous waste determination. Any ash that exhibits a characteristic when exiting the combustion building must be managed in compliance with all applicable Subtitle C requirements. EPA's interpretation merely clarifies the location at which the determination for waste characterization purposes must occur (and the point at which future LDRs requirements will begin to apply).

2. Illustrative Examples

Today's interpretation is perhaps best explained through the use of specific examples. For instance, many WTE facilities automatically convey, via enclosed conveyor, the fly ash collected at its various locations (including any air pollution control devices such as the acid gas scrubbers, baghouse filters, and electrostatic precipitators that may exist outside the combustion building) to a quench tank within the combustion building where it is combined with the bottom ash. The combined ash is then conveyed to a separate, detached storage building or to trucks for direct transport to an off-site disposal facility. The point at which RCRA hazardous waste jurisdiction would begin for these facilities would be the point where the ash exits the combustion building. Under this interpretation, the owner/operator could combine fly ash and bottom ash within the combustion building before making any hazardous waste determination. Any type of device could be used within the building for ash management activities such as collection, mixing, and conditioning.

EPA includes in its interpretation of ''resource recovery facility'' those air pollution control devices that are integral components of the combustion process. Ash from air pollution control devices that is reconveyed back to the combustion building in enclosed ducts has, in EPA's view, not left the ''resource recovery facility'' exempted under § 3001(i). Moreover, the ducts and air pollution control devices contain the ash so it does not come into contact with the environment.

A few WTE facilities may exist where the combustion device is not housed within a building. In these instances, the combustion device (including air pollution control equipment and proximate areas for handling ash) may constructively constitute a combustion building, within the meaning discussed above. Thus, if fly ash and bottom ash

were handled in enclosed systems that operate in the same manner as they would if a building existed and the fly ash and bottom ash were mixed in an enclosed unit proximate to the combustion device, that management activity would be considered to take place within a combustion building as described above. In this circumstance, the point at which hazardous waste jurisdiction would begin would be the point where the combined ash exits the last enclosed ash management unit that is located proximate to the combustion device.

By contrast, where a WTE facility collects bottom ash within the combustion building and collects the fly ash outside the combustion building in, for example, roll-off containers, two distinct exit points from the combustion building exist: (1) the point where the bottom ash ultimately leaves the combustion building and (2) the point where the fly ash leaves the air pollution control devices (located outside the combustion building). The WTE facility operator would thus sample and make a hazardous waste determination at each location. Should the operator determine that either the bottom ash or fly ash as is hazardous, management of that ash would have to be conducted pursuant to RCRA Subtitle C.

B. Other Interpretations Considered

Since the Supreme Court decision, the Agency has received numerous letters from states, local governments, industry, environmental groups, and others suggesting various approaches to determining the point at which the ash initially becomes subject to RCRA Subtitle C jurisdiction. For example, a number of comments received in response to the Agency's draft sampling and analysis guidance notice of May 24, 1994, addressed this issue. Some members of the public urged EPA to adopt the interpretation described above. Other members, however, suggested two additional options for interpreting § 3001(i) to establish the point at which ash becomes subject to Subtitle C regulation.

1. Facility Property Boundary

Some members of the public argued that the hazardous waste exclusion under RCRA § 3001(i) applies to all ash management operations within the property boundary of the WTE facility. This interpretation potentially would allow all ash generated at a WTE facility to be managed on-site, without testing, as a non-hazardous waste. It could allow a WTE facility to dispose of ash that would have otherwise failed the TCLP within the facility property boundary in a landfill that does not meet the requirements of RCRA Subtitle C.

EPA is rejecting the option of designating the point of Subtitle C jurisdiction at the property boundary. The most natural reading of the term ''resource recovery facility'' is the combustion device itself. Nothing in the text of the statute or the legislative history refers to land holdings or suggests that Congress was familiar with them and the types of waste management conducted on them. Rather, the discussion focuses on the combustion process. EPA believes that an exemption for the entire property would conflict with the general goals of Subtitle C because it would provide too many opportunities for potential mismanagement of ash at the WTE facility without the proper environmental controls. Such a broad reading of RCRA could allow potential mismanagement of ash that tested hazardous within the land boundaries of the facility in units (e.g., waste piles, landfills) that were not appropriately regulated under Subtitle C of RCRA. EPA believes that this option would not strike the balance that Congress intended between section 3001(i)'s goal of promoting resource recovery facilities and the general environmental protection goals of the rest of RCRA Subtitle C.

2. Inside the Combustion Building

Other members of the public argued that the exemption in section 3001(i) ends at the instant that ash is generated. In particular, they objected to any temporary exemption for ash that would allow facility owners to combine fly ash and bottom ash before making hazardous waste determinations. Since combined ash tends to ''pass'' the TC, postponing regulation until combination has occurred could allow the ash to escape Subtitle C management. These commentors argued that such a ''de facto'' exemption for WTE ash would be inconsistent with the spirit of the Supreme Court's decision in *City of Chicago.*

EPA has decided not to read the statute to require regulation of ash within the combustion building. This interpretation would permit regulation of the management of hazardous ash within the ''resource recovery facility,'' in apparent contradiction with the text of section 3001(i). Further, requiring sampling, testing, and management of ash from multiple locations could, as described below, be unnecessarily expensive and burdensome in relation to the environmental benefits received. Thus, this interpretation could conflict with Congress' goal of ''promoting resource recovery facilities.'' S. Rep. 98–284, 98th Cong. at 61.

Many of the people advocating this interpretation maintained that this interpretation would require bottom ash and fly ash to be sampled separately, before a facility owner combines them. Ash, however, may collect in as many as 20 separate locations within an average WTE facility. This interpretation, if applied literally to the first locations where ash becomes identifiable, could lead to a policy requiring that a waste determination be made at each of these locations. Such a policy would only increase the impediments to viable resource recovery facilities.

C. Additional Policy Considerations

EPA believes that today's interpretation of § 3001(i) designating the point of Subtitle C jurisdiction at the exit of the combustion building provides an approach that local governments will find practical and implementable, yet environmentally protective. In accordance with today's interpretation, ash that is combined (and conditioned, for example, with lime and/or phosphoric acid) at the end of the combustion process and within the combustion building, and exhibits no hazardous waste characteristics (i.e., it passes the TCLP) when it exits that building, may be sent to a nonhazardous waste facility for disposal.

In comparison, if the Agency had selected the option requiring hazardous waste determinations inside the combustion building, the fly ash and bottom ash that would have been tested separately at locations inside the combustion building and found to exhibit the toxicity characteristic would not be handled much differently. The WTE facility operator could treat (using similar conditioning techniques that are performed inside the combustion building under today's interpretation) the fly ash and bottom ash in on-site tanks, containers, or containment buildings under the provisions of § 262.34. Such treatment does not require a federal hazardous waste (Subtitle C) permit so long as the ash is not retained for more than 90 days. Once the ash ceased to exhibit hazardous waste toxicity characteristics, it too would be combined and sent for disposal in a nonhazardous waste facility. Similarly, once the LDR treatment standards for WTE ash hazardous constituents are promulgated, the ash would be treated (perhaps using some of the same conditioning techniques used today) to meet those standards at which point the ash could

then be sent for disposal in a nonhazardous waste facility.

EPA also believes that current regulations promulgated under RCRA Subtitle D provide protection for the disposal of ash as a nonhazardous waste. In 1991, the Agency promulgated new criteria for municipal solid waste landfills, including landfills and monofills that accept MWC ash (40 CFR Part 258). These criteria impose a comprehensive set of requirements on municipal solid waste landfills (MSWLFs) including requirements for location restrictions, facility design and operation, ground-water monitoring and corrective action, closure and post-closure care, and financial assurance. The Agency has conducted studies on the land disposal of MWC ash from WTE facilities and has found no evidence to suggest that disposal in a Subtitle D landfill will endanger human health and the environment. Copies of these studies are available in the docket for this notice.

For example, EPA has conducted a study on the effects of MWC ash leachate on natural and synthetic lining materials commonly employed in the construction of municipal solid waste landfill liners. That study indicates that carefully selected landfill liner materials can, when exposed to MWC ash leachate, be expected to function as an effective barrier to leachate migration. In addition, EPA is conducting ongoing, *in situ* studies of leachate from monofills receiving ash from a WTE facility. These studies reveal leachate concentrations of relevant metals are below their respective TC limits. The States have indicated that their data also corroborates EPA's findings.

It is important to note that while states may allow varying liner designs for ash monofills or co-disposal facilities, these designs must still meet a performance standard intended to protect ground water resources. In addition, all landfills regulated under RCRA Subtitle D are required to perform ground-water monitoring as a way of detecting a release should one occur. In the event of a release to ground water, the owner/operator of the landfill must perform corrective action to clean up the ground water.

The Agency also does not believe that the process of combining and treating ash within the combustion building will pose risks to human health. The Agency understands that many State environmental programs allow the ash to be combined and conditioned prior to exiting the combustion building for testing. These states have not indicated to the Agency that these current practices are presenting a risk to human health. In fact, the risk of exposure to fugitive ash emissions could be heightened if WTE facilities were required to sample or otherwise manage fly ash separately from bottom ash. This is because fly ash is generally a fine powdery substance that would become readily airborne were it not for such normal practices as combining the fly ash with the bottom ash in a quench tank to impede air emissions. Handling fly ash before it is combined could increase the risk of release to the environment.

Further, EPA recently published proposed regulations under the Clean Air Act for new and existing municipal waste combustors that address ash. These regulations would prohibit visible emissions of fugitive fly ash and/or bottom ash from all ash handling activities at the facility. They also address the ash loading areas and ash transport vehicles (59 FR 48222, September 20, 1994).

Finally, the Agency understands that some groups are concerned about the potential environmental risk posed by the reuse of ash in projects such as road base, building blocks, and sidewalks. These groups have expressed a desire that the Agency either ban ash reuse or place stringent controls on reuse. While reuse of ash currently is not common in the U.S. (the Agency believes that significantly less than ten percent of the ash generated in the U.S. is reused), the Agency does not believe that today's interpretation will stimulate increased interest in ash reuse. It is important to note that, if the WTE facility were required to test bottom ash and fly ash separately and found that either ash failed the TC determination, that facility could treat the ash on-site to either below TC limits or in accordance with the land disposal restrictions (when they are set). After this treatment, ash would no longer be classified as a hazardous waste and could be used without further hazardous waste regulation (e.g., in construction projects). EPA does not currently anticipate that future LDR treatment will differ significantly from some of the ash conditioning techniques currently used at WTE facilities. It also is important to note that many states have programs addressing the management of ash from WTE facilities. Currently, over one-half of the states address the reuse of ash.

Should information come to EPA's attention suggesting that WTE ash is being managed or disposed of in a manner that is not protective of human health and the environment under Subtitle D, the Agency will consider additional actions, including issuing management guidelines and, if appropriate, promulgating additional regulations to address those situations. In addition, at individual sites, if the disposal of ash presents an imminent and substantial endangerment to human health and the environment, EPA may require responsible persons to undertake appropriate action under § 7003(a) of RCRA.

IV. Conclusion

In conclusion, today's interpretation of RCRA § 3001(i) designates the point of Subtitle C jurisdiction for WTE ash at the exit of the combustion building following the combustion and air pollution control processes. The Agency believes that this reading is a reasonable interpretation of the statute that serves the stated goals of § 3001(i).

EPA emphasizes that today's decision on the appropriate location to make the hazardous waste determination for MWC ash is unique based on its interpretation of RCRA § 3001(i). EPA's analysis and conclusions are not relevant to facilities that do not fall within the scope of RCRA § 3001(i).

EPA considers this action to be an interpretative rule exempt from the requirement for prior notice and opportunity to comment under section 553(b)(3)(A) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(A). The notice merely informs the public of EPA's view of the definition of ''facility'' in section 3001(i) as derived from the text of the statute, legislative history, and EPA's view of Congressional intent.

Dated: January 27, 1995.

Carol M. Browner,

Administrator.

[FR Doc. 95–2627 Filed 2–2–95; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

Radio Broadcasting Services; Various Communities

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, on its own motion, editorially amends the Table of FM Allotments to specify the actual classes of channels allotted to various communities. The changes in channel classifications have been authorized in response to applications filed by licensees and permittees operating on these channels. This action is taken

pursuant to *Revision of Section 73.3573(a)(1) of the Commission's Rules Concerning the Lower Classification of an FM Allotment*, 4 FCC Rcd 2413 (1989), and the *Amendment of the Commission's Rules to Permit FM Channel and Class Modifications [Upgrades] by Application*, 8 FCC Rcd 4735 (1993).

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, adopted January 18, 1995, and released January 26, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW, Suite 140, Washington, D.C. 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by deleting Channel 232A and adding Channel 232C3 at Abbeville; and deleting Channel 293C3 and adding Channel 293C2 at Bay Minette.

3. Section 73.202(b), the Table of FM Allotments under Alaska, is amended by deleting Channel 280C3 and adding Channel 280A at College.

4. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by deleting Channel 223C and adding Channel 223C1 at Eagar.

5. Section 73.202(b), the Table of FM Allotments under California, is amended by deleting Channel 300C1 and adding Channel 300A at Mount Shasta.

6. Section 73.202(b), the Table of FM Allotments under Colorado, is amended by deleting Channel 292C2 and adding Channel 292C3 at Kremmling.

7. Section 73.202(b), the Table of FM Allotments under Florida, is amended by deleting Channel 268C1 and adding Channel 268C at Pensacola; and deleting Channel 276A and adding Channel 276C3 at Plantation Key.

8. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by deleting Channel 258C and adding Channel 258C1 at Douglas.

9. Section 73.202(b), the Table of FM Allotments under Indiana, is amended by deleting Channel 224A and adding Channel 223A at Kokoma.

10. Section 73.202(b), the Table of FM Allotments under Kentucky, is amended by deleting Channel 250A and adding Channel 250C3 at Hyden; and deleting Channel 296A and adding Channel 299A at Owingsville.

11. Section 73.202(b), the Table of FM Allotments under Louisiana, is amended by deleting Channel 230C2 and adding Channel 230C3 at Bastrop.

12. Section 73.202(b), the Table of FM Allotments under Michigan, is amended by deleting Channel 258C1 and adding Channel 258C2 Sault Ste. Marie.

13. Section 73.202(b), the Table of FM Allotments under Mississippi, is amended by deleting Channel 243C3 and adding Channel 243A Clarksdale.

14. Section 73.202(b), the Table of FM Allotments under New Mexico, is amended by deleting Channel 268C and adding Channel 268C1 at Clovis.

15. Section 73.202(b), the Table of FM Allotments under New York, is amended by deleting Channel 263A and adding Channel 262B1 at Warrensburg.

16. Section 73.202(b), the Table of FM Allotments under North Carolina, is amended by deleting Channel 260C and adding Channel 260C1 at Burgaw.

17. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by deleting Channel 232A adding Channel 232C3 at Elk City.

18. Section 73.202(b), the Table of FM Allotments under Oregon, is amended by deleting Channel 258C and adding Channel 258C1 at Klamath Falls.

19. Section 73.202(b), the Table of FM Allotments under South Dakota, is amended by deleting Channel 264C and adding Channel 264C1 at Lowry.

20. Section 73.202(b), the Table of FM Allotments under Texas, is amended by deleting Channel 234A and adding Channel 234C3 at Corpus Christi; deleting Channel 234C1 and adding Channel 234C at El Paso; and deleting Channel 231C2 and adding Channel 231C3 at Point Comfort.

21. Section 73.202(b), the Table of FM Allotments under Utah, is amended by deleting Channel 238C and adding Channel 238C1 at Ogden.

22. Section 73.202(b), the Table of FM Allotments under Wisconsin, is amended by deleting Channel 297C2 and adding Channel 297C3 at Iron River; and deleting Channel 249C2 and adding Channel 249C3 at Rice Lake.

23. Section 73.202(b), the Table of FM Allotments under Wyoming, is amended by deleting Channel 250C and adding Channel 250C1 at Cheyenne.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–2682 Filed 2–2–95; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN: 1018–AB88

Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for Ten Plants and Threatened Status for Two Plants From Serpentine Habitats in the San Francisco Bay Region of California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) determines endangered status pursuant to the Endangered Species Act of 1973, as amended (Act) for 10 plants: *Castilleja affinis* ssp. *neglecta* (Tiburon paintbrush), *Ceanothus ferrisae* (coyote ceanothus), *Cirsium fontinale* var. *fontinale* (fountain thistle), *Clarkia franciscana* (Presidio clarkia), *Cordylanthus tenuis* ssp. *capillaris* (Pennell's bird's-beak), *Dudleya setchellii* (Santa Clara Valley dudleya), *Eriophyllum latilobum* (San Mateo woolly sunflower), *Pentachaeta bellidiflora* (white-rayed pentachaeta), *Streptanthus albidus* ssp. *albidus* (Metcalf Canyon jewelflower), and *Streptanthus niger* (Tiburon jewelflower). The Service also determines threatened status for two plants, *Calochortus tiburonensis* (Tiburon mariposa lily) and *Hesperolinon congestum* (Marin dwarf-flax). These species are restricted to serpentine soil outcrops in the area near San Francisco Bay, California. The 12 plants have been variously affected and are threatened by one or more of the following: urbanization, pedestrian, and off-road vehicular traffic, the invasion of alien plants, road maintenance, soil erosion and slipping, unauthorized dumping, livestock grazing, seed predation by beetles, and stochastic extinction by virtue of the small,

isolated nature of the remaining populations. This rule implements the Federal protection and recovery provisions afforded by the Act for these plants.

EFFECTIVE DATE: March 6, 1995.

ADDRESSES: The complete file for this rule is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, 2800 Cottage Way, Room E–1803, Sacramento, California 95825–1846.

FOR FURTHER INFORMATION CONTACT: Elizabeth Warne at 916/978–4866 at the above address.

SUPPLEMENTARY INFORMATION:

Background

Cordylanthus tenuis ssp. *capillaris, Calochortus tiburonensis, Castilleja affinis* ssp. *neglecta, Streptanthus niger, Clarkia franciscana, Cirsium fontinale* var. *fontinale, Eriophyllum latilobum, Hesperolinon congestum, Pentachaeta bellidiflora, Ceanothus ferrisae, Dudleya setchellii,* and *Streptanthus albidus* ssp. *albidus* are endemic to serpentine soils in the region of the San Francisco Bay in California. Serpentine soils are derived from ultramafic rocks such as serpentinite, dunite, and peridotite, which are found in discontinuous outcrops in the Sierra Nevada and in the Coast Ranges from Santa Barbara County, California to British Columbia. The chief constituent of the parent rock is some variant of iron-magnesium silicate. Most serpentine soils are formed in place over the parent rock, and are, therefore, shallow, rocky, and highly erodible. Serpentine soils, because of the parent material, tend to have high concentrations of magnesium, chromium, and nickel and low concentrations of calcium, nitrogen, potassium, and phosphorus (Kruckeberg 1984). These characteristics make serpentine soil inhospitable for the growth of most plants. Nevertheless, some plants have adapted to the rigors of life on serpentine soils. In fact, serpentine soils often support a high diversity of plants including many rare species (McCarten 1988). Over 200 taxa in California are endemic (restricted) to serpentine soils (Kruckeberg 1984).

Serpentine soils in the San Francisco Bay region are derived from intrusive igneous rocks associated with fault zones in the sedimentary Franciscan formation. Outcrops occur south of the Bay in the Coyote Valley of Santa Clara County; west of the Bay at Edgewood County Park, near Crystal Springs Reservoir, at Stanford University's Jasper Ridge Preserve in San Mateo County, and at the Presidio in San Francisco County; east of the Bay in the Oakland Hills of Alameda County and at Mt. Diablo in Contra Costa County; and north of the Bay on the Tiburon Peninsula in eastern Marin County and at Mt. Tamalpais, Carson Ridge, and near Nicasio Reservoir in western Marin County, as well as in Sonoma and Napa Counties. Serpentine soils are variable in soil chemistry, texture, and water availability, both within and between sites (McCarten 1987b). This variability and the variety of micro-climates in the San Francisco Bay region have a profound effect upon the local flora. Several serpentine plant communities are found in the San Francisco Bay region (McCarten 1987b). Grassland and annual forb communities (serpentine bunchgrass grasslands and serpentine wildflower fields) tend to occur on level ground or on gentle slopes with soils to 1 meter (m) (3 feet (ft)) or more in depth. Shrub communities (Franciscan serpentine coastal scrub, mixed serpentine chaparral, and Sargent cypress woodlands) tend to occur on steep rocky slopes with shallow soils. In some areas, soil development is minimal and parent rock is extensively exposed. These serpentine barrens support a distinctive community composed of only a few species, usually growing at low densities. Another unique habitat on serpentine soils occurs near seasonal springs and seeps, which support species requiring moist soil.

Most of the 12 species in this rule occur in the serpentine bunchgrass grassland and serpentine wildflower field communities. *Cirsium fontinale* var. *fontinale* occurs in serpentine seep areas. *Cordylanthus tenuis* ssp. *capillaris* and *Ceanothus ferrisae* occur in chaparral, as do a few populations of *Hesperolinon congestum*. *Dudleya setchellii* and *Streptanthus albidus* ssp. *albidus* are found on serpentine barrens. *Eriophyllum latilobum* grows on serpentine-influenced soil in the coast live oak woodland community.

Serpentine endemics may have limited or widespread distributions. Some species are restricted to a single outcrop; others occur on serpentine soils within a particular region; a few species occur throughout almost the entire range of serpentine soils in California (Kruckeberg 1984). Of the taxa considered in this rule, (*Calochortus tiburonensis*) is thought to always have been restricted to the single outcrop on which it occurs. Others, including *Cordylanthus tenuis* ssp. *capillaris, Streptanthus niger, Eriophyllum latilobum, Dudleya setchellii,* and *Streptanthus albidus* ssp. *albidus,* have a known historical range of only a few miles or less. The widest ranging species in historic times was *Pentachaeta bellidiflora,* which occurred from Marin County to Santa Cruz County. It is now restricted to a single population as a result of habitat destruction.

The human population of the San Francisco Bay region has grown rapidly over the last several decades. Urban development (including highway construction) has reduced the amount of serpentine habitat by nearly 20 percent in the past 20 years (McCarten 1987b). The construction of roads, houses, recreational facilities, and waste disposal sites continues. The increasing numbers of people also place an ever greater strain on undeveloped wildlands, through activities such as pedestrian and off-road vehicle traffic, unauthorized garbage dumping, and changes in the pattern of wildland fires. Serpentine habitats, because of their often limited vegetative cover, may appear to the uninitiated as unoccupied space, and so they are especially likely to be subject to disturbances. Recreational activities may directly impact plants; or may result in increased erosion and facilitate the invasion of alien species including many introduced annual grasses common in California. Competition with introduced species is a serious threat to serpentine natives (McCarten 1987b). The destruction of serpentine habitats due to urban development also has increased the fragmentation of rare plant populations, thus, increasing the risks of extinction due to chance events such as fire, pest or disease outbreaks, reproductive failure, or other natural or human-caused disaster.

The land that supports these 12 taxa is owned by local, State, and Federal agencies, parks, and private parties.

Discussion of the Twelve Species

North Bay Species

Cordylanthus tenuis ssp. *capillaris* (Pennell's bird's-beak) was collected by Herbert Mason about 3.2 kilometers (km) (2 miles (mi)) north of Occidental in Sonoma County, California, in 1946. Francis Whittier Pennell described the plant as *Cordylanthus capillaris* in 1950, using Mason's specimen as the type (Pennell 1950). Pennell was misled by an erroneous label to think that the plants had been collected in Merced County (Bacigalupi 1966), which may have affected his treatment of the taxon (Chuang and Heckard 1986). Artificial hybridization studies of *C. brunneus* and *C. capillaris* (Chuang and Heckard 1975) showed a close relationship between the two plants. The name *C. brunneus* ssp. *capillaris* was proposed

for *C. capillaris* by Chuang and Heckard (Heckard 1977), but was never formally published. In 1986, Chuang and Heckard published a revision of the genus, in which both *C. brunneus* and *C. capillaris* were treated as subspecies of *C. tenuis* (Chuang and Heckard 1986).

Cordylanthus tenuis ssp. *capillaris* is a branching herbaceous annual of the snapdragon family (Scrophulariaceae). The plant grows 30 to 40 centimeters (cm) (12 to 16 inches (in)) tall, with yellow-green hairless herbage that becomes purplish with age. The leaves are entire, or those of the primary stem three-parted, and threadlike. The floral bracts are three-parted up to two-thirds of their length, with fine marginal hairs on bracts and calyx. The tubular corolla is 1.5 cm (0.6 in) long and garnet-brown laterally, paler dorsally. Each capsule contains 10 to 16 seeds. The three-lobed outer bracts of *Cordylanthus tenuis* ssp. *capillaris distinguish it from its nearest relative (C. tenuis* ssp. *brunneus*) and from *C. pilosus,* another *Cordylanthus* found in the area. A further distinguishing character is that *C.* pilosus is densely hairy throughout.

Cordylanthus tenuis ssp. *capillaris* is known only from two locations: the type locality in western Sonoma County and a second occurrence a few miles to the west. A third population may occur on property adjacent to the second location, but permission for botanical surveys on that property has been consistently refused (Betty Guggolz, Milo Baker Chapter, California Native Plant Society, pers. comm., 1992). The total number of plants fluctuates from year to year, as is typical of annual plants. *C. tenuis* ssp. *capillaris* is threatened with potential residential development, garbage dumping, and roadside maintenance.

Calochortus tiburonensis (Tiburon mariposa lily) was discovered in 1971 by Robert West on Ring Mountain on the Tiburon Peninsula in Marin County, California. Albert Hill collected the type specimen on Ring Mountain the following year and published the description in 1973 (Hill 1973).

Calochortus tiburonensis is a bulbous perennial of the lily family (Liliaceae) with a single persistent, basal, linear-oblong leaf 30 to 60 cm (1 to 2 ft) long. The flowering stem, about 50 cm (20 in) tall, is usually branched and bears erect flowers in twos or threes at the ends of the branches. The three petals and three sepals are light yellow-green with reddish or purplish-brown markings. The capsule is triangular in cross-section and about 4 cm (2 in) long. The long slender hairs on the upper surface and margins of the petals and the lack of wings on the capsule distinguish *C. tiburonensis* from the other two *Calochortus* species found on the Tiburon Peninsula, *C. umbellatus* and *C. luteus.*

Calochortus tiburonensis is known only from its type locality, where it grows on rocky serpentine slopes among annual and perennial herbs and grasses. The population, estimated at 40,000 individuals in 1991 (Larry Serpa, The Nature Conservancy, pers. comm., 1992), occurs on land that has been owned and managed by The Nature Conservancy since 1982. The occurrence of this plant in a single population, its proximity to human population centers, and intensive development activities renders it vulnerable to catastrophic events such as fire, disease or pest outbreak, severe drought, or other natural or human-caused disasters.

The type specimen of *Castilleja affinis* ssp. *neglecta* (Tiburon paintbrush) was collected by Katherine Brandegee in the early 1900s. The plant was described by Zeile in 1925 in Willis Jepson's *Manual of the Flowering Plants of California.*

Castilleja affinis ssp. *neglecta* is a semi-woody perennial of the snapdragon family (Scrophulariaceae), with erect, branched stems 30 to 60 cm (1 to 2 ft) tall and a sparse covering of soft, spreading hairs. The lance-shaped leaves have one or two pairs of narrow lobes. The conspicuous floral bracts are yellowish and sometimes red-tipped; the flowers are yellow to red and 18 to 20 millimeters (mm) (0.7 to 0.8 in) long. The simple (unbranched) hairs and the lack of glands below the inflorescence distinguish *C. affinis* spp. *neglecta* from other species of *Castilleja* on the Tiburon Peninsula (*C. latifolia* var. *rubra* and *C. foliosa*) (Howell 1970).

Castilleja affinis ssp. *neglecta* occurs in serpentine bunchgrass communities on north to west facing slopes. It is known from four populations in Marin County, three of which occur on the Tiburon Peninsula, one population in Napa County, and one population in Santa Clara County. The range of this plant is approximately 50 km (30 miles) from east to west and 112 km (70 miles) from north to south. Population sizes are small, ranging from 13 plants at a location in Santa Clara County (Roxanne Bittmann, California Natural Diversity Data Base, pers. comm., 1993) to 600 plants at Ring Mountain Preserve on the Tiburon Peninsula (Hunter 1989a). A total of approximately 1,500 plants exist. The Marin County populations are threatened by residential development, foot traffic, grazing, and soil slumping; the Napa County population is threatened by gravel mining and grazing.

Streptanthus niger (Tiburon jewelflower) was described by Edward L. Greene, from a type specimen he had collected at St. Hilary's Church in the town of Tiburon in Marin County (Greene 1886a). Greene later redefined the limits of *Euclisia,* formerly a subgenus of Streptanthus, treating it as a genus in its own right (Greene 1904). *S. niger,* as a member of the Euclisia group, was thus referred to as *E. niger.* Jepson (1925) returned *Euclisia* to subsection status and later authors followed his treatment. Munz treated *S. niger* as a subspecies of *S. glandulosus* in *A California Flora* (1959), and then returned it to *S. niger* in his supplement (1968), following Kruckeberg (1958).

Streptanthus niger is an annual herb of the mustard family (Brassicaceae) that reaches 30 to 60 cm (1 to 2 ft) in height. The lower leaves are toothed, the upper leaves less toothed or not at all. The sepals are a very dark purple; the petals have a purple claw and a white blade with a purple midvein. The zig-zag inflorescence pattern and the lack of hairs distinguish *S. niger* from its near relative *S. glandulosus.*

Streptanthus niger is found on shallow rocky serpentine soils on southwest-facing slopes on the Tiburon Peninsula of Marin County. Two populations are known from the southern end of the peninsula where they occur within 3 km (2 miles) of one another. Populations number from 50 to 2,000 plants (Hunter 1989b, Andrew Allen, Belvedere-Tiburon Landmarks Society, *in litt.,* 1991). The plant is threatened by residential development, foot traffic, and road construction.

Central Bay Species

The type specimen of *Clarkia franciscana* (Presidio clarkia) was collected by Peter Raven in 1956. *C. franciscana* was described by Harlan Lewis and Peter Raven (1958).

Clarkia franciscana is a slender, erect, herbaceous annual of the evening-primrose family (Onagraceae), 40 cm (16 in) tall with few, very small, and narrow leaves. The lavender-pink petals have a lighter basal portion and a reddish-purple basal spot. The slender capsule is 2 to 4 cm (1 to 2 in) long. *C. franciscana* can be distinguished from *C. rubicunda,* a related species that may occur in the same area, by its petals that have irregular teeth on the apical margin. *C. rubicunda* has petals that are rounded at the apex.

Clarkia franciscana is restricted to serpentine soils in grassland communities in San Francisco and Alameda Counties. Two populations are known from the Presidio in San Francisco. Three populations are known

from the Oakland Hills in Alameda County, 27 km (17 mi) east of San Francisco, all within 1.0 km (0.6 mi) of each other. A fourth population in the Oakland Hills was reported in 1988 (California Department of Fish and Game, Natural Diversity Data Base) but could not be relocated during a search conducted in 1991 (David Bigham, East Bay Chapter, California Native Plant Society, *in litt.*, 1991). Population sizes fluctuate greatly; the upper limit to the total numbers of plants reported in recent years is approximately 8,000 plants. The first of the Alameda County populations was discovered in 1980 at the Redwood Regional Park. Because this discovery occurred so long after the original discovery of the plant and because this population was relatively far from the previously known population at the Presidio, it was suggested that this population might not be a natural occurrence. This suggestion gained credence because seed collected from the type location in 1964 had been sown in the East Bay Regional Parks Tilden Botanic Garden and plants had grown there for several years (Roof 1971). Seed collected from plants at the botanic garden had been sown in several sites at the Presidio in 1972 (Roof 1972). It was thought that seed might also have been sown at Redwood Regional Park in Alameda County. However, an electrophoretic comparison of the San Francisco and Alameda populations ''strongly suggests that the Oakland Hills population did not originate by seed transfer from San Francisco and it must be regarded as indigenous to its present locality'' (Gottlieb and Edwards 1992). *C. franciscana* is threatened by potential development, roadside maintenance, foot traffic, mowing, competition from alien plants, and shade from native and introduced shrubs and trees.

Cirsium fontinale var. *fontinale* (fountain thistle) was first described as *Cnicus fontinalis* (Greene 1886b). In 1892, Greene reassigned the plant to the genus *Carduus* (Greene 1892). Willis Jepson, in his *Flora of Western Middle California* (1901), put the taxon in the genus *Cirsium*. In 1938, John Thomas Howell described a close relative of the fountain thistle, *Cirsium fontinale* var. *obispoense* (Chorro Creek bog thistle) (Howell 1938). According to the rules for botanical nomenclature, when a new variety is described in a species not previously divided into infraspecific taxa, a ''type'' variety is automatically created. In this case, the type variety is *C. fontinale* var. *fontinale*.

Cirsium fontinale var. *fontinale* is an herbaceous perennial of the aster family (Asteraceae) with several stout, erect reddish stems 30 to 60 cm (1 to 2 ft) high. The basal leaves are 10 to 20 cm (4 to 8 in) long with spine-tipped lobes; the leaves on the stems are smaller. The flowers are dull white to pinkish, becoming brown with age. The egg-shaped, recurved bracts beneath the flower head distinguish *C. fontinale* var. *fontinale* from the most similar thistle in the area, brownie thistle (*C. quercetorum*). The nearest relative of *C. fontinale* var. *fontinale* is *C. fontinale* var. *obispoense*, found further south in San Luis Obispo County.

Cirsium fontinale var. *fontinale* is restricted to perpetually moist clay openings in riparian or serpentine chaparral. Historically, this plant occurred in both San Mateo and Santa Clara Counties, but it is now found in only three locations in San Mateo County. One population of 1,000 to 2,800 plants occurs east of Crystal Springs Reservoir, on both sides of Interstate 280. A second population of 100 to 200 plants occurs 10 km (6 miles) to the south in the ''Triangle area,'' a triangular piece of land west of Edgewood County Park that is bounded by Interstate 280 to the east, Edgewood Road on the north, and Canada Road on the west. A single plant was found in Edgewood County Park in 1987. In 1992, only one plant remained in this location (Susan Sommers, Santa Clara Valley Chapter, California Native Plant Society, pers. comm., 1992). The taxon is threatened by proposed recreational development, competition with alien plant species, garbage dumping, and roadside maintenance.

Eriophyllum latilobum (San Mateo woolly sunflower) was first collected by Elmer in 1903. The type specimen was collected by A.A. Heller in 1907. The plant was described by Per Axel Rydberg (1915). *E. latilobum* is believed to have originated as a hybrid between *E. confertiflorum* and *E. lanatum* var. *arachnoideum* (Munz 1959, John Mooring, Santa Clara University, pers. comm., 1992).

Eriophyllum latilobum is a bushy perennial of the aster family (Asteraceae) with leafy stems 30 to 40 cm (12 to 16 in) high. The upper surfaces of the deeply three-cleft leaves are a smooth dark green and the lower surfaces are covered with densely interwoven white hairs. The golden flower heads are borne in loose clusters. *E. latilobum* differs from *E. confertiflorum* in having eight ray flowers rather than five, larger flower heads, and a more open inflorescence. *E. lanatum* var. *arachnoideum* differs from the other two species in having 13 ray flowers and shallowly cleft leaves.

Eriophyllum latilobum is found in shaded moist sites on steep grassy or sparsely wooded slopes of serpentine-influenced soil. The single remaining occurrence of *E. latilobum* consists of a few hundred plants scattered along 4 km (2.5 miles) of Crystal Springs Road in San Mateo County. These subpopulations are probably the fragments of a once-continuous population. E. *latilobum* has also been reported from southern San Mateo County, on Pescadero Road southwest of La Honda, but this report is most likely erroneous. At least one of the specimens collected at this site (in 1929) is actually *E. confertiflorum* (Barry Prigge, University of California, Los Angeles herbarium, pers. comm., 1992), and searches in recent years have found only *E. confertiflorum* (Toni Corelli, Santa Clara Valley Chapter, California Native Plant Society, pers. comm., 1992). The plant is threatened by erosion and soil slippage, road maintenance, garbage dumping, and recreational development.

Henry Nicholas Bolander collected the type specimen of *Hesperolinon congestum* (Marin dwarf-flax) in 1863 in Marin County, while working on the State Geological Survey. Asa Gray described the new species as *Linum congestum*, including it in the section *Hesperolinon* that he described in the same paper (Gray 1865). J.K. Small (1907) established *Hesperolinon* as a distinct genus in 1907. Jepson (1925) treated *Hesperolinon* as a section of the genus *Linum* and treated *H. congestum* as a subspecies of *L. californicum*. Helen K. Sharsmith (1961) conducted an extensive study of *Hesperolinon* and concluded that it definitely warrants distinction as a separate genus. She also returned *H. congestum* to the status of a species.

Hesperolinon congestum is an herbaceous annual of the flax family (Linaceae) with slender, threadlike stems, 10 to 40 cm (4 to 16 in) tall. The leaves are linear. The flowers are borne in congested clusters; the pedicels are 0.2 to 2 mm (.01 to .08 in) long. The sepals are hairy and the five petals are rose to whitish. The anthers are deep pink to purple; this character helps distinguish *H. congestum* from *H. californicum*, found in the same geographic area, which has white to rose anthers, as well as hairless sepals. Two other species that are found in the same region are *H. micranthum* and *H. spergulinum*. They differ from *H. congestum* in having hairless sepals and a long, open inflorescence, with pedicels 2 to 25 mm (.08 to 1 in) long.

Hesperolinon congestum is endemic to serpentine soils from Marin County

south to San Mateo County, a range of 80 km (50 miles). Two populations are found in serpentine chaparral; the others occur in serpentine bunchgrass habitat. Six populations are known from Marin County, one from San Francisco County, and seven from San Mateo County. Populations fluctuate in size from hundreds to thousands of plants (Robison and Morey 1992a). The species is threatened with residential and recreational development, foot traffic, and competition with alien species.

Pentachaeta bellidiflora (white-rayed pentachaeta) was first collected in 1853–54 near Corte Madera by John Milton Bigelow, surgeon and botanist for a railway route exploration (Van Horn 1973). The plant was described as *P. bellidiflora* (Greene 1885). Keck (1958) transferred the entire genus to *Chaetopappa.* Van Horn (1973) studied *Chaetopappa* and *Pentachaeta* and concluded that the two genera are not closely related. Based on differences in floral and vegetative morphology and chromosome number, Van Horn reinstated the genus *Pentachaeta.*

Pentachaeta bellidiflora is a small annual plant of the aster family (Asteraceae) with one or a few branches that bear narrow, linear leaves. Each flower head has numerous yellow disk florets and 5 to 16 white to purplish ray florets. The fruits are tawny, coarse-haired achenes (dry one-seeded fruits). Related species in the San Francisco Bay area (*P. exilis* ssp. *exilis* and *P. alsinoides*) differ from *P. bellidiflora* in that they have no ray flowers.

Pentachaeta bellidiflora is known only from one location, in a serpentine bunchgrass community in San Mateo County. Historically, *P. bellidiflora* was known from at least nine sites in Marin, San Mateo, and Santa Cruz Counties. The other populations have been destroyed by urbanization, off-road vehicles, or highway construction over the past 50 years (Robison and Morey 1992b). As is common among annual plants, the size of this population fluctuates dramatically from year to year. Numbers have ranged from 10,000 to just under 100 million in the last 10 years, with about 1.5 million plants growing in each of the last 2 years (Zoe Chandik, Santa Clara Valley Chapter, California Native Plant Society, pers. comm., 1992). The species is threatened by recreational development.

South Bay Species

Ceanothus ferrisae (coyote ceanothus) was collected in 1917 by LeRoy Abrams, professor of botany at Stanford University, on Madrone Springs Road above Coyote Creek, in Santa Clara County. The species was described in 1933 by Howard E. McMinn (McMinn 1933), professor of botany at Mills College and author of An Illustrated Manual of California Shrubs.

Ceanothus ferrisae is an erect evergreen shrub of the buckthorn family (Rhamnaceae) that grows 1 to 2 m (3 to 6 ft) high, with long stiff divergent branches. Its round leaves are dark green and hairless on the upper surface and lighter green with minute hairs below. The leaf margins have short teeth or sometimes no teeth at all; the leaf base is abruptly tapering or rounded. The small white flowers are borne in clusters 1.3 to 2.5 cm (0.5 to 1 in) long. The seed capsules are 7 to 9 mm (.3 to .35 in) in width and have three conspicuous apical horns. The related *C. cuneatus* has entire leaves with wedge-shaped (not rounded) bases and seed capsules only 5 to 6 mm (0.2 in) wide.

Ceanothus ferrisae grows on dry slopes in serpentine chaparral. It is known from only three locations, all within 6 km (4 miles) of each other, in Santa Clara County. Fewer than 6,000 plants are known to exist. It was thought at one time to occur in both San Mateo and Santa Cruz Counties as well, but these reports have been found to be erroneous (Corelli 1991). The existing populations are threatened by residential and recreational development, unauthorized dumping, and lack of natural recruitment.

The type specimen of *Dudleya setchellii* (Santa Clara Valley dudleya) was collected by Willis L. Jepson in 1896 on Tulare Hill in Santa Clara County. He described it as *Cotyledon laxa* var. *setchellii* (Jepson 1901). At the same time, he described *Cotyledon caespitosa* var. *paniculata,* which he had collected from Morrison Canyon near what is now Fremont. Britton and Rose (1903) elevated both taxa to full species and transferred them to the newly-created genus *Dudleya.* Subsequently, *Dudleya setchellii* was variously treated as *Cotyledon setchellii* (Fedde 1904), *Echeveria setchellii* (Nelson and Macbride 1913), and *E. laxa* var. *setchellii* (Jepson 1936). Reid Moran (1959) combined the material referred to as *D. setchellii* and *D. paniculata* in *D. cymosa* ssp. *setchellii.* Kei Nakai (1987) separated the two entities into *D. cymosa* ssp. *paniculata* and *D. cymosa* ssp. *setchellii* on the basis of leaf shape, inflorescence branching patterns, and pedicel length. According to Jim Bartel (U.S. Fish and Wildlife Service, pers. comm., 1992), *D. setchellii* should not be placed within *D. cymosa* and is, in fact, intermediate to *D. cymosa* and *D. abramsii.* His treatment of *Dudleya* retains Nakai's *D. cymosa* ssp. *paniculata* and resurrects Britton and Rose's *D. setchellii* for the Santa Clara Valley dudleya (Bartel 1993).

Dudleya setchellii is a low-growing perennial of the stonecrop family (Crassulaceae) with fleshy, glabrous leaves. The oblong to triangular, slightly glaucous leaves are 3 to 8 cm (1 to 3 in) long and 7 to 15 mm (0.3 to 0.6 in) wide. Two or three flowering stems ascend to heights of 5 to 20 cm (2 to 8 in) in mid to late spring. The pale yellow petals are 8 to 13 mm (0.3 to 0.5 in) long. There are two related species in the area. *D. cymosa* ssp. *cymosa* has bright yellow to red petals rather than pale yellow and is, therefore, easily distinguished from *D. setchellii* with its pale yellow flowers. *D. cymosa* ssp. *paniculata* can be distinguished from *D. setchellii* by its oblong to oblanceolate leaves (in contrast to the oblong-triangular leaves of *D. setchellii*), its greater degree of rebranching of the inflorescence branches, and its longer pedicels.

Dudleya setchellii is restricted to rocky outcrops within serpentine grasslands in Santa Clara County. It is found only in the Coyote Valley area, from San Jose south about 30 km (20 miles) to San Martin, at elevations of 100 to 300 m (300 to 900 ft). *D. cymosa* ssp. *paniculata* ranges from Contra Costa County to Fresno and Monterey Counties; the reports of Moran's combination *D. cymosa* ssp. *setchellii* from Alameda, Contra Costa, and San Benito Counties (Munz 1959, Olson and Lake 1991) reflect the distribution of *D. cymosa* ssp. *paniculata* and do not refer to *D. setchellii,* as now recognized. Fourteen sites and a total of approximately 33,000 plants are known to exist. The plant is threatened by development, unauthorized dumping, and off-road vehicles.

Streptanthus albidus ssp. *albidus* (Metcalf Canyon jewelflower) was first collected in 1887 by Volney Rattan, a botany teacher and author of an early California flora, from hillsides a few miles south of San Jose. Edward Greene described *S. albidus* ssp. *albidus* in 1887 (Greene 1887); later he redefined the limits of *Euclisia,* formerly a subgenus of *Streptanthus,* treating it as a genus in its own right (Greene 1904). *S. albidus* ssp. *albidus,* as a member of the *Euclisia* group, was included in this change. Jepson (1925) returned *Euclisia* to subsection status, and later authors followed his treatment. Jepson (1925) also treated *S. albidus* ssp. *albidus* as a subspecies of *S. glandulosus.* Kruckeberg published a revision of the *Streptanthus glandulosus* complex in which he recognized the close relationships among *S. glandulosus, S.*

albidus, and *S. niger* (Kruckeberg 1958). In this paper, he notes that the ''sharp genetic discontinuity between *S. albidus* and all other populations, coupled with the morphological distinctness and regional restriction of *S. albidus,* warrant the restoration of this Greeneian species.'' He recognized two subspecies: *S. albidus* ssp. *albidus* and *S. albidus* ssp. *peramoenus* (Kruckeberg 1958).

Streptanthus albidus ssp. *albidus* is an annual herb of the mustard family (Brassicaceae) that reaches up to 1 m (3 ft) in height. It has bristly hairs at the base and pale green, strongly glaucous stem and leaves. The flowers are borne in leafless terminal racemes. The upper three of the white to yellow to whitish-green sepals are fused with the lower (fourth) sepal free and spreading. The four petals, 8 to 11 mm (.3 to .4 in) long, are whitish with light purple veins. The erect flattened pods are 3 to 8 cm (1 to 3 in) long. The only *Streptanthus* species likely to co-occur with *S. albidus* ssp. *albidus* is its close relative *Streptanthus albidus* ssp. *peramoenus. S. albidus* ssp. *peramoenus* is distinguished by its dark purple sepals.

Streptanthus albidus ssp. *albidus* always has been rare. It is endemic to serpentine outcrops with little soil development. It can be locally abundant but its range is limited, extending less than 30 km (20 miles) from San Jose south to Anderson Lake, which lies northeast of Morgan Hill. Furthermore, the serpentine outcrops on which *S. albidus* ssp. *albidus* occurs are patchily distributed and comprise only a small percentage of the area within its range. Nine populations and a total of 20,000 to 25,000 plants have been recorded (McCarten 1992b). The plant is threatened by urbanization and off-road vehicles.

Previous Federal Action

Federal government actions on the 12 plants began as a result of section 12 of the Endangered Species Act of 1973, as amended (Act), which directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct in the United States. This report, designated as House Document No. 94–51, was presented to Congress on January 9, 1975, and included *Cordylanthus tenuis* ssp. *capillaris* (listed as *Cordylanthus brunneus* ssp. *capillaris*), *Calochortus tiburonensis, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Hesperolinon congestum, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* as endangered species and *Castilleja neglecta* (now known as *Castilleja affinis* ssp. *neglecta*) and *Eriophyllum latilobum* as threatened taxa. The Service published a notice in the July 1, 1975, **Federal Register** (40 FR 27823) of its acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2) (petition provisions are now found in section 4(b)(3) of the Act) and its intention thereby to review the status of the plant taxa named therein. The above 10 taxa were included in the July 1, 1975, notice. As a result of that review, on June 16, 1976, the Service published a proposal in the **Federal Register** (41 FR 24523) to determine approximately 1,700 vascular plant species to be endangered species pursuant to section 4 of the Act. The list of 1,700 plant taxa was assembled on the basis of comments and data received by the Smithsonian Institution and the Service in response to House Document No. 94–51 and the July 1, 1975, **Federal Register** publication. *Calochortus tiburonensis, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris* (listed as *Cordylanthus brunneus* ssp. *capillaris*), *Hesperolinon congestum, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* were included in the June 16, 1976, **Federal Register** document.

General comments received in response to the 1976 proposal were summarized in an April 26, 1978, **Federal Register** publication (43 FR 17909). The Endangered Species Act Amendments of 1978 required that all proposals over 2 years old be withdrawn. A 1-year grace period was given to those proposals already more than 2 years old. In the December 10, 1979, **Federal Register** (44 FR 70796), the Service published a notice of withdrawal of the June 16, 1976, proposal, along with four other proposals that had expired.

The Service published an updated notice of review for plants on December 15, 1980 (45 FR 82480). This notice included *Calochortus tiburonensis, Castilleja neglecta, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris, Hesperolinon congestum, Pentachaeta bellidiflora, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* as category-1 candidates for Federal listing and *Eriophyllum latilobum* as a category-2 candidate. Category-1 taxa are those for which the Service has on file substantial information on biological vulnerability and threats to support preparation of listing proposals. Category-2 taxa are those for which data in the Service's possession indicate listing is possibly appropriate, but for which substantial data on biological vulnerability and threats are not currently known or on file to support proposed rules. On November 28, 1983, the Service published in the **Federal Register** a supplement to the Notice of Review (48 FR 39526). This supplement changed *Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Pentachaeta bellidiflora,* and *Streptanthus albidus* ssp. *albidus* from category-1 to category-2 candidates.

The plant notice was again revised on September 27, 1985 (50 FR 39526). *Calochortus tiburonensis, Castilleja neglecta, Clarkia franciscana, Eriophyllum latilobum, Hesperolinon congestum,* and *Streptanthus niger* were included as category-1 candidates; *Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Cordylanthus tenuis* ssp. *capillaris, Pentachaeta bellidiflora,* and *Streptanthus albidus* ssp. *albidus* were included as category-2 candidates. Another revision of the plant notice was published on February 21, 1990 (55 FR 6184). In this revision, *Castilleja neglecta, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris, Dudleya setchellii, Eriophyllum latilobum, Hesperolinon congestum, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* were included as category-1 candidates; *Calochortus tiburonensis* and *Pentachaeta bellidiflora* were included as category-2 candidates. Since the publication of that notice, additional information was received on *Pentachaeta bellidiflora* that elevated it to category-1 status. The Service also re-evaluated the information available for *Calochortus tiburonensis* and elevated it to category 1-status. The Service, therefore, determines that sufficient information is now available to support the listing of these two species.

Section 4(b)(3)(B) of the Act requires the Secretary to make certain findings on pending petitions within 12 months of their receipt. Section 2(b)(1) further requires that all petitions pending on October 13, 1982, be treated as having been newly submitted on that date. That was the case for *Calochortus tiburonensis, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris, Hesperolinon congestum, Streptanthus albidus* ssp. *albidus, Streptanthus niger, Castilleja neglecta,* and *Eriophyllum latilobum,* because the 1975 Smithsonian report had been accepted as a petition. On October 13, 1982, the Service found that the petitioned listing of these species was warranted, but precluded by other

pending listing actions, in accordance with section 4(b)(3)(B)(iii) of the Act; notification of this finding was published on January 20, 1984 (49 FR 2485). Such a finding requires the petition to be recycled, pursuant to section 4(b)(3)(c)(i) of the Act. The finding was reviewed in October of 1984 through 1991. There are no pending petitions for *Pentachaeta bellidiflora* or *Dudleya setchellii.*

A proposed rule to list *Castilleja neglecta, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris, Dudleya setchellii, Eriophyllum latilobum, Pentachaeta bellidiflora, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* as endangered and *Calochortus tiburonensis* and *Hesperolinon congestum* as threatened was published in the **Federal Register** on December 14, 1992 (57 FR 59053). This proposal was based primarily on information supplied by reports from the Natural Diversity Data Base and observations by botanists.

Summary of Comments and Recommendations

In the December 14, 1992, proposed rule and associated notifications, all interested parties were requested to submit factual reports or information that might contribute to the development of a final rule. The public comment period ended on February 12, 1993. Appropriate State agencies, county and city governments, Federal agencies, scientific organizations, and other interested parties were contacted and requested to comment. Newspaper notices were published in The Napa Register on January 5, 1993, The Oakland Tribune, January 2, 1993, San Jose Mercury News, January 3, 1993, San Francisco Chronicle, December 31, 1992, and Santa Rosa Press Democrat, no date recorded, which invited general public comment. No public hearing was requested or held.

Fifteen written comments were received from 14 individuals. Among the 11 commenters supporting the listing were The California Native Plant Society, Sierra Club, and Missouri Botanic Garden. Three comments were neutral. One commenter opposed the listing of one species. Several commenters provided detailed information on the location and size of newly recorded populations and the condition of previously recorded populations. This data has been incorporated into this rule. The opposing comment and other comments questioning the rule have been organized into specific issues. These issues and the Service's response to each are summarized as follows:

Issue 1. One commenter stated that the serpentine soils in the Santa Clara Valley between the City of San Jose and Anderson Lake have not been adequately surveyed for *Dudleya setchellii*; therefore, the current level of knowledge does not warrant listing of this species as endangered.

Service Response: The Santa Clara Valley is the only known habitat for this edaphically restricted species, first collected on Tulare Hill in 1896. Many surveys have been done in this area, particularly in recent years (Entomological Consulting Services 1990; City of San Jose 1991; City of San Jose 1992; CH^{2}M Hill 1992; City of San Jose 1993). The Service uses the best information available at the time of listing to make the determination of endangered status. Current information indicates that the majority of known populations are located on private land and are threatened imminently with urbanization. Three proposed projects, which include residential development, a school, a church, roads, and a golf course, in the Santa Clara Valley are planned to be built on sites containing populations of *Dudleya setchellii.* Although more populations of this species may be discovered, the amount of remaining suitable habitat is limited and close to rapidly expanding urban areas. Santa Clara County, which contains the Santa Clara Valley from San Jose south to Anderson Lake, grew by 1.5 percent from 1991 to 1992 and is predicted to grow by 12.0 percent by year 2000 (Calif. Dept. of Finance 1992). Any newly found sites, therefore, likely will be subject to the same threats as known populations. In support of the contention that unrecorded populations of *D. setchellii* exist in the Valley, the commenter included a list of 11 new populations that he had submitted for addition to the CNPS rare plant inventory. Only two of these sites have been accepted by CNPS as new populations (R. Bittmann, pers. comm., 1993). In addition, the largest of the sites noted by the commenter is an extension of a previously known population and is threatened by the proposed Cerro Plata Residential and Golf Course Project (CNDDB 1993, City of San Jose 1993).

Issue 2. The Director of Public Works, County of San Mateo, voiced a concern that the responsibility of maintaining roads for the well being and safety of citizens may be in conflict with the Act when road crews remove soil and debris containing plants and seeds of *Eriophyllum latilobum*.

Service Response: Acts prohibited under section 9(a)(2)(B) of the Act are described in detail in Available Conservation Measures. The Service is concerned over the loss of this species during regular road maintenance and continuing soil slippage that results in plant loss; however, removal from roadways of debris containing *E. latilobum* plants or seeds that has fallen by natural causes into the roadway is not a violation of the Act.

Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, the Service has determined that *Castilleja affinis* (Hook and Arn.) ssp. *neglecta* (Zeile) Chuang and Heck. (Tiburon paintbrush), *Ceanothus ferrisae* McMinn (coyote ceanothus), *Cirsium fontinale* Jeps. var. *fontinale (fountain thistle), Clarkia franciscana* Lewis and Raven (Presidio clarkia), *Cordylanthus tenuis* Gray ssp. *capillaris* (Penn.) Chuang and Heck. (Pennell's bird's-beak), *Dudleya setchellii* (Santa Clara Valley dudleya), *Eriophyllum latilobum* Rydb. (San Mateo woolly sunflower), *Pentachaeta bellidiflora* Greene (white-rayed pentachaeta), *Streptanthus albidus* Greene ssp. *albidus* (Metcalf Canyon jewelflower), and *Streptanthus niger* Greene (Tiburon jewelflower) should be classified as endangered species and that *Calochortus tiburonensis* Hill (Tiburon mariposa lily) and *Hesperolinon congestum* (A. Gray) Small (Marin dwarf-flax), should be classified as threatened species. Procedures found at section 4 of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act were followed. A species may be determined to be endangered or threatened due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Calochortus tiburonensis* Hill (Tiburon mariposa lily), *Castilleja affinis* (Hook and Arn.) ssp. *neglecta* (Zeile) Chuang and Heck. (Tiburon paintbrush), *Ceanothus ferrisae* McMinn (coyote ceanothus), *Cirsium fontinale* Jeps. var. *fontinale* (fountain thistle), *Clarkia franciscana* Lewis and Raven (Presidio clarkia), *Cordylanthus tenuis* Gray ssp. *capillaris* (Penn.) Chuang and Heck. (Pennell's bird's-beak), *Dudleya setchellii* (Santa Clara Valley dudleya), *Eriophyllum latilobum* Rydb. (San Mateo woolly sunflower), *Hesperolinon congestum* (A. Gray) Small (Marin dwarf-flax), *Pentachaeta bellidiflora* Greene (white-rayed pentachaeta), *Streptanthus albidus* Greene ssp.

albidus (Metcalf Canyon jewelflower), and *Streptanthus niger* Greene (Tiburon jewelflower) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* The destruction of habitat through residential or recreational development is the greatest threat faced by these species. All 12 plants are limited to serpentine soils. Serpentine outcrops in the San Francisco Bay area are limited; 20 percent of those outcrops have already been eliminated as plant habitat due to development (McCarten 1987b). The pressure to build more houses, roads, and other facilities for humans is great in all the counties under consideration. In the 3 counties in which 10 of the species are found (Marin, San Mateo and Santa Clara), estimated percent population growth by year 2000 is 2.8, 6.4, and 12.0 percent, respectively (Calif. Dept. of Finance 1992). Sonoma County, which contains one of the species, is expected to grow by 21.4 percent by year 2000 (Calif. Dept. of Finance 1992). Serpentine habitats also have been fragmented by the construction of roads such as Interstate 280. Habitat fragmentation increases the risks of extinction due to chance events such as fire, flood, landslide, pest or disease outbreaks, severe drought, or other natural or human-caused disaster.

Cordylanthus tenuis ssp. *capillaris* has never been known from more than the two populations that occur today. Ownership of the type locality is mixed; part of the population occurs on the Harrison Grade Preserve, which is owned and managed by the California Department of Fish and Game. Habitat on the preserve is threatened by unauthorized activities such as off-road vehicle use. Plants on private parcels are threatened with potential development. The second population of *Cordylanthus tenuis* ssp. *capillaris* occurs on private property a few miles to the west of the type locality. Plans for residential development of this site have been reviewed by the Sonoma County Planning Department (Sigrid Swedenborg, Sonoma County Planning Office, pers. comm., 1993). The owner of this property has been working with the California Department of Fish and Game to minimize impacts to C. *tenuis* ssp. *capillaris* (Ann Howald, California Department of Fish and Game, pers. comm., 1992). Plans include the donation of 87 hectares (ha) (212 acres), including C. *tenuis* ssp. *capillaris* habitat, to the county for use as a park (S. Swedenborg, pers. comm., 1993). The county is considering restricting the park to passive recreation only; however, no final policy has yet been determined (Betty Guggolz, pers. comm., 1993). This donation may afford protection to part of the second population of C. *tenuis* ssp. *capillaris*, but since the transfer has not yet taken place and final plans have not been made concerning protection of the plant, the population still should be considered threatened by development.

Calochortus tiburonensis is, at present, protected from development and fenced to reduce the incidence of off-road vehicle use because the land on which it occurs is owned and managed by The Nature Conservancy (TNC), a group whose management goals are the maintenance of biodiversity and the protection of rare and endangered species (Larry Serpa, pers. comm., 1992). The preserve is still accessible to bicycles, motorbikes, and pedestrians, however, and it is not patrolled. The proximity of the preserve to residential areas renders it vulnerable to overuse and vandalism. Because TNC cannot completely control access to the site or activities on the site, listing is needed. Furthermore, this preserve, being on The Nature Conservancy's list of potential divestitures, will transfer ownership when a suitable organization is found to manage it (Larry Serpa, pers. comm., 1992).

Castilleja affinis ssp. *neglecta* has never been widespread. Three of the six populations occur on the Tiburon Peninsula in Marin County, one occurs in Napa County, and one in Santa Clara County. Two recently discovered populations, one on the Golden Gate National Recreation Area and one east of Anderson Lake, extend the known range to western Marin and Santa Clara Counties, respectively. Each of the three occurrences on the Tiburon Peninsula has multiple landowners. The Nature Conservancy owns over half of the Ring Mountain occurrence and the town of Tiburon owns portions of the occurrence in the Middle Ridge area of the peninsula. The remainder of each of these occurrences is privately-owned. The third occurrence on the peninsula is on private property near St. Hilary's Church in Tiburon. Development on the Tiburon Peninsula is extensive and rapid; over 60 percent of *C. affinis* ssp. *neglecta* habitat has already been destroyed by development (Hunter 1989a). Residential development is ongoing on several parcels of the Middle Ridge occurrence and proposed for both parcels of the St. Hilary's occurrence (Andrew Allen, pers. comm., 1993). The habitat at both of these sites also is threatened by pedestrian traffic. The plants on Ring Mountain Preserve are protected from development but are threatened by sliding of the slope on which they occur. The toe of the slope was removed to accommodate residential development in the 1960s. Soil material that slides into the street at the base of the slope is removed by the City of Corte Madera, and the slope continues to slump. Managers from The Nature Conservancy estimate that approximately one-third of the population is at risk (Lynn Lozier, The Nature Conservancy, pers. comm., 1992). The Napa County population occurs on private property near a gravel quarry. Although quarry expansion plans that would result in the destruction of more than 80 percent of the population are no longer actively being pursued, the potential for expansion still exists. The Santa Clara population consists of 13 plants that may be subject to grazing (R. Bittmann, pers. comm., 1993).

Streptanthus niger is an extremely narrowly-distributed species; its entire range amounts to less than one-third of a square mile. Urban development has destroyed over 40 percent of potential *S. niger* habitat (Hunter 1989b). Both of the two known occurrences have multiple landowners. The town of Tiburon owns portions of the occurrence on the Middle Ridge of the peninsula, and the occurrence at St. Hilary's Church in Tiburon is owned in part by the Tiburon Landmark Society. The remainder of each of these two occurrences is privately-owned and proposed for development. An area containing 20 plants adjacent to one of the parcels recently was bulldozed for construction of condominiums (Andrew Allen, pers. comm., 1993). Residential development is ongoing at several parcels of the Middle Ridge occurrence (Eva Buxton, Belvedere-Tiburon Landmark Society, pers. comm., 1993, Andrew Allen, pers. comm., 1993).

Clarkia franciscana was once thought to be restricted to the Presidio in San Francisco County but about 10 years ago, a population was discovered in Alameda County in the Oakland Hills. The two populations in San Francisco County occur at the Presidio, currently owned by the National Park Service. These populations are threatened by habitat degradation. Pedestrian and mountain bicycle traffic on and near casually established ''social trails'' threatens the habitat.

The three populations of *Clarkia franciscana* in Alameda County are all threatened by alien species (see Factor E). The smallest of the three, consisting of 30 plants (Olson 1991c), occurs on an undeveloped site adjacent to a proposed 32-unit residential development (Nixon

Lamb, Oakland Planning Dept., pers. comm., 1993).

One occurrence of *Cirsium fontinale* var. *fontinale* has been reported from Santa Clara County, but the site is thought to have been destroyed by urbanization (Niehaus 1977). The three remaining populations grow in San Mateo County. The largest population occurs to the east of Crystal Springs Reservoir and north of State Highway 92, along both sides of Interstate 280. It occurs partly on San Francisco Water Department land and partly on a California Department of Transportation right-of-way. Given its proximity to the roadside, it is likely to be affected by any highway projects in the area. Major realignments of Highway 92 were planned several years ago but the plans have been abandoned due to lack of funding (Richard Vonarb, California Department of Transportation, pers. comm., 1992). They could be revived, however, if funding becomes available. At present, a smaller project to widen Highway 92 east of the reservoir causeway is under review. Provision for the removal of water from the increased road surface may adversely affect some of the plants. The California Department of Transportation is aware of the plant locations and vulnerability. The proposed construction of multi-use recreational trails on San Francisco Water Department land presents an additional threat. Trail construction would threaten the plants through direct destruction of the habitat or through modification of hydrologic regimes. Because *C. fontinale* var *fontinale* is dependent upon seeps and springs to provide abundant soil moisture, any disruption in the flow of water (such as that caused by road, trail, or drain construction) would threaten the plants.

A second and substantially smaller population of *Cirsium fontinale* var. *fontinale* occurs in the ''Triangle'' west of Interstate 280. One to two hundred plants have been observed on San Francisco Water Department lands; an outlying colony of about 25 plants occurs on an easement held by the California Department of Transportation. This colony occupied a smaller territory in 1992 than it had in previous years (Susan Sommers, pers. comm., 1992). The plants on Water Department land are threatened by proposed trail construction, as discussed for *Hesperolinon congestum*. In addition, a general management plan for the Water Department lands currently is being developed (Ed Stewart, San Francisco Water Department, pers. comm., 1992).

The single specimen of *Cirsium fontinale* var. *fontinale* in Edgewood County Park occurs in a drainage ditch beside a trail. Clearing of the ditch to improve or maintain drainage could damage or destroy this plant or any seedlings it may produce.

Eriophyllum latilobum has been reported from only two locations, one of which is likely erroneous (specimen misidentified, according to Barry Prigge, pers. comm., 1992). The single remaining population consists of about 300 plants that occur along 4 km (2.5 miles) of Crystal Springs Road in San Mateo County. Seventy-five percent of the plants occur within 9 m (30 ft) of the road, where land ownership is poorly defined (McGuire and Morey 1992). The City of Hillsborough, the County of San Mateo, and the San Francisco Water Department have varying jurisdictions over the land. The steep slopes along Crystal Springs Road provide a very unstable habitat for *E. latilobum*. The slopes are subject to erosion and soil slippage. After soil slippage occurs, road maintenance crews remove the slumped soil, which may contain mature individuals, seedlings, and/or seeds of *E. latilobum*. The road cut is then reshaped, which may damage plants remaining on the banks. The proposed construction of the San Mateo Creek Trail (McGuire and Morey 1992) would have adverse impacts on the plant if trail design does not incorporate plant conservation. The paved trail, which is 3 m (10 ft) wide, is expected to run adjacent to Crystal Springs Road from Skyline Boulevard to the San Mateo City boundary. Construction of the trail could damage or eliminate colonies of *E. latilobum*, alter site hydrology, accelerate soil erosion through increased pedestrian and bicycle traffic, and allow for the introduction of aggressive alien plant species.

Fourteen populations of *Hesperolinon congestum* exist. One Marin County population is protected at The Nature Conservancy's Ring Mountain Preserve. Two relatively small populations occur on land owned by the Marin Municipal Water District. Another small population is found in the Golden Gate National Recreation Area above Nicasio Reservoir. A fifth population occurs, in part, on a small preserve at St. Hilary's Church and, in part, on private land which recently has been proposed for development (Robison and Morey 1992a). The sixth Marin County site is the Middle Ridge area of the Tiburon Peninsula, on which occur a few scattered groups of plants. Some plants grow on land designated as open space by the city of Tiburon. The remainder of the plants occur on private land and are threatened by ongoing or proposed residential development.

One population of *Hesperolinon congestum* is known from San Francisco County. Footpaths through the population threaten the plants with trampling (Robison and Morey 1992a).

In San Mateo County, three populations of *Hesperolinon congestum* are known to occur on private property. These plants are threatened by proposed development and by the consequences of recently completed development, such as trampling, trash dumping, and changes in hydrology caused by irrigation runoff (Robison and Morey 1992a). Two populations occur on land owned by the San Francisco Water Department. Their habitat is threatened by the proposed construction of trails in the watershed. The construction of these trails and the accompanying fences may damage *Hesperolinon congestum* habitat.

Pentachaeta bellidiflora historically ranged from Marin County to Santa Cruz County. Three populations in Marin County and two in San Mateo County were destroyed by urbanization. One Marin County occurrence was destroyed by off-road vehicles. Two sites in Santa Cruz County no longer support *P. bellidiflora* (Robison and Morey 1992b). The single remaining population of *P. bellidiflora* was bisected by the construction of California Interstate 280 in the late 1960s. The largest portion of the population occurs in the Triangle, on land administered by the San Francisco Water Department. A small remnant of this population is located to the east of Interstate 280, on Edgewood County Park. The proposed construction of trails on Water Department land threaten the *P. bellidiflora* habitat (Robison and Morey 1992b).

Ceanothus ferrisae is known from three populations in Santa Clara County. The largest population, consisting of approximately 5,000 plants, occurs near Anderson Dam, partially on Santa Clara County Park property and partially on private property. The county proposes further recreational development in the park, which threatens *Ceanothus ferrisae* (Chris Nagano, U.S. Fish and Wildlife Service, pers. comm., 1992). An outlying population occurs 3.2 km (2 miles) west on land leased and managed by a waste management firm. Waste Management, Inc. and The Nature Conservancy jointly funded research on *C. ferrisae;* a three-year monitoring program at the Waste Management site has shown no evidence of natural recruitment. A fire killed 95 percent of the plants in this population in 1992. No seed production or seedlings have been observed since that time (Kathy Freas, CH²M Hill, *in litt.*, 1993).

Researchers have found that *C. ferrisae* is relatively easy to propagate from seed, and both Waste Management and the Santa Clara Valley Water District have been experimenting with the use of *C. ferrisae* for revegetation projects. The third population, consisting of approximately 500 plants (Corelli 1989) occurs on private land scheduled for development.

Dudleya setchellii always has been restricted to the Coyote Valley area of Santa Clara County. Eleven of the 14 populations are on private land and are subject to various levels of threat due to development. The three northernmost populations, which occur in southeastern San Jose, and the three southernmost populations, which occur in the area around Morgan Hill, approximately 27 km (17 miles) southeast of San Jose, are at greatest risk. One of the northern populations is threatened with the proposed Cerro Plata Project, consisting of 550 dwelling units and a 67 ha (164 ac) golf course on a 236 ha (575 ac) site. This population contains approximately 20,000 plants, 61 percent of all known plants, of which approximately 2,380 would be directly eliminated by planned construction activities (City of San Jose 1993). All remaining plants would be exposed to human activities during and after construction that would result in significant impacts to the population. These impacts include potentially harmful runoff from an upslope golf course, introduction of weedy species during construction, and uncontrolled foot traffic. Another of the northern sites is threatened by the proposed construction of the Valley Christian School and South Valley Christian Church. This construction would eliminate 74 percent of the approximately 1,900 *D. setchellii* plants found on the site (City of San Jose 1992). The other four sites also are developing rapidly and have been proposed for development at one time or another. Two of the central populations also are threatened with imminent development including residential development and road construction. One central population, due to its proximity to an off-road motorcycle park, may be threatened by off-road motorcycle traffic and unauthorized dumping. The remaining two populations that occur on private land are on the grounds of the IBM Bailey Avenue laboratory. The company apparently plans to preserve the habitat (McCarten 1992a). Three populations occur on land owned by Santa Clara County. Of these, two populations occur in county parks.

The known historical distribution of *Streptanthus albidus* ssp. *albidus* is as restricted as its current distribution. It is found only in the Coyote Valley area of Santa Clara Valley, primarily on the east side of the valley. Of the 13 documented sites, 9 are known to still harbor plants. Two populations are known to have been extirpated, one by the construction of Anderson Dam, and the other as a result of being covered by fill from a housing development. Two occurrences are known from herbarium records only. One of these historical sites was revisited in 1990, but no plants were found. *Streptanthus albidus* ssp. *albidus* was last observed at the other historical site in 1895. One population consisting of approximately 9,000 plants, approximately 45 percent of all known plants, occurs on the proposed site of the Cerro Plata residential and golf course project (City of San Jose 1993). Although no direct destruction of any plants is planned, construction activities, human disturbance, and habitat fragmentation would result in significant impacts to the population. The proposed construction of the Valley Christian School and South Valley Christian Church would destroy 61 percent of the 2,700 plants occurring on the site (City of San Jose 1992). The remaining seven populations also are threatened by impending or potential development.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* Overutilization is not currently known to be a factor for any of the 12 plants, but unrestricted collecting for scientific or horticultural purposes or excessive visits by individuals interested in seeing rare plants could result from increased publicity as a result of this final rule. *Calochortus tiburonensis* is a strikingly unusual member of a much-collected genus. *Eriophyllum latilobum*, with its showy golden flowers and proximity to roads and the proposed San Mateo Creek trail, might prove to be especially tempting to collectors. *Dudleya setchellii* also is vulnerable because of the horticultural appeal of succulents and the slow growth of the plants. The remaining plants are usually not spectacular in flower, but may nonetheless appeal to collectors because of their rarity.

C. *Disease or predation.* Both horses and deer have been reported to browse on *Cordylanthus tenuis* ssp. *capillaris* but the number of plants damaged generally appears to be minimal (Lynn Lozier, pers. comm., 1992). Cattle grazing has been reported to threaten the western Marin population of *Castilleja affinis* ssp. *neglecta* (Martin 1991) and a portion of the American Canyon occurrence (Hunter 1989a). Another source suggests, however, that cattle provide little threat to the American Canyon population because the plants occur on a very steep slope (Jake Ruygt, Napa Valley Chapter, California Native Plant Society, pers. comm., 1992). Grazing threatens one population of *Streptanthus albidus* ssp. *albidus* in southeast San Jose and three populations in the Metcalf Canyon/south Coyote area (McCarten 1992b).

Seed predation by beetle larvae has been reported for *Cirsium fontinale* var. *fontinale* (Dean Kelch, University of California, Davis, pers. comm., 1992), however, the impact of this seed predation on *C. fontinale* var. *fontinale* is unknown. Beetle larvae also have been observed in seed heads of *Eriophyllum latilobum*, however, the extent of predation is unknown (McGuire and Morey 1992).

D. *The inadequacy of existing regulatory mechanisms.* Under the Native Plant Protection Act (Division 2, Chapter 10, section 1900 *et seq.* of the Fish and Game Code) and California Endangered Species Act (Division 3, Chapter 1.5, section 2050 *et seq.*), the California Fish and Game Commission has listed three of these species (*Cirsium fontinale* var. *fontinale, Clarkia franciscana*, and *Streptanthus niger*) as endangered, two species (*Calochortus tiburonensis* and *Castilleja affinis* ssp. *neglecta*) as threatened, and one species (*Cordylanthus tenuis* ssp. *capillaris*) as rare. The California Fish and Game Commission recently voted to list two other species (*Eriophyllum latilobum* and *Pentachaeta bellidiflora*) as endangered, and one species (*Hesperolinon congestum*) as threatened. Although both statutes prohibit the ''take'' of State-listed plants (Chapter 1.5 section 2080 and Chapter 10 section 1908), State law appears to exempt the taking of such plants via habitat modification or land use change by the landowner. After the California Department of Fish and Game notifies a landowner that a State-listed plant grows on his or her property, State law requires only that the landowner notify the agency ''at least ten days in advance of changing the land use to allow salvage of such plant.'' (Chapter 10 section 1913).

The California Environmental Quality Act (CEQA) requires a full public disclosure of the potential environmental impacts of proposed projects. The public agency with primary authority or jurisdiction over the project is designated as the lead agency and is responsible for conducting a review of the project and consulting with other agencies concerned with resources affected by

the project. Section 15065 of the CEQA Guidelines requires a finding of significance if a project has the potential to ''reduce the number or restrict the range of a rare or endangered plant or animal.'' Species that are eligible for listing as rare, threatened, or endangered, but are not so listed, are given the same protection as those species that are officially listed with the State. Once significant effects are identified, the lead agency has the option to require mitigation for effects through changes in the project or to decide that overriding considerations make mitigation infeasible. In the latter case, projects may be approved that cause significant environmental damage, such as destruction of endangered species or their habitat. The protection of threatened and endangered species through CEQA is, therefore, dependant upon the discretion of the lead agency involved and, in practice, statements of overriding considerations are commonly prepared.

Three of the species occur at Edgewood County Park in San Mateo County. The park was designated on May 5, 1992, as a natural preserve; however, this designation was revoked in August of the same year. The park, subsequently, was considered as a site for construction of a golf course, although this plan has been rejected and the park will continue to be managed as public open space (Richard Silver, San Mateo County Board of Supervisors, pers. comm., 1993).

Section 404 of the Clean Water Act regulates the placement of dredge and fill materials into waters of the United States (including small acreages above the headwaters of streams). The U.S. Army Corps of Engineers (Corps) is the agency responsible for administering the section 404 program. The Service, as part of the section 404 review process, provides advisory comments on both pre-discharge notices for nationwide permits and public notices for individual permits.

Under section 404, nationwide permits, which undergo minimal public and agency review, can be issued for projects involving less than 10 acres of waters of the United States and adjacent wetlands, unless a listed species may be adversely affected. Individual permits, which are subject to more extensive review, are required for projects that affect greater than 4.1 ha (10 acres). A project proponent planning to fill less than 0.4 ha (1 acre) is only required to notify the Corps of their intent to fill wetlands. Compensatory mitigation generally is not required for projects affecting less than 0.4 ha (1 acre). Additionally, the loss of upland watersheds, which are not protected, may result in altered wetland hydrology and may adversely affect the plants. In practice, the Corps' actions under section 404 would not adequately protect *Cirsium fontinale* var. *fontinale*, which occurs in riparian serpentine seep areas.

Most projects within the range of *Cirsium fontinale* var. *fontinale* may require approval from the Corps, as currently described in section 404 of the Clean Water Act. Federal listing of this species would ensure greater consideration of the effects of permitted actions during the review process as well as provide the protections of section 7 of the Act.

E. *Other natural or manmade factors affecting its continued existence.* As discussed in the ''Background'' section, the large and still increasing numbers of people in the San Francisco Bay area place a great strain on undeveloped wildlands, through activities such as pedestrian and off-road vehicle traffic, hiking and bicycle trails, and unauthorized garbage dumping. Disturbance may directly impact plants; it can increase erosion and allow the invasion of alien species such as the many introduced annual grasses common in California. Competition with introduced species is a serious threat to serpentine natives (McCarten 1987b). Edaphic specialists (plants restricted to a certain soil type) with small populations such as the serpentine species discussed herein, may have low genetic variability (Menges 1991). As a result, populations that become subdivided by alterations in habitat from road construction and urbanization or from natural catastrophes such as disease, fire, or drought, may be at high risk of genetic changes that decrease the ability of the populations to survive (Menges 1991).

Cordylanthus tenuis ssp. *capillaris* growing along roadsides is threatened by roadside maintenance such as mowing and spraying (Lynn Lozier, pers. comm., 1992). Vehicular traffic threatens plants in and near the parking area at the Harrison Grade Reserve, which is poorly defined and close to the plant population (McCarten 1987a). Unauthorized dumping of large items such as bottles, furniture, appliances, and cut wood is also a threat. Light disturbance at the Harrison Grade Reserve, such as infrequent grading of dirt roads, appears to increase the numbers of *C. tenuis* ssp. *capillaris* (Lynn Lozier, pers. comm., 1992), but higher levels of disturbance may facilitate the invasion of alien species (McCarten 1987a) and result in a decline of *C. tenuis* ssp. *capillaris*. The limited number and isolated condition of these populations make this species susceptible to stochastic extinction (Menges 1991).

Calochortus tiburonensis is threatened, by virtue of its occurrence in a single population, with chance events such as fire, severe drought, pest or disease outbreak, landslides, or other natural or human-caused disasters. The proximity of the plant to a large human population increases the likelihood that human-caused disasters or acts of vandalism could affect the plants or their habitat. The preserve is fenced to reduce the incidence of off-road vehicle use, but is still accessible to bicycles, motorbikes, and pedestrians, and it is not patrolled. Pedestrian traffic threatens both of the *Streptanthus niger* populations.

The Presidio, which contains one of the two populations of *C. franciscana*, represents a significant natural and cultural resource within San Francisco city limits, and is expected to be heavily used by visitors since its transfer to the National Park Service (T. Thomas, pers. comm., 1992). The heavy use will increase the negative impact of traffic on *C. franciscana*. The species presently is threatened by road maintenance (mowing) at the Presidio. Mowing of grasslands before the *C. franciscana* has set seed also threatens the populations. Populations at the Presidio also are threatened by the encroachment of alien plant species, including *Senecio mikanioides* (German ivy), *Carpobrotus* sp. (iceplant), *Rubus* spp. (blackberries), and by natives planted outside their natural range, such as *Pinus radiata* (Monterey pine) (California Department of Fish and Game 1988). The population size at the type locality increased following removal of alien plant species in the late 1980s. Constant vigilance and effort is needed to prevent reinvasion.

At latest report, the largest population of *Clarkia franciscana*, occurring at Redwood Regional Park in Alameda County, consisted of 4,000 to 5,000 plants (Gottlieb and Edwards 1992, Olson 1991a). The East Bay Regional Park District is aware of the *Clarkia franciscana* population and has been taking it into account in their management plans (Ray Budzinski, East Bay Regional Park District, pers. comm., 1992). The habitat is threatened by competition with annual grasses (Ray Budzinski, pers. comm., 1992) and other alien plants, including *Cortaderia selloana* (pampas grass) and *Cytisus monspessulanus* (French broom) (Olson 1991a). The two smaller populations in Alameda County, consisting of 200 plants (Olson 1991b) and 30 plants (Olson 1991c), respectively, also are

threatened by alien species *Cytisus monspessulanus* and *Cortaderia jubatum*. Low viability caused by harmful genetic changes may result from inbreeding in small populations (Barrett and Kohn 1991). The larger of the two populations occurs on a roadcut.

The Crystal Springs Reservoir population of *Cirsium fontinale* var. *fontinale* is threatened by several factors, including roadside maintenance. The California Department of Transportation is aware of the rare plants in this area, and the maintenance division submits spraying plans for internal environmental review before spraying in the area where plants are known to occur (Richard Vonarb, pers. comm., 1992). Alien plants such as *Cortaderia selloana* have established themselves near the *C. fontinale* var. *fontinale,* and threaten several subpopulations (Zoe Chandik, pers. comm., 1992). Dumping of garden debris from households on the ridge above the plants covers plants and renders the habitat unsuitable for plant establishment and growth. It has been suggested that *C. fontinale* var. *fontinale* may be threatened with hybridization with *Cirsium quercetorum*, but only one hybrid has been collected in recent years, so this is not thought to be a serious problem (Dean Kelch, pers. comm., 1992). In addition, seed predation of this species has been observed (Dean Kelch, pers. comm., 1992) and may add to the vulnerability of the species to elimination by chance events.

Eriophyllum latilobum is threatened by many factors. Dumping of garden debris and downhill seepage of pesticides from homeowners living above the population may have negative impacts on *E. latilobum* habitat. The plant also is threatened by competition with alien plants; its habitat is more densely populated with *Carduus* sp. and *Bromus* sp. than it was 10 years ago (John Mooring, pers. comm., 1992). Road maintenance also threatens *E. latilobum*. San Mateo County road maintenance crews were alerted to the existence of *E. latilobum* in 1990, and instructed to avoid the plants by the San Mateo County Planning Department; however, road maintenance activities are not monitored to ensure protection (Roman Gankin, San Mateo County Planning Division, pers. comm. to Teri McGuire, Botanist, California Department of Fish and Game, cited in McGuire and Morey 1992). San Mateo County Department of Public Works has eliminated the use of weed sprays along the section of road where the species occurs (Robert Sans, Director of Public Works, San Mateo Co., *in litt.,* 1993). *E. latilobum* is not a vigorous reproducer; low germination rates and low seedling survival have been observed under greenhouse conditions (John Mooring, *in litt.*, 1992; McGuire and Morey 1992). Because of the existence of only a single population exhibiting low viability and located in an unstable habitat, this species is extremely vulnerable to stochastic extinction (Menges).

Hesperolinon congestum is threatened by the encroachment of native shrubs in San Francisco County. In San Mateo County, all three populations are threatened by trash dumping as a consequence of recently completed development. In addition, a portion of the *H. congestum* population located in Edgewood Park is suffering from foot traffic and inadequate trail maintenance (S. Sommers, *in litt.*, 1993).

Pentachaeta bellidiflora potentially is threatened by competition from alien plant species; this competition becomes a problem when the soils are disturbed (Robison and Morey 1992b). If proposed trail construction occurs on the site, the soil disturbance could result in encroachment and competition from non-native species.

Ceanothus ferrisae is threatened by unauthorized dumping of litter and larger debris at the Anderson Dam site. Dumping can degrade or threaten a habitat by directly killing the plants, depriving them of light, or disturbing the soil, thus promoting erosion and the invasion of weedy, competitive species.

Streptanthus albidus ssp. *albidus* is threatened by dumping and off-road motorcycle use. Road maintenance or construction threaten populations that occur on roadcuts.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by these species in determining to make this rule final. These 12 plants are endemic to a very specific habitat that occurs in scattered outcrops. The rapid urban development in the San Francisco Bay region offers the greatest threat to these plants. Development has eliminated nearly 20 percent of the serpentine habitat in the last 20 years (McCarten 1987b). The remaining habitat is fragmented from road and urban construction and increasingly will become impacted with predicted growth in population centers. The 12 species are threatened further by the invasion of alien species, roadside maintenance, soil erosion and slipping, garbage dumping, livestock grazing, seed predation, and small population sizes that increase their vulnerability to chance events such as fire, flood, drought, pest and disease outbreaks, and other natural and human-caused disasters.

Cordylanthus tenuis ssp. *capillaris* occurs in only two sites. One is threatened by off road vehicle use; the second site, although proposed for protection as a county park, is threatened potentially by foot traffic. Five of the six populations of *Castilleja affinis* ssp. *neglecta* are threatened by development, foot traffic, and a nearby quarry. The two populations of *Streptanthus niger* are threatened by residential development and road construction. *Clarkia franciscana* is known from five populations that are imperiled by potential development, foot traffic and competition from alien plants. Proposed trail and road construction threaten the three remaining populations of *Cirsium fontinale* var. *fontinale.* The single remaining population of *Eriophyllum latilobum* occurs on steep slopes subject to erosion that could be accelerated by a proposed bike trail. It is extremely vulnerable to extinction from random events. The single remaining population of *Pentachaeta bellidiflora,* which has been bisected by Highway 280, is threatened by proposed trail construction. It is also extremely vulnerable to random events. *Ceanothus ferrisae* occurs in three populations threatened by proposed residential and recreational development; 95 percent of one population was recently destroyed by fire. Eleven of the 14 populations of *Dudleya setchellii* occur on private land and are threatened by a proposed golf course and by residential, school, church and road construction. Proposed residential and golf course construction, and grazing threaten the nine populations of *Streptanthus albidus* ssp. *albidus.*

These species are in danger of extinction throughout all or a part of their range, and the preferred action is, therefore, to list *Castilleja affinis* ssp. *neglecta, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris, Dudleya setchellii, Eriophyllum latilobum, Pentachaeta bellidiflora, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* as endangered. Two species are not now in immediate danger of extinction throughout all or a significant portion of their range. The single known population of *Calochortus tiburonensis* is protected by The Nature Conservancy, however, its proximity to human population centers and surrounding development make it vulnerable to catastrophic events. Proposed residential development and foot traffic

threaten 10 of the 14 populations of *Hesperolinon conjestum*. If appropriate management actions are not taken to protect these two species, they are likely to become in danger of extinction in the near future. As a result, the preferred action is to list *Calochortus tiburonensis* and *Hesperolinon congestum* as threatened.

Alternatives to this action were considered but not preferred. Not listing the species or listing *Castilleja affinis* ssp. *neglecta, Ceanothus ferrisae, Cirsium fontinale* var. *fontinale, Clarkia franciscana, Cordylanthus tenuis* ssp. *capillaris, Dudleya setchellii, Eriophyllum latilobum, Pentachaeta bellidiflora, Streptanthus albidus* ssp. *albidus,* and *Streptanthus niger* as threatened would not provide adequate protection and would not be in keeping with the Act.

Critical Habitat

Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, the Secretary designate critical habitat concurrently with determining a species to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for these species. Because the 12 plants face numerous anthropogenic threats (see Factors A and E in ''Summary of Factors Affecting the Species'') and occur predominantly on private land, the publication of precise maps and descriptions of critical habitat in the **Federal Register** would make these plants more vulnerable to incidents of vandalism and, therefore, could contribute to the decline of these species and increase enforcement problems. The listing of these species as endangered or threatened also publicizes the rarity of these plants and, thus, can make them attractive to researchers or collectors of rare plants. Furthermore, critical habitat designation is not prudent due to lack of benefit to the species. All 12 species discussed herein are restricted to serpentine soils. Several of the species, *Eriophyllum latilobum, Calochortus tiburonensis, Streptanthus niger,* and *Streptanthus albidus* ssp. *albidus* likely have always been confined to their present habitat. No areas outside of their present range are known to have supported these plants in the past; therefore, no additional sites exist that could be considered essential to the species' recovery. For these reasons, the Service finds that designation of critical habitat for the 12 species is not prudent because it would provide no additional benefits to the species beyond those they would receive by virtue of their designation as endangered or threatened species. The proper agencies have been notified of the locations and importance of protecting the habitat of these species.

Protection of the habitat of these species will be addressed through the recovery process and through the section 7 consultation process. Therefore, the Service finds that designation of critical habitat for these plants is not prudent at this time, because such designation likely would increase the degree of threat from vandalism, collecting, or other human activities.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the State and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal activities potentially affecting 1 or more of the 12 plants will likely involve recreation-related projects and perhaps grazing practices on Federal land. Populations of 3 of the 12 plants occur on Federal land. Two populations of *Hesperolinon congestum* and one of *Castilleja affinis* ssp. *neglecta* occur on the Golden Gate National Recreation Area. Two populations of *Clarkia franciscana* occur at the Presidio.

The San Francisco Water Department owns 9,300 ha (23,000 acres) of land in San Mateo County. In 1969, a four-party agreement among the U.S. Department of the Interior, the State of California, San Mateo County, and the City and County of San Francisco established easements on the watershed lands to ensure that all future land use would be compatible with water quality criteria. These easements were granted to the U.S. Department of the Interior and are jointly administered by the San Francisco Water Department and the Golden Gate National Recreation Area. Populations of *Cirsium fontinale* var. *fontinale, Eriophyllum latilobum, Hesperolinon congestum,* and *Pentachaeta bellidiflora* occur on Water Department land.

Hesperolinon congestum, Pentachaeta bellidiflora, Dudleya setchellii, and *Streptanthus albidus* ssp. *albidus* co-occur with the bay checkerspot butterfly (*Euphydryas editha bayensis*) in San Mateo and Santa Clara counties. The bay checkerspot is listed as a threatened species under the Endangered Species Act. Permits for incidental take of this species granted under section 10(a) of the Act may affect the plant species listed above. Preparation of Habitat Conservation Plans for the bay checkerspot butterfly may, therefore, require internal section 7 consultation with regard to the four species listed above.

The 12 plants also may be affected by Federal mortgage programs, including the Veterans' Administration and the U.S. Department of Housing and Urban Development (Federal Home Administration loans), or by construction of roads and highways by the Federal Highway Administration. The Service is concerned over the loss of *Eriophyllum latilobum* during regular road maintenance and continuing soil slippage that results in plant loss; however, removal from roadways of debris containing *E. latilobum* plants or seeds that has fallen by natural causes into the roadway is not a violation of the Act.

At least one proposed project that may affect two of the plants also involves wetlands under the jurisdiction of the U.S. Army Corps of Engineers.

Listing these 12 plants will provide for development of a recovery plan (or plans) for them. Such plan(s) would bring together both State and Federal efforts for conservation of the plants. The plan(s) would establish a framework for agencies to coordinate

activities and cooperate with each other in conservation efforts. The plan(s) would set recovery priorities and estimate costs of various tasks necessary to accomplish them. They also would describe site-specific management actions necessary to achieve conservation and survival of the 12 serpentine plant species.

The Act and its implementing regulations found at 50 CFR 17.61, 17.62, and 17.63 for endangered species and 17.71 and 17.72 for threatened species set forth a series of general prohibitions and exceptions that apply to all endangered or threatened plants. With respect to the 12 plants from San Francisco Bay area serpentine habitats, all prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61 or 17.71, would apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export; transport in interstate or foreign commerce in the course of a commercial activity; sell or offer for sale in interstate or foreign commerce; remove and reduce to possession the species from areas under Federal jurisdiction; maliciously damage or destroy any such species on any area under Federal jurisdiction; or remove, cut, dig up, damage, or destroy any such endangered plant species on any other area in knowing violation of any State law or regulation or in the course of any violation of a State criminal trespass law. Certain exceptions apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.62, 17.63, and 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered or threatened plant species under certain circumstances. The Service anticipates few trade permits would ever be sought or issued for the 12 species because the plants are not common in cultivation or in the wild.

It is the policy of the Service (59 FR 34272) to identify to the maximum extent practicable at the time a species is listed those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of the listing on proposed or ongoing activities. Activities affected by the listing were discussed previously in this section. The Service does not at this time know of any other activities affected by this listing.

Questions regarding whether specific activities will constitute a violation of section 9 should be directed to the Field Supervisor of the Service's Sacramento Office (see **ADDRESSES** section). Requests for copies of the regulations on listed plants and inquiries regarding them may be addressed to the U.S. Fish and Wildlife Service, Ecological Services, Permits Branch, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181 (503/231–6241; FAX 503/231–6243).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited herein is available, upon request, from the Field Supervisor, Sacramento Field Office (see **ADDRESSES** section).

Author: The primary author of this final rule is Elizabeth Warne, U.S. Fish and Wildlife Service, Sacramento Field Office (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Regulations Promulgation

Accordingly, Part 17 subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, is amended as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Section 17.12(h) is amended by adding the following species, in alphabetical order under the families indicated, and by adding a new family ''Linaceae—Flax Family,'' in alphabetical order, to the List of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
* *	*	*	*	*	*	
Asteraceae—Aster family:						
* *	*	*	*	*	*	
Cirsium fontinale var. *fontinale*	Fountain thistle	U.S.A. (CA)	E	575	NA	NA
* *	*	*	*	*	*	
Eriophyllum latilobum	San Mateo woolly sunflower.	U.S.A. (CA)	E	575	NA	NA
* *	*	*	*	*	*	
Pentachaeta bellidiflora	White-rayed pentachaeta.	U.S.A. (CA)	E	575	NA	NA
* *	*	*	*	*	*	
Brassicaceae—Mustard family:						
* *	*	*	*	*	*	
Streptanthus albidus ssp. *albidus.*	Metcalf Canyon jewelflower.	U.S.A. (CA)	E	575	NA	NA
Streptanthus niger	Tiburon jewelflower ..	U.S.A. (CA)	E	575	NA	NA

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
* * *	*	*	*	*	*	
Crassulaceae—Stonecrop family:						
* * *	*	*	*	*	*	
Dudleya setchellii	Santa Clara Valley dudleya.	U.S.A. (CA)	E	575	NA	NA
* * *	*	*	*	*	*	
Liliaceae—Lily family:						
* * *	*	*	*	*	*	
Calochortus tiburonensis	Tiburon mariposa lily	U.S.A. (CA)	T	575	NA	NA
* * *	*	*	*	*	*	
Linaceae—Flax family:						
Hesperolinon congestum	Marin dwarf-flax	U.S.A. (CA)	T	575	NA	NA
* * *	*	*	*	*	*	
Onagraceae—Evening-primrose family:						
* * *	*	*	*	*	*	
Clarkia franciscana	Presidio clarkia	U.S.A. (CA)	E	575	NA	NA
* * *	*	*	*	*	*	
Rhamnaceae—Buckthorn family:						
* * *	*	*	*	*	*	
Ceanothus ferrisae	Coyote ceanothus	U.S.A. (CA)	E	575	NA	NA
* * *	*	*	*	*	*	
Scrophulariaceae—Snapdragon family:						
* * *	*	*	*	*	*	
Castilleja affinis ssp. *neglecta*	Tiburon paintbrush ...	U.S.A. (CA)	E	575	NA	NA
* * *	*	*	*	*	*	
Cordylanthus tenius ssp. *capillaris*.	Pennell's bird's beak	U.S.A. (CA)	E	575	NA	NA
* * *	*	*	*	*	*	

Dated: December 16, 1994.

Mollie H. Beattie,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 95–2689 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 60, No. 23
Friday, February 3, 1995

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95–ASO–4]

Proposed Amendment to Class E Airspace; Smithfield, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Class E airspace area at Smithfield, NC, A LOC/DME RWY 3 Standard Instrument Approach Procedure (SIAP) has been developed for Johnston County Airport. Additional controlled airspace extending upward from 700 feet above the surface (AGL) is needed to accommodate this SIAP and for instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before March 20, 1995.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 95–ASO–4, Manager, System Management Branch, ASO–530, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586.

FOR FURTHER INFORMATION CONTACT: Michael J. Powderly, System Management Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5570.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 95–ASO–4.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM'S

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, System Management Branch ASO–530, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class E airspace area at Smithfield, NC, A LOC/DME RWY 3 SIAP has been developed for Johnston County Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate this SIAP and for IFR operations at the airport. Designations for Class E airspace extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9B dated July 18, 1994 and effective September 16, 1994 which is incorporated by reference in CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994 and effective September 16, 1994, is amended as follows:

Para. 6005 Class E airspace areas extending upward from 700 feet above the surface of the earth.

* * * * *

ASO NC E5 Smithfield, NC [Revised]

Johnston County Airport, NC
(Lat. 35°26′28″ N, long. 78°23′25″)
Jnall NDB
(Lat. 35°26′25″ N, long. 78°21′16″ W)

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of Johnston County Airport and within 2.4 miles each side of the 024° bearing from the Jnall NDB, extending from the 7.5-mile radius to 7 miles northeast of the NDB.

* * * * *

Issued in College Park, Georgia, on January 24, 1995.

Michael J. Powderly,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 95–2733 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–13–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL12–39–6822, FRL–5149–2]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; notice of public hearing; reopening the public comment period.

SUMMARY: The United States Environmental Protection Agency (USEPA) promulgated the Chicago ozone Federal Implementation Plan (FIP) on June 29, 1990 (55 FR 26814). Included in USEPA's FIP was a requirement that staple manufacturing facilities such as Duo-Fast Corporation's Franklin Park, Illinois facility be subject to specific emission limits. On November 27, 1990, Duo-Fast filed a petition for reconsideration with USEPA in which it contended that USEPA failed to respond to Duo-Fast's March 2, 1990, comments in response to USEPA's December 27, 1990, proposed promulgation of the Chicago FIP. On November 18, 1994 (59 FR 59739), USEPA published a proposed rule on this reconsideration which offered the opportunity for a public hearing. A public hearing was requested on the November 18, 1994, proposed rule. This notice announces that a public hearing on the proposed rule is scheduled for March 8, 1995, and reopens the public comment period from February 3, 1995 until April 7, 1995.

DATES: The public comment period is reopened from February 3, 1995 until April 7, 1995. A public hearing has been scheduled for Wednesday March 8, 1995, at 1:30 pm.

ADDRESSES: Written comments on the proposed rule should be addressed to: J. Elmer Bortzer, Chief, Regulation Development Section (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Comments should be strictly limited to the subject matter of the November 18, 1994, proposed rule. The location of the public hearing is the Lake Ontario Room on the twelfth floor of the Ralph H. Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Steven Rosenthal, Regulation Development Branch, 18th Floor Southwest, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6052.

Dated: January 25, 1995.

Michelle D. Jordan,

Acting Regional Administrator.

[FR Doc. 95–2628 Filed 2–2–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Chapter I

[CGD 95–007]

Alternate Compliance for Inspection and Certification of Certain U.S. Flag Commercial Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice; solicitation for participants; request for comments.

SUMMARY: On January 12, 1995, the U.S. Coast Guard and the American Bureau of Shipping (ABS) signed a Memorandum of Understanding (MOU) concerning delegation of vessel inspections and examinations, tonnage measurement, and acceptance of plan review and approval. Under this MOU, the Coast Guard and the ABS will develop a program to provide owners and operators of certain ABS classed, Coast Guard inspected commercial vessels with an alternative to undergoing inspection by the Coast Guard under existing applicable Federal regulations. Owners and operators of certain ABS classed, Coast Guard inspected vessels are invited to participate in a pilot program designed to evaluate standards, processes, and procedures under development for use in the Alternate Compliance Program (ACP), and interested persons are invited to submit comments.

DATES: A pilot program will begin February 3, 1995. Applications for participation in the pilot program must be received not later than May 4, 1995. Written comments should be submitted not later than August 2, 1995.

ADDRESSES: Applications for participation in the pilot program must be submitted to Commandant (G–MVI–1), ATTN: ACP Pilot Program, U.S. Coast Guard, 2100 Second Street, S.W., Washington, DC 20593–0001. Written comments may be mailed to the Executive Secretary, Marine Safety Council (G–LRA), U.S. Coast Guard, 2100 Second Street S.W., Washington, DC 20593–0001, or may be delivered to room 3406 at the same address between 8 AM and 3 PM, Monday through Friday, except Federal holidays. Comments will become part of this docket and will be available for inspection or copying at room 3406, Coast Guard Headquarters, between 8 AM and 3 PM, Monday through Friday, except Federal holidays. Copies of referenced materials are available for inspection and copying in room 1400, U.S. Coast Guard, 2100 Second Street S.W., Washington, DC 20593–0001, and may also be obtained from the American Bureau of Shipping, 16855 Northchase Drive, Houston, TX 77060, or the International Maritime Organization, Publications Section, 4 Albert Embankment, London SE1 7SR, United Kingdom, telephone 44 (71) 735 7611, facsimile 44 (71) 587 3210, as indicated.

FOR FURTHER INFORMATION CONTACT: LCDR David L. Scott, Project Manager, Commandant (G–MV1–1), U.S. Coast Guard, 2100 Second Street, S.W., Washington, DC 20593–0001, telephone (202) 267–1464.

SUPPLEMENTARY INFORMATION:

Background

Under 46 U.S.C. 3316, the Secretary of Transportation may rely upon reports, documents, and certificates issued by ABS. The Secretary may also delegate authority to ABS to inspect or examine a vessel of the U.S. The same statute authorizes the Secretary to use ABS for reviewing and approving plans required for issuance of a certificate of inspection. These authorities have been delegated to the Coast Guard. The MOU signed on January 12, 1995, by the Coast Guard and the ABS further delegates these authorities to the ABS.

Currently, the Coast Guard conducts vessel inspections and the ABS conducts vessel surveys. For U.S. flag, ABS classed, Coast Guard inspected

commercial vessels, these inspections and surveys are largely duplicative. The U.S. Coast Guard's ABS Based Alternate Compliance Program (ACP) is a cooperative effort between the Coast Guard and ABS. The goal of the ACP is to allow a vessel to be inspected by ABS under the applicable ABS class rules, international treaties and agreements to which the U.S. is a party, and other prescribed standards which have been determined by the Coast Guard to provide a level of safety equivalent to compliance with current regulations. Under current regulations, the Coast Guard may accept a wide range of equivalencies or alternative compliance methods on a case-by-case basis.

The ABS, in cooperation with the Coast Guard, has reviewed the current regulations in 33 CFR Chapter I and 46 CFR Chapter I, the ABS Rules for Building and Classing Steel Vessels, and applicable international treaties and agreements such as the International Convention for the Safety of Life at Sea as amended (SOLAS 74/78), the 1973 International Convention for the Prevention of Pollution from Ships, as modified by the Protocol of 1978 (MARPOL 73/78), and the 1969 International Convention on Tonnage Measurement of Ships. Based on this review, the ABS developed the U.S. Supplement to the ABS Rules to address current regulatory requirements that are not satisfied by compliance with the other standards. The U.S. Supplement also contains amplifying information necessary to ensure compliance with SOLAR 74/78. The Coast Guard has determined that the U.S. Supplement to the ABS Rules, when used in conjunction with the ABS Rules for Building and Classing Steel Vessels, and applicable international treaties and agreements, provides a degree of safety consistent with the minimum standards set forth in the subchapters of Titles 33 and 46 of the Code of Federal Regulations relating to tankers and cargo vessels.

Under the ACP pilot program, an ABS surveyor would examine the vessel to determine compliance with these alternative standards. A Coast Guard Officer in Charge of Marine Inspection (OCMI) may then issue a Certificate of Inspection to the vessel based upon a determination by the Coast Guard that the required international and classification certificates are valid and properly endorsed, other reports from the ABS, and that the vessel is properly manned and maintained by the operator.

The purpose of the ACP is to increase the international competitiveness of the U.S. maritime industry by eliminating unnecessary regulations and duplication of the inspections conducted by the Coast Guard with surveys conducted by the ABS. The ACP also improves the regularity in the processing of requests for equivalency determinations. Owners and operators of vessels which participate in the ACP may realize substantial time savings in the vessel certification process, as well as increased flexibility in scheduling required tests and examinations. While the ACP is designed to eventually include inspection and examination of newly-constructed vessels, the pilot program is limited to existing vessels.

Although broader application of this program will be accomplished through rulemaking, the Coast Guard has developed a Navigation and Vessel Inspection Circular (NVIC) which provides an overall description of the ACP, identifies the conditions for enrollment, and describes the duties and responsibilities of participating vessel owners and operators, ABS and the Coast Guard. Persons interested in obtaining a copy of this NVIC are invited to contact the Program Manager identified above in **FOR FURTHER INFORMATION CONTACT**.

Copies of all referenced documents may be viewed at Room 1400, Coast Guard Headquarters, 2100 Second Street, S.W., Washington, DC 20593–0001, between the hours of 8 AM and 3 PM Monday through Friday, except Federal holidays. Copies of the ABS Rules for Building and Classing Steel Vessels and the U.S. Supplement to the ABS Rules for Steel Vessels for Vessels on International Voyages may be obtained from ABS as listed under **ADDRESSES** above. Consolidated editions of the SOLAS Convention and MARPOL 73/78 may be obtained from the International Maritime Organization as listed under **ADDRESSES** above.

Pilot Program

The Coast Guard intends to initiate rulemaking on this subject through publication of a notice of proposed rulemaking. Beginning February 3, 1995, it will conduct a limited pilot program to test and evaluate the standards and procedures that have been developed in cooperation with the ABS. The Coast Guard will also use the pilot program to check the application of these standards and procedures to existing tankers and cargo vessels. Therefore, during the pilot program, ABS surveyors will apply these standards during classification surveys, damage surveys, drydock examinations and other required tests and inspections for participating vessels. The cognizant Coast Guard OCMI may rely upon the ABS reports to issue a Certificate of Inspection. The Coast Guard will also provide oversight to ensure that vessels participating in this program maintain a level of safety equivalent to that experienced by vessels inspected under the traditional process. The high level of safety present on vessels of the U.S. merchant marine will not be compromised.

Coast Guard user fees are the subject of a separate ongoing rulemaking. Participants in the pilot program may be responsible for payment for both Coast Guard user fees and costs of ABS services. Participants in the pilot program should not expect that any applicable user fees will be reduced. However, the Coast Guard will collect data on the level of Coast Guard resources utilized in the ACP and evaluate the need for future changes to applicable user fee regulations.

Eligibility

The Coast Guard invites companies which own or operate U.S. flag, ABS classed, Coast Guard inspected commercial vessels to apply to participate in a pilot program beginning February 3, 1995. At present, only cargo ships and tank ships possessing valid international certificates are eligible to enter the pilot program because currently the U.S. Supplement to the ABS Rules is only applicable to cargo ships and tank ships surveyed for international voyages. In addition, ships offered for the pilot program must currently be classed by the ABS and have a valid Certificate of Inspection.

A company may not participate in the pilot program if it has a history of recurring marine casualties, oil spills, civil penalties or a record of poor maintenance of its vessel or vessels.

Due to resource limitations during the pilot program, the Coast Guard may, on a case by case basis, reject an application for vessels which will undergo inspection for certification in a foreign port. Additionally, due to limited resources, the Coast Guard will also consider scheduling and location of inspection services as criteria for participation.

Selected participants should be prepared to provide feedback and suggestions for improvement of the program and to participate in other activities to help the Coast Guard and the ABS refine the ACP.

Companies may apply to enroll in the pilot program by submitting a written request to the address listed in **ADDRESSES** above. Applications must indicate the name and official number of the vessel or vessels offered for enrollment, the expiration date of each

Certificate of Inspection, and identify a company representative as the point of contact.

The Coast Guard also requests comments from interested persons on the pilot program and the standards and processes developed for use in the ACP. Written comments should be submitted as indicated under **ADDRESSES** above.

Dated: January 30, 1995.

J.C. Card,

Rear Admiral, U.S. Coast Guard Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 95–2648 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–14–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 95–15, RM–8574]

Radio Broadcasting Services; Pago Pago, American Samoa

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Oceania Broadcasting Network, Inc., seeking the allotment of Channel 226C1 to Pago Pago, American Samoa, as the community's second local FM service. Channel 226C1 can be allotted to Pago Pago in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction, at coordinates –14–16–41 South Latitude and 170–42–09 West Longitude.

DATES: Comments must be filed on or before March 24, 1995, and reply comments on or before April 10, 1995.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Christopher J. Racine, President, Oceania Broadcasting Network, Inc., 970 North Kalaheo Avenue, Suite C314, Kailua, Hawaii 96734 (Petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 95–15, adopted January 24, 1995, and released January 30, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 2100 M Street, NW, Suite 140, Washington, D.C. 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–2681 Filed 2–2–95; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 95–14; RM–8552]

Radio Broadcasting Services; Leavenworth, Othello, and East Wenatchee, Washington

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Ronald A. Murray, d/b/a Murray Broadcasting, proposing the substitution of Channel 266A for Channel 249A at Leavenworth, Washington, and the modification of Station KLVH(FM)'s construction permit accordingly. In order to accommodate the substitution, petitioner also requests the downgrade of Channel 248C1 to Channel 248C3 at Othello, Washington, and the modification of Station KZLN-FM's construction permit accordingly; the substitution of Channel 249A for Channel 266A at East Wenatchee, Washington, and the modification of Station KYSN(FM)'s license accordingly. Channel 266A can be allotted at Leavenworth in compliance with the Commission's minimum distance separation requirements at petitioner's presently authorized site. The coordinates for Channel 266A at Leavenworth are North Latitude 47–35–32 and West Longitude 120–38–35. *See* Supplementary Information, *supra.*

DATES: Comments must be filed on or before March 24, 1995 and reply comments on or before April 10, 1995.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Melodie A. Virtue, Haley, Bader & Potts, Suite 900, 4350 North Fairfax Drive, Arlington, Virginia 22203–1633 (Counsel for Petitioner).

FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making and Order to Show Cause,* MM Docket No. 95–14, adopted January 24, 1995, and released January 30, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW, Suite 140, Washington, D.C. 20037.

Additionally, Channel 248C3 can be allotted at Othello and Channel 249A at East Wenatchee in compliance with the Commission's minimum distance separation requirements without the imposition of site restrictions. The coordinates for Channel 248C3 at Othello are North Latitude 46–45–55 and West Longitude 119–16–49; and the coordinates for Channel 249A at East Wenatchee are North Latitude 47–22–52 and West Longitude 120–17–16. Since Leavenworth, Othello and East Wenatchee are located within 320 kilometers (200 miles) of the U.S-Canadian border, concurrence of the Canadian government has been requested.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–2680 Filed 2–2–95; 8:45 am]

BILLING CODE 6712–01–F

Notices

Federal Register

Vol. 60, No. 23

Friday, February 3, 1995

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.

DEPARTMENT OF AGRICULTURE

Food and Consumer Service

Nutrition Program for the Elderly; Adjusted Level of Assistance From October 1, 1993 to September 30, 1994 and Initial Level of Assistance From October 1, 1994 to September 30, 1995

AGENCY: Food and Consumer Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces both the final level of per-meal assistance for the Nutrition Program for the Elderly (NPE) for Fiscal Year 1994 and the initial level of per-meal assistance for Fiscal Year 1995. The Fiscal Year 1994 initial level of assistance of $.6146 is adjusted to $.6057 for all eligible meals served during the fiscal year in accordance with section 311(c)(2)(A) of the Older Americans Act of 1965, as amended by section 310 of the Older Americans Act Amendments of 1992 and preempted by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Act of 1993. Rates are subject to change because NPE receives a finite amount of annual appropriations, but meal service is a variable which cannot be accurately projected. Therefore, if meal service exceeds Department projections, the rate must be adjusted accordingly. The Fiscal Year 1995 initial level of assistance is set at $.60 for each eligible meal in accordance with section 311(a)(4) of the Older Americans Act of 1965, as amended by section 310 of the Older Americans Act Amendments of 1992.

EFFECTIVE DATE: Fiscal Year 1994 Adjusted Level of Assistance: October 1, 1993. Fiscal Year 1995 Initial Level of Assistance: October 1, 1994.

FOR FURTHER INFORMATION CONTACT: Philip K. Cohen, Chief, Program Administration Branch, Food Distribution Division, Food and Consumer Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302–1594 or telephone (703) 305–2662.

SUPPLEMENTARY INFORMATION: Executive Order 12866

This action is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12372

This program is listed in the Catalog of Federal Domestic Assistance under Nos. 10.550 and 10.570 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials (7 CFR part 3015, subpart V, and final rule-related notices published at 48 FR 29114, June 24, 1983 and 49 FR 22676, May 31, 1984.)

Paperwork Reduction Act

This notice imposes no new reporting or recordkeeping provisions that are subject to Office of Management and Budget review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act.

Legislative Background

Section 310 of Pub. L. 102–375, the Older Americans Act Amendments of 1992, amended section 311(a)(4) of the Older Americans Act of 1965, 42 U.S.C. 3030a(a)(4), to require the Secretary of Agriculture to maintain an annually programmed level of assistance equal to the greater of: (1) The current appropriation divided by the number of meals served in the preceding fiscal year; or (2) 61 cents per meal adjusted annually beginning with Fiscal Year 1993 to reflect changes in the Consumer Price Index. Section 311(c)(2) of the Act (42 U.S.C. 3030a(c)(2)) was amended to provide that the final reimbursement claims must be adjusted so as to utilize the entire program appropriation for the fiscal year for per-meal support.

Notwithstanding the initial rates established by the Older Americans Act, the Department is required to comply with the spending clause of the U.S. Constitution and 31 U.S.C. 1341(a)(1)(A) (known as the Antideficiency Act), which prohibit the obligation or expenditure of funds in excess of the available appropriation. Thus the Department is required to establish (and if necessary, adjust) rates in such a manner as to not exceed the program appropriation.

Fiscal Year 1994 Adjusted Level of Assistance

The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Act of 1993 (Pub. L. 103–111), which appropriated NPE funding for Fiscal Year 1994, imposed different NPE rate management requirements for Fiscal Year 1994. Title IV, Domestic Food Programs, of the Act provides that ''* * * a maximum rate of reimbursement to States will be established by the Secretary, subject to reduction if obligations would exceed the amount of available funds, with any unobligated funds to remain available for obligation in the fiscal year beginning October 1, 1994.''

Based on its projection of the number of meals to be claimed during the fiscal year, and in light of constitutional and statutory prohibitions on obligating or spending funds in excess of the available appropriation, the Department announced an initial per-meal reimbursement rate of $.6146, the highest rate which it believed could be sustained throughout the fiscal year. This initial level of per-meal assistance was announced in the January 3, 1994 **Federal Register** (57 FR 59).

The Department's meal service projection for Fiscal Year 1994 assumed a .45 percent meal service increase over virtually complete Fiscal Year 1993 meal counts. This growth factor represented one-half of the highest rate of growth (.9 percent) the program had experienced in any one of the four previous fiscal years. However, meal service, which is the basis for rate setting, cannot always be accurately projected because it follows no discernible pattern from year to year. In some recent years, for example, meal service declined when the per-meal support level remained unchanged or increased.

Data for the first three quarters of Fiscal Year 1994 revealed that the program had experienced a .31 percent meal service increase over the number of meals served in the first three quarters in Fiscal Year 1993, well within the Department's projected .45 percent increase for the year. However, the program experienced an almost

unprecedented increase in meal service during the fourth quarter, resulting in a 1.18 percent increase over the number of meals served in Fiscal Year 1993, the highest annual increase in the program since 1989. The Department monitors meal service on a monthly basis by comparing data from each month of the current fiscal year to the corresponding month in the previous fiscal year. However, the increase experienced in the fourth quarter was unpredictable given that, as in past years, there has been no discernible pattern from month to month during the fiscal year.

Final Fiscal Year 1994 meal counts exceeded Departmental projections by little more than one-half of one percent. However, this marginal unanticipated program growth necessitated a retroactive per-meal rate reduction since the program appropriation was consequently insufficient to support all meals served at the initially announced level. Therefore, the Department announces a reduced Fiscal Year 1994 per-meal reimbursement rate of $.6057. This final rate applies to all eligible meals served during Fiscal Year 1994 and claimed in a timely manner. The Department anticipates that a minimal amount of funds will remain unspent after close-out for the fiscal year has been completed. In accordance with the mandate of the Agriculture, Rural Development, Food and Drug Administration and Related Agencies Act of 1993, these funds will be carried over into Fiscal Year 1995 and expended in per-meal reimbursement for that year.

Fiscal Year 1995 Initial Level of Assistance

In the absence of overriding appropriations legislation such as was enacted for Fiscal Year 1994, the Department will for Fiscal Year 1995 be operating under the Older Americans Act of 1965, as amended. In Fiscal Year 1995, a situation exists similar to that at the beginning of Fiscal Years 1993 and 1994, i.e., the Fiscal Year 1995 appropriation will not sustain reimbursement at the mandated annually adjusted rate.

It is the Department's goal to establish the highest rate that can be sustained throughout the fiscal year so as to maximize the flow of program funds to States. Program operators would prefer to receive their per-meal support steadily throughout the year, rather than to operate at a lower rate during the year and receive a compensatory payment in connection with a rate increase after the year has ended. However, the Department wants also to minimize the possibility of a rate reduction and the hardship that it could cause program operators. In order to guard against the need for a reduction, the Department has projected continued significant growth in the number of meals that will be served in Fiscal Year 1995. Based on such projections, the Department announces an initial per-meal support level of $.60.

If this initial rate does not exhaust available funds per the mandate by the Older Americans Act of 1965, as amended, the rate will be increased to achieve compliance with this requirement. However, in the unlikely event that the number of meals served exceeds the Department's projection of significantly expanded participation, it will be necessary to reduce the rate. In either event, the rate will experience two adjustments: an intermediate and final per-meal level of support. The intermediate rate, based on final meal counts and available funds, will be announced in January 1996. A final rate exhausting any unspent funds, which are anticipated to be minimal, will be announced in March 1996 after close-out for the fiscal year has been completed. States will be notified directly of changes in the Fiscal Year 1995 rate.

Dated: January 27, 1995.

George A. Braley,

Acting Administrator.

[FR Doc. 95–2711 Filed 2–2–95; 8:45 am]

BILLING CODE 3410–30–U

Forest Service

Bull Lake Easement; Kootenai National Forest, Lincoln County, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare environmental impact statement.

SUMMARY: The USDA, Forest Service, will prepare an environmental impact statement (EIS) to disclose the environmental effects of the granting of a road easement and of road reconstruction needed to access a subdivision in the vicinity of Bull Lake. The area is located in the Kootenai National Forest, Three Rivers Ranger District, Lincoln County, Montana.

The proposal's actions to grant an easement to Lincoln County, Montana for a county easement over portions of roads #398 and #8019, and to reconstruct these roads to county standards, for public access to a subdivision of land located in Section 29, T29N, R33W, Principle Meridian, Montana, are being considered together because they represent either connected or cumulative actions as defined by the Council on Environmental Quality (40 CFR 1508.25). This project-level EIS will tier to the Kootenai National Forest Land and Resource Management Plan (Forest Plan) and Final EIS (September 1987), which provides overall guidance of all land management activities on the Kootenai National Forest, including road management.

DATES: Written comments and suggestions should be received on or before March 20, 1995.

ADDRESSES: Submit written comments and suggestions on the proposed management activities or a request to be placed on the project mailing list to Michael L. Balboni, District Ranger, Three Rivers Ranger District, Kootenai National Forest, 1437 N. Hwy 2, Troy, Montana, 59935.

FOR FURTHER INFORMATION CONTACT:

Mark Natale, EIS Team Leader, Three Rivers Ranger District, Kootenai National Forest, Phone (406) 295–4693.

SUPPLEMENTARY INFORMATION: A county easement is proposed on approximately 1.0 mile of road #398 and 2.0 miles of road #8019 to access a subdivision on private land that has received conditional approval from the county. If approved, the road would then be reconstructed to meet county standards.

The Kootenai Forest Plan provides guidance for management activities within the potentially affected area through its goals, objectives, standards and guidelines, and management area direction. The area of the proposed easement would occur within Management Areas 6 and 11. Road reconstruction would occur in these two management areas. Below is a brief description of the applicable management direction.

Management Area 6—These are recreational areas (campgrounds, boat ramps, picnic areas, etc.). There is no restriction on easements within this management area.

Management Area 11—These are areas of big game winter range that allow for easements while including provisions for scheduling to prevent conflicts during periods of wildlife use.

The Forest Service has identified two alternatives. These are: (1) The ''no action'' alternative, in which the easement would not be granted and (2) to issue the requested easement.

The EIS will analyze the direct, indirect, and cumulative environmental effects of the alternatives. Past, present, and projected activities on both private and National Forest lands will be considered. The EIS will disclose the analysis of site-specific mitigation measures and their effectiveness.

Public participation is an important part of the analysis, commencing with the initial scoping process (40 CFR 1501.7), which will occur in the period February/March 1995. In addition, the public is encouraged to visit with Forest Service officials at any time during the analysis and prior to the decision. The Forest Service will be seeking information, comments, and assistance from Federal, State, and local agencies and other individuals or organizations who may be interested in or affected by the proposed action. A public meeting will be held late February or early March 1995 in Troy, Montana.

Comments from the public and other agencies will be used in preparation of the Draft EIS. The scoping process will be used to:

1. Identify potential issues.
2. Identify major issues to be analyzed in depth.
3. Eliminate minor issues or those which have been covered by a relevant previous environmental analysis, such as the Kootenai Forest Plan EIS.
4. Identify alternatives to the proposed action.
5. Identify potential environmental effects of the proposed action and alternatives (i.e., direct, indirect, and cumulative effects).
6. Determine potential cooperating agencies and task assignments.

Some public comments have already been received. The following preliminary issues have been identified so far:

1. How may proposed road reconstruction and subdivision of the private land affect the water quality in Bull Lake?
2. How will the proposed road construction and subdivision affect threatened, endangered and sensitive species in the area?
3. How may the proposed road construction affect big game winter range use?

Other issues commonly associated with such activities include: effects on cultural resources, soils, old growth, and scenery values. This list may be verified, expanded, or modified based on public scoping for this proposal.

The Draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and available for public review in September of 1995. At that time, the EPA will publish a Notice of Availability of the Draft EIS in the **Federal Register.** The comment period on the Draft EIS will be 45 days from the date the EPA's notice of availability appears in the **Federal Register.** It is very important that those interested in management of this area participate at that time. To be most helpful, comments on the Draft EIS should be as site-specific as possible. The Final EIS is scheduled to be completed by January 1996.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC, 435 U.S. 519, (1978).* Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day scoping comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in developing issues and alternatives.

To assist the Forest Service in identifying and considering issues on the proposed action, comments should be as specific as possible. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

I have the final authority for issuing a decision regarding this proposal. I have delegated the responsibility of preparing the EIS to Three Rivers District Ranger, Michael Balboni. My address is Kootenai National Forest, 506 U.S. Hwy 2 West, Libby, MT 59923.

Dated: January 27, 1995.

Robert L. Schrenk,

Forest Supervisor.

FR Doc. 95–2633 Filed 2–2–95; 8:45 am]

BILLING CODE 3410–11–M

Skyline Ridge EIS, Kootenai National Forest, Lincoln County, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare environmental impact statement.

SUMMARY: The USDA, Forest Service, will prepare an environmental impact statement (EIS) to disclose the environmental effects associated with fire recovery activities in the areas of four 1994 wildfires, including Pulpit, Studebaker, Gunsight, and Seventeenmile fires. The project area is located in the Seventeenmile, O'Brien, and Lower Yaak Physiographic Areas of the Three Rivers Ranger District, Kootenai National Forest, Lincoln County, Montana. Part of the proposed project's activities lie within Inventoried Roadless Areas (IRA's).

The Forest Service proposes to salvage timber, construct and reconstruct roads, reduce fuel concentrations, revegetate with trees, native shrubs, and grass, and obliterate roads. These activities are being considered together because they represent either connected or cumulative actions as defined by the Council on Environmental Quality (40 CFR 1508.25). The purposes of the proposed action's activities are to harvest fire killed timber in a timely manner, manage the road systems, reduce future potential for catastrophic fire, sustain timber productivity, improve wildlife and riparian habitat, specifically for threatened, endangered, or sensitive (TES) species, and accelerate watershed recovery. An amendment to the Kootenai Forest Plan is also part of this proposal.

Overall guidance of land management activities on the Kootenai National Forest, including timber harvest and road management, are regulated by the Kootenai National Forest Land and Resource Management Plan (Forest Plan) (September, 1987). In addition we considered more recent scientific thinking on the functioning of forest ecosystems (Ecosystems Management). Based on this analysis we developed a proposed action that does not meet Forest Plan standards. Specifically we proposed timber harvest in management Area 2, roadless recreation.

DATE: Written comments and suggestions should be received on or before March 6, 1995.

ADDRESSES: Submit written comments and suggestions on the proposed management activities or a request to be placed on the project mailing list to Michael L. Balboni, District Ranger, Three Rivers Ranger District, Kootenai National Forest, 1437 North Hwy 2, Troy, Montana 59935.

FOR FURTHER INFORMATION CONTACT: Steve Prieve, EIS Team Leader, Three Rivers Ranger District, Kootenai National Forest, Phone (406) 295–4693.

SUPPLEMENTARY INFORMATION: The project area consists of approximately 6375 acres of National Forest land. The Seventeenmile fire was 1773 acres and is located within all or portions of T33N, R32W, Sections 2, 3, 4, 5, 9, 10, 11 and T34N, R32W, Sections 33 and 34. The Studebaker fire was 1896 acres and located within all or portions of T33N, R33W, Section 36; T33N, R32W, Sections 30, 31 and 32; and T32N, R33W, Sections 1, 2 and 3. The Pulpit fire was 2085 acres and is located within all or portions of T32N, R33W, Sections 9, 14, 15, 16, 21, 22, 23 and 27. The Gunsight fire was 621 acres and is located within all or portions of T33N, R33W, Sections 21, 22, 27 and 28.

Timber salvage harvest of dead and dying timber is proposed on 2556 acres of forested land within the four fires using a variety of logging systems. Approximately 20 MMBF is proposed for harvest. This includes 750 acres within the 1773-acres Seventeenmile fire, 429 acres within the 621-acre Gunsight fire, 588 acres within the 2085-acre Pulpit fire and 789 acres within the 1896-acre Studebaker fire. Fuel reduction accomplished in conjunction with the timber harvest includes grapple piling and prescribed burning. Watershed restoration activities are proposed within and in the vicinity adjacent to the fires. This includes road obliteration (approximately 15 miles) which consists of scarification, seeding, and pulling culverts from roads, recontouring, and riparian planting and debris placement in stream channels (approximately 10 miles). Replanting is proposed on approximately 4412 acres of land—including both conifer seedlings for reforestation and native shrubs and herbaceous plants for wildlife habitat. The timber harvest operations would require construction of approximately 2 miles of temporary road and reconstruction of approximately 22 miles of existing roads. This action would require temporarily opening approximately 31 miles of roads currently restricted from vehicle traffic.

Approximately 1131 acres proposed for harvest lie within one of two Inventoried Roadless Areas: Roderick IRK (#684)—710 acres in the Seventeenmile fire, and Saddle IRA (#168)—421 acres in the Gunsight fire. No road construction would occur within these areas.

The areas proposed for salvaging fire damaged timber occur in a wide range of Management Areas (MA's) as defined in the Kootenai Forest Plan.

Below is a brief description of the affected Management Areas for the proposed action, along with the number of acres proposed for harvest within each MA:

Management Area 2—These areas are characterized by a natural-appearing environment offering roadless recreation opportunities and are within an unsuitable timber base 680 acres proposed for salvage harvest.

Management Area 2–OG—These MA 2 areas consist of scattered parcels of existing old growth or mature timber stands which contain component of old growth and are within an unsuitable timber base. 83 acres.

Management Area 33—These are areas with a natural-appearing environment and a minimal number of adjacent or internal roads offering roaded recreation opportunities and are within an unsuitable timber base. They occur mostly in upper elevations from 4,500′ and up. 49 acres.

Management Area 10—These are areas that are used by various species of big game for winter range, usually between December 1 and April 30 and are within an unsuitable timber base. 15 acres.

Management Area 12—These areas are generally located at or above elevations of 4000′ and contain inclusions of moist or wet habitat types. Most species of big game use this management area during the period from late spring through late fall. This management area is characterized by suitable timber producing sites and moderate to rolling topography. 891 acres.

Management Area 13—These areas consist of scattered parcels of existing old growth or mature timber stands which contain components of old growth and are within an unsuitable timber base. 628 acres.

Management Area 14—These areas are identified Interagency Grizzly situations 1 and 2 in conjunction with suitable timber land. 105 acres.

Management Area 18—This management area occurs on areas of slopes in excess of 40% where timber productivity is moderate to high. It is distinguished by the difficulty in establishing coniferous regeneration and is within an unsuitable timber base. 105 acres.

For those management areas classified an unsuitable for timber production, an amendment to the Forest Plan would be required to implement the ecosystem management based proposal or any alternative which would harvest timber in unsuitable timber MA's. These would include MA's 2, 2–OG, 3, and 13.

The Forest Service will consider a range of alternatives. One of these will be the ''no action'' alternative, in which none of the proposed activities would be implemented. Another alternative will be analyzed which meets Forest Plan direction. Additional alternatives will examine varying levels and locations for the proposed activities to achieve the purpose and need, as well as respond to the issues and concerns identified by the public.

The interdisciplinary team (IDT) has identified tentative or preliminary issues briefly described as follows:

(1) The effects of the proposed action and alternatives on the characteristics of the IRA's and unsuitable management areas.

(2) The effects of the proposed action and alternatives on water quality and fisheries.

(3) The effects of the proposed action and alternatives on ecosystem health and the risk of catastrophic wildfires and insert or disease outbreaks.

(4) The effects of the proposed action and alternatives on threatened, endangered, or sensitive (TES) species, such as the grizzly bear and bull trout.

(5) The effects of the proposed action and alternatives on timber supply.

The EIS will analyze the direct, indirect, and cumulative environmental effects of the proposed action and each alternative, including no action. These include past, present, and projected activities on both private and National Forest lands along with proposed mitigation measures and their effectiveness.

The decision to be made is how much, if any, fire damaged timber should be salvaged in these fire areas, within the context of ecosystem management and Forest Plan direction.

Public participation is an important part of the analysis, commencing with the initial scoping process (40 CFR 1501.7), which will occur February 3, 1995 to March 6, 1995. In addition, the public is encouraged to visit with Forest Service officials at any time during the analysis and prior to the decision. The Forest Service will be seeking information, comments, and assistance from Federal, State, and local agencies and other individuals or organizations who may be interested in or affected by the proposed action. A public meeting will be scheduled in Troy, Montana on February 28, 1995, and at the Upper Ford Work Center on March 1, 1995.

Comments from the public and other agencies will be used in preparation of the Draft EIS. The scoping process will be used to:

1. Identify potential issues.
2. Identify major issues to be analyzed in depth.
3. Eliminate minor issues or those which have been covered by a

relevant previous environmental analysis, such as the Kootenai Forest Plan.
4. Identify alternatives to the proposed action.
5. Identify potential environmental effects of the proposed action and alternatives (i.e., direct, indirect, and cumulative effects).
6. Determine potential cooperating agencies and task assignments.

The Draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and available for public review in April of 1995. At that time, the EPA will publish a Notice of Availability of the Draft EIS in the **Federal Register**. The comment period on the Draft EIS will be 45 days from the date the EPA's notice of availability appears in the **Federal Register**. It is very important that those interested in management of the analysis area participate at that time. To be most helpful, comments on the Draft EIS should be as site-specific as possible. The Final EIS is scheduled to be completed by September, 1995.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC, 435 U.S. 519, 553 (1978).* Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 30-day scoping comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in developing issues and alternatives.

To assist the Forest Service in identifying and considering issues on the proposed action, comments should be as specific as possible. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

I have the final authority for issuing a decision regarding this proposal. I have delegated the responsibility of preparing the EIS to Three Rivers District Ranger, Michael Balboni. My address is Kootenai National Forest, Supervisor's Office, 506 Hwy 2 West, Libby, MT 59923.

Dated: January 27, 1995.

Robert L. Schrenk,

Forest Supervisor.

[FR Doc. 95–2634 Filed 2–2–95; 8:45 am]

BILLING CODE 3410–11–M

Winter Recreation Plan for the Lakes Basin/Sierra Buttes Area, Tahoe National Forest, Sierra County, CA

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The U.S. Department of Agriculture, Forest Service will prepare an environmental impact statement (EIS) for a Winter Recreation Plan for the Lakes Basin/Sierra Buttes Area on the Downieville District of the Tahoe National Forest. Winter use in the area has been monitored as required by the Forest Land and Resource Management Plan, to determine management needs. The EIS will analyze several proposed snow groomer shed construction sites, possible opportunities for resorts and organizational camps to broaden services to include winter sports activities, and further develop both snowmobile trails and nordic ski trails where snowmobiles may be restricted.

The Tahoe National Forest Land and Resource Management Plan (LRMP), completed March, 1990, proposes to prepare a winter recreation management plan ''to assure orderly development and management of cross country skiing and snowmobiling use within the area.''

The agency invites comments and suggestions on the scope of the analysis. In addition, the agency gives notice of the full environmental analysis and decision-making process that will occur on the plan so that interested and affected people are aware of how they may participate and contribute to the final decision.

DATES: Comments concerning the analysis should be received in writing by March 20, 1995.

ADDRESSES: Written comments concerning the project should be directed to Jean M. Masquelier, District Ranger, Downieville Ranger District, North Yuba Ranger Station, 15924 Hwy 49, Camptonville, CA 95922.

FOR FURTHER INFORMATION CONTACT: Mary Furney, Dispersed Recreation Assistant, Downieville Ranger District, North Yuba Ranger Station, Camptonville, CA 95922, telephone 916 288–3231 or 916 478–6253.

SUPPLEMENTARY INFORMATION: In preparing the environmental impact statement, the Forest Service will identify and analyze a range of opportunities in the plan.

Public participation will be important at several points during the analysis, especially the review of the Draft Environmental Impact Statement. The first point is during the scoping process. The Forest Service will be seeking information, comments, and assistance from Federal, State, and local agencies and other individuals or organizations who may be interested in or affected by the proposed action. This input will be used in preparation of the draft environmental impact statement (DEIS). The scoping process includes:

1. Identifying potential issues.
2. Identifying issues to be analyzed in depth.
3. Eliminating insignificant issues or those both which have been covered by a relevant previous environmental analysis.
4. Exploring additional alternatives.
5. Identifying potential environmental effects of the proposed action and alternatives (i.e., direct, indirect, and cumulative effects and connected actions).
6. Determining potential cooperating agencies and task assignments.

Organizations, and individuals who may be interested in, or affected by the decision, will be solicited to identify significant issues. Public participation has been previously solicited through mailing letters to private land owners, politicians, county supervisors, continued participation will be emphasized through public meetings and mailings.

The draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review by May 30, 1995. The comment period on the draft EIS will be 45 days from the date the EPA publishes the notice of availability in the **Federal Register.**

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the

reviewer's position and contentions. Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft EIS stage but that are not raised until after completion of the final EIS may be waived or dismissed by the courts. City of Angoon v. Hodel, 803 F.2d 1016, 1022 (9th Cir. 1986) and Wisconsin Heritages Inc. v. Harris, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of the court rulings, it is very important that those interested in this proposed action participate by the close of the 45 day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

The responsible official, who is the Downieville District Ranger, Tahoe National Forest, will document the decision and reasons for the decision in the Record of Decision.

William L. Haire,

Public Service Officer.

[FR Doc. 95–2691 Filed 2–2–95; 8:45am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; Teledyne Wah Chang, a Division of Teledyne Industries, Inc.

In the matter of: Teledyne Wah Chang, a division of Teledyne Industries, Inc., 1600 N.E. Old Salem Road, P.O. Box 460, Albany, Oregon 97321–6990, Respondent.

Order

The Office of Export Enforcement, Bureau of Export Administration, United States Department of Commerce (Department), having notified Teledyne Wah Chang, a division of Teledyne Industries, Inc. (hereinafter referred to as Teledyne Wah Chang), of its intention to initiate an administrative proceeding against it pursuant to Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C.A. app. §§ 2401–2420 (1991, Supp. 1993, and Pub. L. No. 103–277, July 5, 1994)) (the Act),[1] and Part 788 of the Export Administration Regulations (currently codified at 15 CFR Parts 768–799 (1994)) (the Regulations), based on allegations that Teledyne Wah Chang violated Sections 787.3(b), 787.a(a), 787.5(a)(1), and 787.6 of the Regulations in that:

(1) on or before October 5, 1989, Teledyne Wah Chang engaged in two separate conspiracies to export zirconium sponge and/or compacts from the United States contrary to the terms of validated export licenses issued by the Department;

(2) in carrying out those conspiracies, on six separate occasions, Teledyne Wah Chang, as a co-conspirator, made false or misleading statements of material fact to the Department on validated export license applications;

(3) in carrying out those conspiracies, on four separate occasions, Teledyne Wah Chang, as a co-conspirator, exported goods from the United States with reason to know that a violation of the Act or any regulation, order, or license issued under the Act would occur in connection with each such export; and

(4) in carrying out those conspiracies, on four separate occasions, Teledyne Wah Chang, as a co-conspirator, made false or misleading statements of material fact on Shipper's Export Declarations that were filed with the U.S. Customs Service;

The Department and Teledyne Wah Chang having entered into a Consent Agreement whereby the Department and Teledyne Wah Chang have agreed to settle this matter in accordance with the terms and conditions set forth therein and the terms of the Consent Agreement having been approved by me;

It is therefore ordered,

First, that a civil penalty of $2,000,000 is assessed against Teledyne Wah Chang, all of which shall be paid to the Department within 30 days from the date of entry of this Order. Payment shall be made in the manner specified in the attached instructions.

Second, Teledyne Wah Chang, a division of Teledyne Industries, Inc., 1600 N.E. Old Salem Road, P.O. Box 460, Albany, Oregon 97321–6990, and all its successors, assigns, and officers, representatives, agents, and employees when acting on behalf of the company shall, for a period of three years beginning on March 1, 1995, be denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction in the United States or abroad involving any commodity or technical data exported or to be exported from the United States, and subject to the Regulations.

A. Without limiting the generality of the foregoing, participation, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (i) as a party or as a representative of a party to any export license application submitted to the Department; (ii) in preparing or filing with the Department any export license application or request for reexport authorization, or any document to be submitted therewith; (iii) in obtaining from the Department or using any validated or general export license, reexport authorization, or other export control document; (iv) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported or to be exported from the United States and subject to the Regulations; and (v) in financing, forwarding, transporting, or other servicing of such commodities or technical data.

B. After notice and opportunity for comment as provided in Section 788.3(c) of the Regulations, any person, firm, corporation, or business organization related to Teledyne Wah Chang by affiliation, ownership, control, or position of responsibility in the conduct of grade or related services may also be subject to the provisions of this Order.

C. As provided by Section 787.12(a) of the Regulations, without prior disclosure of the facts to and specific authorization of the Office of Exporter Services, in consultation with the Office of Export Enforcement, no person may directly or indirectly, in any manner or capacity; (i) apply for, obtain, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to an export or reexport of commodities or technical data by, to , or for another person then subject to an order revoking or denying his export privileges or then excluded from practice before the Bureau of Export Administration; or (ii) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate: (a) in any transaction which may involve any commodity or technical data exported or to be exported from the United States; (b) in any reexport thereof; or (c) in any

[1] The Act expired on August 20, 1994. Executive Order No. 12924 (59 *Fed. Reg.* 43437, August 23, 1994) continued the Regulations in effect under the International Emergency Economic Power Act (50 U.S.C.A. §§ 1701–1706 (1991)).

other transaction which is subject to the Export Administration Regulations, if the person denied export privileges may obtain any benefit or have any interest in, directly or indirectly, any of these transactions.

D. As authorized by Section 788.17(b) of the Regulations, the denial period shall be suspended for a period of two years and nine months beginning on June 1, 1995, and shall thereafter be waived, provided that, during the period of suspension, Teledyne Wah Chang commits no violation of the Act or any regulation, order or license issued thereunder. During the period between June 1, 1995 and March 1, 1996, Teledyne Wah Chang's authority to use general license G–NSG is suspended. Teledyne Wah Chang is eligible to apply for individual validated export licenses for any export that would ordinarily be eligible for export under general license G–NSG during the period that its authority to use general license G–NSG is suspended. Further, for the last two years of the denial period, Teledyne Wah Chang shall report periodically to the Office of Export Enforcement, Bureau of Export Administration, United States Department of Commerce (OEE), all exports made by Teledyne Wah Chang under the authority of general license G–NSG during the previous three months. The first such report shall be provided to OEE on July 1, 1996 and shall cover any exports by Teledyne Wah Chang under the authority of general license G–NSG between March 1, 1996 and May 30, 1996. Subsequent reports shall be made to OEE every three months thereafter. Each report shall include the following information: the date of each general license G–NSG shipment made during that quarter; the country of ultimate destination; the name and address of the ultimate consignee; and a description of the commodities, the quantity, and the value of the commodities included in each shipment.

Third, the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, permission, or privilege granted, or to be granted, to Teledyne Wah Chang. Accordingly, if Teledyne Wah Chang should fail to pay in a timely manner the civil penalty set forth above, the undersigned will enter an Order denying all of Teledyne Wah Chang's export privileges for a period of one year from the date of entry of this Order.

Fourth, that the proposed Charging Letter, the Consent Agreement and this Order shall be made available to the public. Copies of this Order shall be served on Teledyne Wah Chang and published in the **Federal Register**.

This Order, which constitutes the final agency action in this matter, is effective immediately.

Entered this 26th day of January, 1995.

John Despres,

Assistant Secretary for Export Enforcement.

[FR Doc. 95–2635 Filed 2–2–95; 8:45 am]

BILLING CODE 3510–DT–M

International Trade Administration

Intent to Revoke Antidumping Duty Orders and Findings and to Terminate Suspended Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Intent to Revoke Antidumping Duty Orders and Findings and to Terminate Suspended Investigations.

SUMMARY: The Department of Commerce (the Department) is notifying the public of its intent to revoke the antidumping duty orders and findings and to terminate the suspended investigations listed below. Domestic interested parties who object to these revocations and terminations must submit their comments in writing no later than the last day of February 1995.

EFFECTIVE DATE: February 3, 1995.

FOR FURTHER INFORMATION CONTACT: Michael Panfeld or the analyst listed under Antidumping Proceeding at: Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230, telephone (202) 482–4737.

SUPPLEMENTARY INFORMATION:

Background

The Department may revoke an antidumping duty order or finding or terminate a suspended investigation if the Secretary of Commerce concludes that it is no longer of interest to interested parties. Accordingly, as required by § 353.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke the following antidumping duty orders and findings and to terminate the suspended investigations for which the Department has not received a request to conduct an administrative review for the most recent four consecutive annual anniversary months:

Antidumping Proceeding

Austria
Railway Track Maintenance Equipment
A–433–064
43 FR 6937
February 17, 1978
Contact: Art DuBois at (202) 482–6312

Japan
Butt-Weld Pipe Fittings
A–588–602
52 FR 4167
February 10, 1987
Contact: Sheila Forbes at (202) 482–5253

Japan
Melamine
A–588–056
42 FR 6366
February 2, 1977
Contact: Todd Peterson at (202) 482–4195

The People's Republic of China
Paint Brushes
A–570–501
51 FR 5880
February 14, 1986
Contact: Tom Killiam at (202) 482–0665

If no interested party requests an administrative review in accordance with the Department's notice of opportunity to request administrative review, and no domestic interested party objects to the Department's intent to revoke or terminate pursuant to this notice, we shall conclude that the antidumping duty orders, findings, and suspended investigations are no longer of interest to interested parties and shall proceed with the revocation or termination.

Opportunity to Object

Domestic interested parties, as defined in § 353.2(k)(3), (4), (5), and (6) of the Department's regulations, may object to the Department's intent to revoke these antidumping duty orders and findings or to terminate the suspended investigations by the last day of February 1995. Any submission to the Department must contain the name and case number of the proceeding and a statement that explains how the objecting party qualifies as a domestic interested party under § 353.2(k)(3), (4), (5), and (6) of the Department's regulations.

Seven copies of such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, Washington, D.C. 20230. You must also include the pertinent certification(s) in accordance with § 353.31(g) and § 353.31(i) of the Department's regulations.

In addition, the Department requests that a copy of the objection be sent to Michael F. Panfeld in Room 4203. This

notice is in accordance with 19 CFR 353.25(d)(4)(i).

Dated: January 30, 1995.

Holly A. Kuga,

Acting Deputy Assistant Secretary for Compliance.

[FR Doc. 95–2719 Filed 2–2–95; 8:45 am]

BILLING CODE 3510–DS–P

Minority Business Development Agency

Native American Business Development Center Applications: Minnesota

AGENCY: Minority Business Development Agency.

ACTION: Amendment.

SUMMARY: This notice amends the advertisement as it appeared in the Wednesday, January 25, 1995 issue, announcing MBDA's competitive applications for its Native American Business Development Center.

DATES: The closing date for applications is March 1, 1995. Applications must be received on or before March 1, 1995.

FOR FURTHER INFORMATION CONTACT: David Vega at (312) 353–0182.

11.801 Native American Program

(Catalog of Federal Domestic Assistance)

Dated: January 30, 1995.

Donald L. Powers,

Federal Register Liaison Officer, Minority Business Development Agency.

[FR Doc. 95–2721 Filed 2–2–95; 8:45 am]

BILLING CODE 3510–21–P

National Institute of Standards and Technology

[Docket No. 940550–4335]

RIN 0693–AB28

Approval of Federal Information Processing Standards Publication 193, SQL Environments

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce that the Secretary of Commerce has approved a new standard, which will be published as FIPS Publication 193, SQL Environments. On June 22, 1994 (59 FR 32186–32188) notice was published in the **Federal Register** that a Federal Information Processing Standard for SQL Environments was being proposed for Federal use.

NIST reviewed written comments submitted by interested parties and other available material. On the basis of this review, NIST recommended that the Secretary approve the standard as a Federal Information Processing Standard (FIPS), and prepared a detailed justification document for the Secretary's review in support of that recommendation.

The detailed justification document which was presented to the Secretary, and which includes an analysis of the written comments received, is part of the public record and is available for inspection and copying in the Department's Central Reference and Records Inspection Facility, Room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC 20230.

This FIPS contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section, which deals with the technical requirements of the standard. Only the announcement section of the standard is provided in this notice.

EFFECTIVE DATE: This standard is effective February 1, 1995.

ADDRESSES: Interested parties may purchase copies of this standard, including the technical specifications section, from the National Technical Information Service (NTIS). Specific ordering information from NTIS for this standard is set out in the Where to Obtain Copies Section of the announcement section of the standard.

FOR FURTHER INFORMATION CONTACT: Mr. Leonard Gallagher, (301) 975–3251, Computer Systems Laboratory, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Dated: January 30, 1995.

Samuel Kramer,

Associate Director.

Federal Information Processing Standards Publication 193

(Date)

Announcing the Standard for SQL Environments

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology after approval by the Secretary of Commerce pursuant to Section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100–235.

1. Name of Standard. SQL Environments (FIPS PUB 193).

2. Category of Standard. Software Standard, Database.

3. Explanation. An SQL environment is an integrated data processing environment in which heterogeneous products, all supporting some aspect of the FIPS SQL standard (FIPS PUB 127), are able to communicate with one another and provide shared access to data and data operations and methods under appropriate security, integrity, and access control mechanisms. Some components in an SQL environment will be full-function SQL implementations that conform to an entire level of FIPS SQL and support all of its required clauses of schema definition, data manipulation, transaction management, integrity constraints, access control, and schema information. Other components in an SQL environment may be specialized data repositories, lagecy databases, or graphical user interfaces and report writers, all of which support selected portions of the SQL standard and thereby provide a degree of integration between themselves and other products in the same SQL environment.

This FIPS PUB is the beginning of a continuing effort to define appropriate conformance profiles that can be used by both vendors and users to specify and users to specify exact requirements for how various products fit into an SQL environment. The emphasis in this first FIPS for SQL Environments is to specify general purpose, SQL external repository interface (SQL/ERL) profiles for non-SQL data repositories. These profiles specify how a subset of the SQL standard can be used to provide limited SQL access to legacy databases, or to support SQL gateways to specialized data managers such as Geographic Information Systems (GIS), full-text document management systems, or object database management systems. All of the profiles specified herein are for server-side products, that is, products that control persistent data and provide an interface for user access to that data. Subsequent versions of this FIPS PUB may specify SQL environment profiles for client-side products, that is, products that access data and then present that data in graphical or report-writer style to an end user, or process the data in some other way on behalf of the end user.

4. Approving Authority. Secretary of Commerce.

5. Maintenance Agency. Department of Commerce National Institute of Standards and Technology (Computer Systems Laboratory)

6. Cross Index.

—Federal information Resources Management Regulations (FIRMR)

subpart 201.20.303, Standards, and subpart 201.39.1002, Federal Standards, April 1992.

—FIPS PUB 127–2, Fedeal Information Processing Standards Publication—Database Language SQL, adoption of ANSI SQL (ANSI X3.135–1992) and ISO SQL (ISO/IEC 9075:1992) for Federal use, U.S. Department of Commerce, National Institute of Standards and Technology, June 2, 1993.

—ANSI/ISO/IEC 9579, International Standard for Remote Database Access (RDA), Part 1: Generic RDA and Part 2:SQL Specialization, ISO/IEC 9579–1:1993 and ISO/IEC 9579–2:1993, published December, 1993.

—ANSI/ISO/IEC DIS 9075–3, (Draft) International Standard for Database Language SQL, Part 3: Call Level Interface (SQL/CLI), JTC1 Draft International Standard (DIS), document SC21 N9117, 13 October 1994.

—ANSI/ISO/IEC CD 9075–4, (Draft) International Standard for Database Language SQL, Part 4; Persistent Stored Modules (SQL/PSM), JTC1, Committee Draft (CD), CD Ballot document SC21 N8897, August 1994.

7. Related Documents. SQL Environment specifications depend upon existing standards and stable specifications (see Cross Index above) and upon emerging SQL and SQL Multimedia standards. The following items identify formal ISO/IEC international standards projects for which preliminary specifications and base documents exist, but where the development effort has not yet reached a complete and stable stage (i.e., the Committee Draft (CD) stage). AS these specifications mature and move through the standards process, they can be referenced more reliably in procurement requirements.

(Working Draft) Database Language SQL (SQL3)
- Part 1: Framework
- Part 2: Foundation—including Abstract Data Types and Object SQL
- Part 3: Call Level Interface—extensions to ISO/IEC CD 9075–3 identified above
- Part 4: Persistent Stored Modules—extensions to ISO/IEC CD 9075–4 identified above
- Part 5: Language Bindings—extensions to the binding clauses of ISO/IEC 9075:1992
- Part 6: Encompassing Transactions—to support X/Open XA–interface

(Working Draft) SQL Multimedia (SQL/MM)
- Part 1: Framework
- Part 2: Full Text
- Part 3: Spatial
- Part 4: General Purpose Facilities
- Other Parts: Reserved for other SQL/MM sub-projects with no current base document (e.g., images, photographs, motion pictures, sound, music, video, etc.)

For information on the current status of the above Working Drafts, contact NIST personnel working on SQL Standardization at 301–975–3251. For document references to the above and for additional related documents, see the References section of the SQL/ERI Server Profiles specification (attached).

8. Objective. The primary objective of this FIPS PUB for SQL Environments is to specify SQL profiles that can be used by Federal departments and agencies to support integration of legacy databases and other non-SQL data repositories into an SQL environment. The intent is to provide a high level of control over a diverse collection of legacy or specialized data resources. An SQL environment allows an organization to obtain many of the advantages of SQL without requiring a large, complex, and error-prone conversion effort; instead, the organization can evolve, in a controlled manner to a new integrated environment.

9. Applicability. This standard is applicable in any situation where it is desirable to integrate a client-side productivity tool or a server-side data repository into an SQL environment. It is a non-mandatory standard that may be invoked on a case-by-case basis subject to the integration objectives of the procuring department of agency. It is particularly suitable for specifying limited SQL interfaces to legacy databases or to specialized data repositories not under the control of a full-function SQL database management system. It can be used along with other procurement information to specify SQL interface requirements for a wide range of data management procurements.

One special area of application envisioned for this standard is Electronic Commerce, a National Challenge Application area of the National Information Infrastructure. The primary objective of Electronic Commerce is to integrate communications, data management, and security services in a distributed processing environment, thereby allowing business applications within different organizations to interoperate and exchange information without human intervention. At the data management level, electronic commerce requires a logically integrated database of diverse data stored in geographically separated data banks under the management and control of heterogeneous database management systems. An over-riding requirement is that these diverse data managers be able to communicate with one another and provide shared access to data and data operations and methods under appropriate security, integrity, and access control mechanisms. FIPS SQL provides a powerful database language for data definition, data manipulation, and integrity management to satisfy many of these requirements. It is unrealistic to expect that every data manager involved in electronic commerce will conform to even the Entry SQL level of the FIPS SQL standard; however, it is not unrealistic to require that they support a limited SQL interface, even a read-only interface, provided by one of the SQL/ERI Server profiles specified herein. New procurements to add components to the National Information Infrastructure, or to upgrade existing components, can define the necessary SQL schemas and point to appropriate SQL/ERI Server profiles as procurement requirements.

This standard may also be applicable, on a case-by-case basis, in many of the following areas:

Legacy databases
Full-Text document databases
Geographic Information Systems
Bibliographic information retrieval
Object database interfaces
Federal data distribution
Operating system file interface
Open system directory interface
Electronic mail repositories
CASE tool repositories
XBase repositories
C++ sequence class repositories
Object Request Broker interface repository
Real-time database interface
Internet file repositories

Further detail on each of these potential application areas can be found in Section 8, ''Applicability'', of the FIPS specification for SQL Environments.

10. Specifications. See the Specifications for SQL Environments—SQL External Repository Interface (SQL/ERI)—Server Profiles (attached).

11. Implementation. Implementation of this standard involves four areas of consideration: the effective date, acquisition of conforming implementations, interpretation, and validation.

11.1 Effective date. This publication is effective beginning February 1, 1995. Since it is a non-mandatory specification, based on the established

FIPS SQL standard, and used at the discretion of individual Federal procurements, no transitional period or delayed effective date is necessary.

11.2 Acquisition. All conforming implementations of a specific SQL/ERI profile will support some aspects of the FIPS SQL standard. However, such implementations will not normally be full function database management systems and conformance will often be dependent upon SQL schema definitions and other requirements provided as part of each individual procurement. In most cases, a procurement will not be able to simply point to an SQL/ERI profile and demand conformance to it. Instead, successful procurements will normally use an appropriate SQL/ERI profile, together with an application-specific schema definition, as one aspect of overall procurement requirements. In many cases, vendors of products that provide a limited SQL interface will define their interfaces in terms of a fixed SQL schema definition. In those cases, procurements can point to the vendor-provided schema definition and to an appropriate SQL/ERI profile as a procurement requirement. In some cases, especially in those situations where schema definitions and requirements are not known in advance, a request for a proposal (RFP) may require that an SQL schema, and adherence to one of the SQL/ERI Server profiles, be presented as part of the response proposal.

11.3 Interpretation. NIST provides for the resolution of questions regarding specifications and requirements of the FIPS for SQL Environments, and issues official interpretations as needed, Procedures for interpretations are specified in FIPS PUB 29–3. All questions about the interpretation of FIPS SQL Environments should be addressed to: Director, Computer Systems Laboratory, Attn: SQL Environments, National Institute of Standards and Technology, Gaithersburg, MD 20899, Telephone: (301) 975–2833.

11.4 Validation. Implementations of the FIPS for SQL Environments may be validated in accordance with NIST Computer Systems Laboratory (CSL) validation procedures for FIPS SQL (FIPS PUB 127). Recommended procurement terminology for validation of FIPS SQL is contained in the U.S. General Services Administration publication *Federal ADP & Telecommunications Standards Index*, Chapter 4 Part 2. This GSA publication provides terminology for three validation options: Delayed Validation, Prior Validation Testing, and Prior Validation. The agency may select the appropriate validation option and may specify appropriate time frames for validation and correction of nonconformities.

Implementations may be evaluated using the NIST SQL Test Suite, a suite of automated validation tests for SQL implementations. Although this test suite was designed to test conformance of full-function SQL database management systems, it can be modified to accommodate testing of SQL/ERI Server implementations. The results of validation testing by the SQL Testing Service are published on a quarterly basis in the *Validated Products List*, available from the National Technical Information Service (NTIS).

Current information about the NIST SQL Validation Service and the status of validation testing for SQL Environments is available from: National Institute of Standards and Technology, Computer Systems Laboratory, Software Standards Validation Group, Building 225, Room A266, Gaithersburg, Maryland 20899, (301) 975–2490.

12. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, telephone 703–487–4650. When ordering, refer to Federal Information Processing Standards Publication 193 (FIPSPUB193), SQL Environments. Payment may be made by check, money order, or deposit account

[FR Doc. 95–2688 Filed 2–2–95; 8:45 am]

BILLING CODE 3510–CN–M

Workshop on National Voluntary Conformity Assessment Systems Evaluation (NVCASE) Program

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Meeting notice.

SUMMARY: This is to advise the public that the National Institute of Standards and Technology (NIST) will conduct a workshop to brief interested parties on the NVCASE program and to review documents that will be used as the generic basis for requirements of the operational program. The workshop will be in two parts:

(1) A briefing on the purpose and operation of the NVCASE program: the presentation will proceed step-by-step through the procedures set forth in the April 22, 1994 **Federal Register** Notice (15 CFR part 286); and

(2) A review of present and proposed international documents that will be used as the generic basis for program requirements.

The public is encouraged to call to NIST's attention documents useful for this purpose.

DATES: The workshop will be held Thursday, March 9, 1995, from 10:00 a.m. to 6:00 p.m. Registration will start at 9:30 am.

ADDRESSES: The workshop will be held in the Green Auditorium at the National Institute of Standards and Technology, Gaithersburg, Maryland.

FOR FURTHER INFORMATION CONTACT: (1) For administrative and logistic information, contact Ms. Marilyn Stream, National Institute of Standards and Technology, Building 417, Room 107, Gaithersburg, Maryland 20899; Phone: (301) 975–4029. Fax: (301) 963–2871. (2) For information concerning the NVCASE program contact Mr. Robert Gladhill, Program Manager, National Institute of Standards and Technology, Building 417, Room 107, Gaithersburg, Maryland 20899; Phone: (301) 975–4273. Fax: (301) 963–2871. (3) For information on how to obtain copies of the documents, contact the American National Standards Institute (ANSI), 11 West 42nd Street, 13th Floor, New York, New York 10036, USA; Phone: (212) 642–4900. Fax: (212) 398–0023.

SUPPLEMENTARY INFORMATION: The National Institute of Standards and Technology (NIST) offers a voluntary program on a fee-for-service basis to evaluate the competence of conformity assessment activities.

The National Voluntary Conformity Assessment Systems Evaluation (NVCASE) Program may be applied to activities related to laboratory testing, product certification, and quality system registration. NVCASE evaluates and provides official recognition to qualifying bodies in the United States that effectively demonstrate that they satisfy established criteria and applicable regulatory requirements of other countries.

NVCASE recognition (1) provides other governments with a basis for having confidence that qualifying U.S. conformity assessment bodies are competent, and (2) promotes the acceptance of U.S. products in regulated foreign markets based on U.S. conformity assessment results.

NVCASE offers evaluation services to support U.S. trade in regulated foreign markets, but not for domestic applications. NVCASE does not unilaterally establish program areas. All requests to establish evaluation services in a specific product sector are first published for public advice and comment. If another U.S. Government

agency has domestic regulatory responsibility for that sector, the cognizant agency is consulted prior to any program action by NIST.

A U.S. regulatory agency may, at its discretion, defer evaluation and recognition of conformity assessment activities related to foreign trade to NVCASE, or may itself perform required evaluation activities. In the event of deferral to NVCASE, the regulatory agency fully retains its domestic authority and responsibility for the product sector.

NVCASE recognition may be obtained for different levels of activity. For example, a body may be recognized to accredit other bodies, (e.g., an accreditor of laboratories, or of certifiers, or of registrars). If accreditation is not available elsewhere, a body may be accredited directly by NVCASE to perform some specific function (e.g., to certify specific products, or as a quality system registrar).

The NVCASE evaluation process requires that a body provide sufficient information to allow thorough evaluation of its management system and operations. The criteria used are based on internationally accepted requirements.

Prior to obtaining recognition, each participant must undergo an initial on-site assessment by qualified assessors. Any elements of non-conformance must be resolved prior to the granting of recognition. Once recognition has been granted, follow-up assessments are conducted on a regular basis, along with periodic surveillance visits, both announced and unannounced. NVCASE recognition is effective until either voluntary or involuntary termination.

NVCASE listings of all recognized bodies include the name, address, pertinent contacts, and the scope of recognition. NVCASE also maintains listings of qualified bodies that have been accredited or otherwise approved by a NVCASE-recognized accreditor (but only within the scope and period of recognition of the accreditor), indicating they are traceable to NIST via the NVCASE-recognized body. All listings are freely disseminated and available to the public through various media.

In the event that a recognized body is found not to conform with the established criteria, NVCASE will terminate the recognition and delist the body. NIST will no longer assure that body's conformity assessment activities are competent.

If the body is of a type which accredits or otherwise approves other groups (e.g., an accreditation body that accredits laboratories), these accredited groups (e.g., laboratories) may be delisted and lost their traceability to NIST.

However, if the accredited groups were not involved in the circumstances that led to the termination of recognition of the accreditation body, NVCASE will consider granting a grace period during which accreditation can be obtained from another NVCASE-recognized accreditation body prior to being delisted. To the extent that one or more accredited bodies were affected by the circumstances which lead to the termination of recognition of the accrediting body, all those involved will be immediately delisted.

Bodies that have had their NVCASE recognition terminated may regain recognition if and when they can demonstrate conformance with all requirements.

As indicated, the NVCASE Program intends to rely on and utilize international conformity assessment documents such as those developed by the International Organization for Standardization (ISO) Committee on Conformity Assessment. These documents adopted jointly by ISO and the International Electrotechnical Commission (IEC) are as follows:

ISO/IEC Guide 25, ''General Requirements for the Competence of Calibration and Testing Laboratories,'' Third edition; 1990;

ISO/IEC Guide 58, ''Calibration and Testing Laboratory Accreditation Systems—General Requirements for Operation and Recognition,'' First edition, 1993;

In addition, under consideration for adoption are:

ISO/CASCO 226 (rev. 2), ''General requirements for certification or registration body assessment and accreditation systems'';

ISO/CASCO 227 (rev. 2), ''General requirements for bodies operating assessment and certification/registration of quality systems'';

ISO/CASCO 228 (rev. 2), ''General requirements for bodies operating product certification systems'' (or currently available equivalent).

ISO/IEC guides are used as a basis for many conformity assessment activities at international, regional and national levels and have been approved by the American National Standards Institute (ANSI), the U.S. member body to ISO.

Dated: January 31, 1995.

Samuel Kramer,

Associate Director.

[FR Doc. 95–2718 Filed 2–2–95; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atmospheric Administration

[I.D. 013095B]

Pacific Fishery Management Council; Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Salmon Technical Team will hold a public meeting on February 14–17, 1995, at the Council office, 2130 SW Fifth Avenue, Suite 224, Portland, OR; telephone: (503) 326–6352. The meeting will begin on February 14, at 10:00 a.m., and will continue each day from 8:00 a.m. until 5:00 p.m. for the remainder of the week.

The purpose of this meeting is to draft the 1995 stock status report, ''Preseason I: Stock Abundance Analysis for 1995 Ocean Salmon Fisheries.'' The final report will be distributed to the public and reviewed by the Council at its March meeting in South San Francisco.

FOR FURTHER INFORMATION CONTACT: John Coon, Fishery Management Coordinator (Salmon), Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201; telephone: (503) 326–6352.

SUPPLEMENTARY INFORMATION: This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Michelle Perry Sailer at (503) 326–6352, at least 5 days prior to the meeting date.

Dated: January 30, 1995.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–2726 Filed 2–2–95; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be

furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: March 6, 1995.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Cup, Disposable, Paper
7350–01–359–9524
NPA: Royal Maid Association for the Blind, Inc., Hazlehurst, Mississippi
Sweatsuit, USAF
(Sweatshirt)
8415–00–NIB–0054 (X-Small)
8415–00–NIB–0055 (Small)
8415–00–NIB–0056 (Medium)
8415–00–NIB–0057 (Large)
8415–00–NIB–0058 (X-Large)
(Sweatpants)
8415–00–NIB–0059 (X-Small)
8415–00–NIB–0060 (Small)
8415–00–NIB–0061 (Medium)
8415–00–NIB–0062 (Large)
8415–00–NIB–0063 (X-Large)
NPA: The Arkansas Lighthouse for the Blind, Little Rock, Arkansas
Georgia Industries for the Blind, Bainbridge, Georgia at its facility in Atlanta, Georgia
Blind Industries & Services of Maryland, Baltimore, Maryland at its facility in Salisbury, Maryland
Mississippi Industries for the Blind, Jackson, Mississippi
Lions Club Industries for the Blind, Inc., Durham, North Carolina
Winston-Salem Industries for the Blind, Winston-Salem, North Carolina
Winston-Salem Industries for the Blind, Winston-Salem, North Carolina at its facility in Asheville, North Carolina
Lions Volunteer Blind Industries, Inc., Morristown, Tennessee
San Antonio Lighthouse, San Antonio, Texas
Virginia Industries for the Blind, Richmond, Virginia
BESB Industries, West Hartford, Connecticut

Services

Janitorial/Custodial, Denver Federal Center, Buildings 76, 80, 93, and 94, Denver, Colorado, NPA: North Metro Community Services for Developmentally Disabled, Westminister, Colorado

Janitorial/Custodial, John Weld Peck Federal Building, 550 Main Street, Cincinnati, Ohio, NPA: Ohio Valley Goodwill Rehabilitation Center, Inc. Cincinnati, Ohio

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–2715 Filed 2–2–95; 8:45 am]

BILLING CODE 6820–33–P

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the procurement list.

SUMMARY: This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: March 6, 1995.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On December 9, 1994, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (59 F.R. 63764) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services, fair market price, and impact of the additions on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List. Accordingly, the following services are hereby added to the Procurement List:

Administrative Services, U.S. Army Engineer District, Clock Tower Building, Annex and Adjacent Buildings, Rock Island, Illinois

Janitorial/Custodial, U.S. Army Corps of Engineers, Walla Walla District, Headquarters Building, Walla Walla, Washington

Switchboard Operation, Department of Veterans Affairs Medical Center, 718 Smyth Road, Manchester, New Hampshire.

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–2714 Filed 2–2–95; 8:45 am]

BILLING CODE 6820–33–P

COMMODITY FUTURES TRADING COMMISSION

Chicago Mercantile Exchange Application for Designation as a Contract Market in Mexican Peso Futures Options

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of availability of the terms and conditions of proposed commodity futures option contract.

SUMMARY: The Chicago Mercantile Exchange (CME) has applied for designation as a contract market in options on its physical delivery Mexican peso futures contract. The Director of the Division of Economic Analysis (Division) of the Commission, acting pursuant to the authority delegated by Commission Regulation 140.96, has determined that publication of the proposal for comment is in the public interest, will assist the Commission in considering the views of interested persons, and is consistent with the purposes of the Commodity Exchange Act.

DATE: Comments must be received on or before March 6, 1995.

ADDRESS: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581. Reference should be made to the CME option on the physical delivery Mexican peso futures contract.

FOR FURTHER INFORMATION CONTACT: Steve Sherrod of the Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581, telephone 202–254–7303.

SUPPLEMENTARY INFORMATION: The CME physical delivery Mexican peso futures contract, which would underlie the proposed option, currently is dormant within the meaning of Commission Regulation 5.2.[1] Concurrent with its application for designation as a contract market in the subject option, the CME submitted to the Commission for approval, pursuant to Section 5a(a)(12) of the Act, a proposal to reactivate trading in this dormant futures contract. The subject option designation application and the proposed reactivation of trading for the underlying futures contract are under review by the Division.

Copies of the terms and conditions of the proposed contract will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, D.C. 20581. Copies of the terms and conditions can be obtained through the Office of the Secretariat by mail at the above address or by phone at (202) 254–6314.

Other materials submitted by the CME in support of the application for contract market designation may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 C.F.R. part 145 (1987)), except to the extent they are entitled to confidential treatment as set forth in 17 C.F.R. 145.5 and 145.9. Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with 17 C.F.R. 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the terms and conditions, or with respect to other materials submitted by the CME in support of the application, should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581 by the specified date.

Issued in Washington, DC, on January 30, 1995.

Blake Imel,

Acting Director.

[FR Doc. 95–2660 Filed 2–2–95; 8:45 am]

BILLING CODE 6351–01–M

[1] The CME also has applied for designation as a contract market in ''hybrid' Mexican peso futures and futures option contracts, which are currently under review by the Division. The hybrid Mexican peso futures contract provides for cash settlement, in contrast to the existing dormant Mexican peso futures contract which provides for physical delivery of Mexican pesos.

DEPARTMENT OF DEFENSE

Department of the Army

ARMS Initiative Implementation

AGENCY: U.S. Army Materiel Command, DOD.

ACTION: Meeting notice.

SUMMARY: Pursuant to Section 10(a)(2) of Public Law 92–463, notice is hereby given of the next workshop meeting of the Armament Retooling and Manufacturing Support (ARMS) Public/Private Task Force (PPTF). The PPTF is chartered to develop new and innovative methods to maintain the government-owned, contractor-operated ammunition industrial base and retain critical skills for a national industrial emergency. Focus of this meeting will be improving the progresses used in administering the program. Participation of Army contracting office staff and operating contractor staff is strongly encouraged. This session is open to the public.

MEETING DATE: March 22–23, 1995.

PLACE OF MEETING: Blackhawk Hotel, 200 East Third Street, Davenport, IA 52801.

TIME OF MEETING: 8:00 a.m.–5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Auger, ARMS Task Force, HQ Army Materiel Command, 5001 Eisenhower Avenue, Alexandria, Virginia 22333; telephone (703) 274–9838.

SUPPLEMENTARY INFORMATION: Reservations should be made directly with the Blackhawk Hotel; telephone (319) 328–6000. Please be sure to mention that you will be attending the ARMS workshop meeting to assure occupancy in the block of rooms set aside for this meeting. You should confirm your reservation prior to 28 February 1995. Request you contact Debra Yeager in the ARMS Team Office at Rock Island Arsenal; telephone (309) 782–4040, if you will be attending the meeting so that our roster of attendees is accurate. This number may also be used if other assistance regarding the ARMS meeting is required.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 95–2723 Filed 2–2–95; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Group, invites comments on proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: An expedited review has been requested in accordance with the Act, since allowing for the normal review period would adversely affect the public interest. Approval by the Office of Management and Budget (OMB) has been requested by February 13, 1995.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street NW., Room 3208, New Executive Office Building, Washington, DC 20503.

Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 400 Maryland Avenue SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill, (202) 708–9915. Individuals who use a telecommunications device 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 time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 3517) requires that the Director of OMB provide interested Federal agencies and persons an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Director, Information Resources Group, publishes this notice with the attached proposed information collection request prior to submission of this request to OMB. This notice contains the following information: (1) Type of review requested, e.g., expedited; (2) Title; (3) Abstract; (4) Additional Information; (5) Frequency of collection; (6) Affected public; and (7) Reporting and/or Recordkeeping burden. Because an expedited review is requested, a description of the information to be collected is also included as an attachment to this notice.

Dated: January 30, 1995.

Gloria Parker,

Director, Information Resources Group.

Office of Educational Research and Improvement

Type of Review: Expedited
Title: Application for Grants Under the National Diffusion Network
Frequency: Annually
Affected Public: State or local governments; Non-profit institutions
Reporting Burden:
Responses: 48
Burden Hours: 576
Recordkeeping Burden:
Recordkeepers: 25
Burden Hours: 300
Abstract: The National Diffusion Network supports, under grants, dissemination of exemplary programs. The Department will use the information to make grant awards.
Additional Information: Clearance for this information collection is requested for February 13, 1995. As part of the ''reinventing government'' initiative, and in light of comments from the public, the Department is determined to allow the applicants as much time as possible to respond. An expedited review is requested in order to implement the program before the start of the new year.

Office of Educational Research and Improvement

Type of Review: Expedited
Title: Annual Report of Children in Institutions for Neglected or Delinquent Children, Adult Correctional Institutions, and Community Day Programs
Frequency: Annually
Affected Public: State, Local or Tribal Governments
Reporting Burden:
Responses: 52
Burden Hours: 2,000
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0
Abstract: An annual survey is conducted to collect data on (1) the number of children enrolled in educational programs of State-operated institutions for neglected or delinquent children (N or D), community day programs for N or D children, and adult correctional institutions and (2) the October caseload of N or D children in local institutions.
Additional Information: Clearance for this information collection is requested for February 13, 1995. ED must make grant awards to the States based on these allocations by July 1 because the Cash Management Information Act makes ED liable for interest incurred by States and localities for program expenses if Federal funds are not made available on that date. In order to meet that deadline, we must send the revised ED Form 4376 to the States by March 1 to collect the data needed to determine State grant awards before July 1.

[FR Doc. 95–2647 Filed 2–2–95; 8:45 am]
BILLING CODE 4001–01–M

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Group, invites comments on proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: An expedited review has been requested in accordance with the Act, since allowing for the normal review period would adversely affect the public interest. Approval by the Office of Management and Budget (OMB) has been requested by February 6, 1995.

EFFECTIVE DATE: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street NW., Room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 400 Maryland Avenue SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT:

Patrick J. Sherrill, (202) 708–9915. Individuals who use a telecommunications device 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 time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 3517) requires that the Director of OMB provide interested Federal agencies and persons an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Director, Information Resources Group, publishes this notice with the attached proposed information collection request prior to submission of this request to OMB. This notice contains the following information: (1) Type of review requested, e.g., expedited; (2) Title; (3) Abstract; (4) Additional Information; (5) Frequency of collection; (6) Affected public; and (7) Reporting and/or Recordkeeping burden. Because an expedited review is requested, a description of the information to be collected is also included as an attachment to this notice.

Dated: January 30, 1995.

Gloria Parker,

Director, Information Resource Group.

Office of Postsecondary Education

Type of Review: Expedited
Title: William D. Ford Federal Direct Loan Program Participation Application
Frequency: Annually
Affected Public: Business or other for-profit; Not-for-profit institutions
Reporting Burden:
Responses: 3,000
Burden Hours: 600
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0
Abstract: This form will be the means by which a school applies to participate in the William D. Ford Federal Direct Loan Program. The Department will use this information to select schools to participate in the Direct Loan Program during the 1996–1997 school year.
Additional Information: Clerance for this information collection is requested for February 6, 1995. An expedited review is requested due to the publication of a draft of the form soliciting applications. To comment on this form, please refer to the ''Notice of Solicitation of Applications'' In the December 29, 1994 **Federal Register** issue, volume 59, pages 67579–67582.

[FR Doc. 95–2646 Filed 2–2–95; 8:45 am]

BILLING CODE 4000–01–M

Office of Postsecondary Education; Federal Work-Study Programs

AGENCY: Department of Education.

ACTION: Notice of the closing date for institutions to submit a request for a waiver of the requirement that an institution shall use at least 5 percent of the total amount of its Federal Work-Study (FWS) Federal funds granted for the 1994–95 award year to compensate students employed in community service jobs.

SUMMARY: The Secretary gives notice to institutions of higher education of the deadline for an institution to submit a written request for a waiver of the requirement that an institution shall use at least 5 percent of its total FWS Federal funds granted for the 1994–95 award year (July 1, 1994 through June 30, 1995) to compensate students employed in community service jobs.

DATES: Closing Date for Submitting a Waiver Request and any Supporting Information or Documents. An institution that would like to request a waiver of the requirement that an institution use at least 5 percent of the total amount of its FWS Federal funds granted for the 1994–95 award year to compensate students employed in community service jobs, must mail or hand-deliver its waiver request and any supporting information or documents on or before March 6, 1995. The Department will not accept a waiver request submitted by facsimile transmission. The waiver request must be submitted to the Campus-Based Programs Financial Management Division at one of the addresses indicated below.

ADDRESSES: Waiver Request and any Supporting Information or Documents Delivered by Mail. The waiver request and any supporting information or documents delivered by mail must be addressed to Carolyn Short, Financial Management Specialist, Fund Control Branch, Campus-Based Programs Financial Management Division, Accounting and Financial Management Service, Student Financial Assistance Programs, U.S. Department of Education, Room 4621, Regional Office Building 3, 600 Independence Avenue, S.W., Washington, D.C. 20202–5452. An applicant must show proof of mailing consisting of one of the following: (1) A legibly dated U.S. Postal Service postmark; (2) a legible mail receipt with the date of mailing stamped by the U.S. Postal Service; (3) a dated shipping label, invoice, or receipt from a commercial carrier; or (4) any other proof of mailing acceptable to the Secretary of Education.

If a waiver request is sent through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service.

An institution should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an institution should check with its local post office.

An institution is encouraged to use certified or at least first class mail. Institutions that submit waiver requests and any supporting information or documents after the closing date will not be considered for a waiver.

Waiver Requests and any Supporting Information or Documents Delivered by Hand. A waiver request and any supporting information or documents delivered by hand must be taken to Carolyn Short, Financial Management Specialist, Fund Control Branch, Campus-Based Programs Financial Management Division, Student Financial Assistance Programs, U.S. Department of Education, Room 4621, Regional Office Building 3, 7th and D Streets SW., Washington, D.C. Hand-delivered waiver requests will be accepted between 8:00 a.m. and 4:30 p.m. (Eastern time) daily, except Saturdays, Sundays, and Federal holidays. A waiver request for the 1994–95 award year that is delivered by hand will not be accepted after 4:30 p.m. on the closing date.

SUPPLEMENTARY INFORMATION: Under section 443 (b)(2)(A) of the Higher Education Act of 1965, as amended (HEA), an institution must use at least 5 percent of the total amount of its FWS Federal funds granted for an award year to compensate students employed in community service, except that the Secretary may waive this requirement if the Secretary determines that enforcing it would cause hardship for students at the institution. The institution must provide a written waiver request and any supporting information or documents by the established March 6, 1995 closing date. The waiver request must be signed by an appropriate institutional official and above the signature the official must include the statement: ''I certify that the information the institution provided in this waiver request is true and accurate to the best of my knowledge. I understand that the information is subject to audit and program review by representatives of the Secretary of Education.'' If the institution submits a waiver request and any supporting information or documents after the closing date, the request will not be considered.

To receive a waiver, an institution must demonstrate that the 5 percent requirement would cause hardship for students at the institution. To allow flexibility to consider factors that may be valid reasons for a waiver, the Secretary is not specifying specific circumstances that would support granting a waiver. However, the Secretary does not foresee many instances in which a waiver will be granted. The fact that it may be difficult for the institution to comply with this provision of the HEA is not a basis for granting a waiver.

Applicable Regulations

The following regulations apply to the Federal Work-Study program:

(1) Student Assistance General Provisions, 34 CFR part 668.

(2) Federal Work-Study Programs, 34 CFR part 675.

(3) Institutional Eligibility Under the Higher Education Act of 1965, as amended, 34 CFR part 600.

(4) New Restrictions on Lobbying, 34 CFR part 82.

(5) Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants), 34 CFR part 85.

(6) Drug-Free Schools and Campuses, 34 CFR part 86.

FOR FURTHER INFORMATION CONTACT: Carolyn Short, Financial Management Specialist, Fund Control Branch, Campus-Based Programs Financial Management Division, Accounting and Financial Management Service, Student Financial Assistance Programs, U.S. Department of Education, Room 4621, Regional Office Building 3, 600 Independence Avenue, S.W., Washington, D.C. 20202–5452, Telephone (202) 708–7741. Individuals who use a telecommunications device 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 time, Monday through Friday.

(Authority: 42 U.S.C. 2756(b)).
(Catalog of Federal Domestic Assistance Number: 84.033 Federal Work-Study Program)

Dated: January 31, 1995.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

[FR Doc. 95–2712 Filed 2–2–95; 8:45 am]

BILLING CODE 4000–01–P

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: Notice is hereby given that on February 3, 1992, an arbitration panel rendered a decision in the matter of *Karla Todd* v. *Alabama Division of Rehabilitative Services, (Docket No. R–S/90–4).* This panel was convened by the U.S. Department of Education pursuant to 20 U.S.C. 107d–1(a) upon receipt of a complaint filed by Karla Todd on June 13, 1990. The Randolph-Sheppard Act creates a priority for blind individuals to operate vending facilities on Federal property. Under this section of the Randolph-Sheppard Act (the Act), a blind licensee dissatisfied with the State's operation or administration of the vending facility program authorized under the Act may request a full evidentiary hearing from the State licensing agency (SLA). If the licensee is dissatisfied with the State agency's decision, the licensee may complain to the Secretary, who is then required to convene an arbitration panel to resolve the dispute.

FOR FURTHER INFORMATION CONTACT: A copy of the full text of the arbitration panel decision may be obtained from George F. Arsnow, U. S. Department of Education, 600 Independence Avenue, S.W., Room 3230 Switzer Building, Washington, D.C. 20202–2738. Telephone: (202) 205–9317. Individuals who use a telecommunications devise for the deaf (TDD) may call the TDD number at (202) 205–8298.

SUPPLEMENTARY INFORMATION: Pursuant to section 107d–2(c) of the Randolph-Sheppard Act, the Secretary is required to publish a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal property.

Background

Karla Todd is a blind vendor licensed by the Alabama Division of Rehabilitative Services, the SLA under the provisions of the Act. On September 20, 1989, Ms. Todd attended a meeting of blind vendors from the Mobile area. At this meeting, the agenda provided for the election of a committee representative for the Committee of Blind Vendors, pursuant to 34 CFR 395.14, which states that the SLA shall provide for the biennial election of a State Committee of Blind Vendors.

At the September meeting, complainant was one of the two candidates nominated for committee representative. A vote was held that resulted in a three to three tie. A second run-off election was held with the same result. A special meeting of blind vendors to resolve the matter was called for October 4, 1989. Prior to the meeting the candidate opposing complainant withdrew.

The SLA sent a letter to the vendors announcing the October 4 meeting, explaining the problem regarding the election on September 20, and stating that the only purpose of the meeting would be to elect a member of the State Committee of Blind Vendors.

Ten vendors attended the October 4, 1989 meeting, including the complainant. Ms. Todd was again nominated along with another vendor. The other vendor received the majority of the votes and was elected to the committee.

Ms. Todd subsequently challenged the candidacy of the vendor elected at the October 4, 1989 meeting, stating that she should have won the election by default when the previous vendor who had received a tie vote with complainant withdrew her candidacy prior to the October 4th meeting. She asserted that proper procedures under the rules and regulations of the Alabama Randolph-Sheppard vending program had not been followed.

Karla Todd requested and received an administrative review with respect to the matter. The SLA upheld the election of the new candidate. Subsequently, complainant requested a full evidentiary hearing.

On March 19, 1990, an evidentiary hearing was held in Montgomery, Alabama. The hearing officer ruled that Ms. Todd's objections were without merit. Subsequently, Ms. Todd appealed this ruling to a Federal arbitration panel, which held a hearing on September 27, 1991.

Arbitration Panel Decision

The issue before the panel was whether the process followed by the SLA on September 20 and October 4, 1989 was consistent with the State rules and regulations governing the day-to-day operations of the Business Enterprise Program.

The SLA argued that the issue before the arbitration panel was not arbitrable since the policies and procedures of the Business Enterprises Program only allow for review of ''actions arising from the operation or administration of a vending facility.'' However, it was the opinion of the majority of the panel that the complainant's argument was persuasive. The Act, in 20 U.S.C. 107b-1, states that the Committee of Blind Vendors shall participate with the Vocational Rehabilitation Agency regarding administrative decisions, policies, and program development decisions affecting the overall administration of the State Vending Facility Program.

The panel concluded that the actions of the Committee of Blind Vendors indeed had an impact on the operation and administration of all vending facilities, and, therefore, the issue was reviewable by the panel.

The panel found that the policies and procedures of the Business Enterprise Program, specifically the section on elections, covered the issue before the panel. The section on elections states, ''[I]f no candidate receives a majority of the votes, a run-off between the two highest vote getters will be held.'' The SLA interpreted this to mean that only one run-off election had to be held, and in the event of a tie in the run-off election, an entirely new election was appropriate. The panel did not concur with the SLA's interpretation of this language. The panel stated that the common sense meaning of the term ''run-off'' is not necessarily a singular act, but implies the act of breaking a tie regardless of the number of times necessary to achieve that goal.

Additionally, the panel noted that the SLA's policies and procedures are silent regarding holding a new election and also regarding a tie occurring during a run-off election. Therefore, the panel found that the language of the policies and procedures of the Business Enterprise Program regarding elections was clear in that once the two highest vote getters were determined, those two vote getters would continue with a run-off election until one of the vote getters ultimately won the election.

On September 26, 1991, a new election was held. The SLA petitioned the panel to declare the issue moot in light of the new election. The complainant requested that the panel unseat the person elected on October 4, 1989, as well as the person elected on September 26.

The panel ruled that the election process held by the SLA on October 4, 1989 was a violation of the policies and procedures of the Business Enterprise Program and, further, that Karla Todd won the run-off election that began on September 20, 1989. However, since a new and undisputed election was held on September 26, 1991, the panel concluded it was without authority to upset that election, and, therefore, the issue as to the appropriateness of the election held on October 4, 1989 was moot and no remedy could be fashioned.

Panel member Harris dissented, indicating that the rules of the Business Enterprise Program were silent regarding the situation of a run-off election, and, therefore, the SLA did not violate its own policy.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the U.S. Department of Education.

Dated: January 30, 1995.

Judith E. Heumann,

Assistant Secretary, Office of Special Education and Rehabilitative Services.

[FR Doc. 95–2683 Filed 2–2–95; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494–088 Oklahoma]

Grand River Dam Authority; Availability of Environmental Assessment

January 30, 1995.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47910), the Office of Hydropower Licensing (OHL) reviewed the application for non-project use of project lands for the Pensacola Hydroelectric Project. The application proposes to excavate an area approximately 174 feet wide, 500 feet long, and 10 feet deep and to construct a breakwater 10 feet wide (to the approximate elevation of 746 feet mean sea level) on Grand Lake O' The Cherokees, in Delaware County, Oklahoma. The staff prepared an Environmental Assessment (EA) for the action. In the EA, staff concludes that approval of the non-project use of project lands would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Reference and Information Center, Room 3308, of the Commission's offices at 941 North Capitol Street NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 95–2662 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 2114–032 Washington]

Public Utility District No. 2 of Grant County; Availability of Environmental Assessment

January 30, 1995.

In accordance with the National Environmental Policy Act of 169 and the Federal Energy Regulatory Commission's regulations, 18 CFR Part 380 (Order No. 486, 52 F.R. 47910), the Office of Hydropower Licensing (OHL) reviewed the proposal for constructing a prototype fish surface collector at the Priest Rapids Project in Grant County, Washington. The Commission prepared an environmental assessment (EA) for the proposed action. In the EA, the Commission concludes that approval of construction of the proposed prototype fish surface collector will not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Reference and Information Center, Room 3308, of the Commission's offices at 941 North Capitol Street, N.E., Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 95–2663 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. GP94–19–000]

Oklahoma Corporation Commission Tight Formation Area Determination FERC No. JD94–01286T (Oklahoma-57); Preliminary Finding

January 30, 1995.

On November 26, 1993, the Oklahoma Corporation Commission (Oklahoma) determined that the Fanshawe Formation, underlying parts of Latimer County, Oklahoma, qualifies as a tight formation under Section 107(c)(5) of the Natural Gas Policy Act of 1978 (NGPA). ARCO Oil and Gas Company (ARCO) is the applicant before Oklahoma.

By letter dated January 10, 1994, staff tolled the Commission's 45-day review period and requested additional support for Oklahoma's conclusion that the Fanshawe Formation meets the Commission's tight formation guidelines in § 271.703(c)(2) of the Commission's regulations.[1] Staff requested additional information because the record did not show whether the premeability and prestimulation stabilized flow rates on which the determination was based reflected initial characteristics or characteristics resulting from years of sustained production.

The Commission has received no response to the January 10, 1994 tolling letter. Without additional information showing that the determination is based on initial permeability and prestimulation stabilized flow rates characteristics, we are unable to find that Oklahoma's determination is supported by substantial evidence. Under § 275.202(a) of the regulations, the Commission's may make a preliminary finding, before any determination becomes final, that the determination is not supported by substantial evidence in the record.[2] Therefore, the Commission hereby makes a preliminary finding that Oklahoma's determination is not supported by substantial evidence in the

[1] Section 271.703(c)(2) requires a jurisdictional agency's tight formation area determination to show that: (1) The estimated average *in situ* gas permeability, throughout the pay section, is expected to be 0.1 millidarcy or less; (2) the average pre-stimulation stabilized natural gas flow rate (against atmospheric pressure) of wells completed for production in the formation does not exceed the applicable maximum allowable flow rate; and (3) wells in the recommended area is expected to produce, without stimulation, more than 5 barrels of crude oil per day.

[2] Order No. 567, issued on July 28, 1994, rescinded Part 275 of the Commission's NGPA's regulations as of that date (68 FERC ¶ 61,135). The Commission stated, however, that rescission of Part 275 is prospective only and that timely filed applications for well determination proceedings still pending before the Commission will continue to be subject to the requirements of Part 275 as it existed before July 28, 1994.

record upon which it was made. Oklahoma or ARCO may, within 30 days from the date of this preliminary finding, submit written comments and request an informal conference with the Commission, pursuant to § 275.202(f) of the regulations. A final Commission order will be issued within 120 days after the issuance of this preliminary finding.

By direction of the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 95–2708 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER94–1691–000]

AIG Trading Corp.; Notice of Issuance of Order

January 27, 1995.

On September 29, 1994, as completed on November 23, 1994, AIG Trading Corporation (AIG Trading) submitted for filing a rate schedule under which AIG Trading will engage in wholesale electric power and energy transactions as a marketer. AIG Trading also requested waiver of various Commission regulations. In particular, AIG Trading requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by AIG Trading.

On January 19, 1995, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by AIG Trading should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol 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).

Absent a request for hearing within this period, AIG Trading is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of AIG Trading's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 21, 1995.

Copies of the full text of the order are available from the Commission's Public Reference Branch, Room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–2664 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG95–2–000]

Columbia Gas Transmission Corp.; Filing

January 30, 1995.

Take notice that on January 20, 1995, Columbia Gas Transmission Corporation (Columbia), submitted revised standards of conduct under Order Nos. 497 *et seq.* [1] and Order Nos. 566 *et seq.* [2] Columbia states that it is revising its standards of conduct to incorporate the changes required by Order Nos. 566 and 566–A. The modifications are also necessary to reflect organizational changes within Columbia as a result of implementing Order No. 636.

Columbia states that copies of its filing are available for inspection at its offices at 1700 MacCorkle Avenue, SE., Charleston, West Virginia; 700 Thirteenth Street, NW., Suite 900, Washington, DC; and have been mailed to all firm customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC, 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before February 14, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–2665 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG95–3–000]

Columbia Gulf Transmission Co.; Filing

January 30, 1995.

Take notice that on January 20, 1995, Columbia Gulf Transmission Company (Columbia Gulf) submitted revised standards of conduct under Order Nos. 497 *et seq.*[1] and Order Nos. 566 *et seq.*[2]

[1] Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497–A, *order on rehearing,* 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. 30,868 (1989); Order No. 497–B, *order extending sunset date,* 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); order No. 497–C, *order extending sunset date,* 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC p 61,139 (1992); Tenneco Gas. v. FERC (affirmed in part and remanded in part), 969 F. 2d 1187 (D.C. Cir. 1992); Order No. 497–D, *order on remand and extending sunset date,* III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497–E, *order on rehearing and extending sunset date,* 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497–F, *order denying rehearing and granting clarification,* 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497–G, *order extending sunset date,* 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

[2] Standards of conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats & Regs. ¶ 30,997 (June 17, 1994); Order No. 566–A, *order on rehearing,* 59 FR 52896 (October 20, 1994), 69 FERC ¶ 61,044 (October 14, 1994); Order No. 566–B, *order on rehearing,* 59 FR 65707 (December 21, 1994); 69 FERC ¶ 61,334 (December 14, 1994); *appeal docketed sub nom. Conoco, Inc.* v. *FERC,* D.C. Cir. No. 94–1745 (December 13, 1994).

[1] Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497–A, *order on rehearing,* 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. 30,868 (1989); Order No. 497–B, *order extending sunset date,* 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497–C, *order extending sunset date,* 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); *Tenneco Gas* v. *FERC* (affirmed in part and remanded in part), 969 F. 2d 1187 (D.C. Cir. 1992); Order No. 497–D, *order on remand and extending sunset date,* III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497–E, *order on rehearing and extending sunset date,* 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497–F, *order denying rehearing and granting clarification,* 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497–G, *order extending sunset date,* 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

[2] Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,997 (June 17, 1994); Order No. 566–A, *order on rehearing,* 59 FR 52896 (October 20, 1994), 69 FERC ¶ 61,044 (October 14, 1994); Order No. 566–B, *order on*

Columbia Gulf states that it is revising its standards of conduct to incorporate the changes required by Order Nos. 566 and 566–A. The modifications are also necessary to reflect organizational changes within Columbia Gulf as a result of implementing Order No. 636.

Columbia Gulf states that copies of its filing are available for inspection at its offices at 2603 Augusta, Houston, Texas; 700 Thirteenth Street, N.W., Suite 900, Washington, D.C.; and have been mailed to all firm customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E. Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before February 14, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–2666 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER94–1612–000]

Destec Power Services, Inc.; Issuance of Order

January 27, 1995.

On August 31, 1994, as amended November 23, 1994, Destec Power Services, Inc. (Destec) submitted for filing a rate schedule under which Destec will engage in wholesale electric power and energy transactions as a marketer. Destec also requested waiver of various Commission regulations. In particular, Destec requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Destec.

On January 20, 1995, by direction of the Commission, the Secretary of the Commission issued an order granting requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Destec should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol 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).

Absent a request for hearing within this period, Destec is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Destec's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 21, 1995.

Copies of the full text of the order are available from the Commission's Public Reference Branch, Room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–2667 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP95–169–000]

Williams Natural Gas Co.; Request Under Blanket Authorization

January 30, 1995.

Take notice that on January 20, 1995, Williams Natural Gas Company (WNG), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket No. CP95–169–000 a request pursuant to Section 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to install bi-directional measurement facilities for the receipt and delivery of transportation gas to Manchester Pipeline Corporation (Manchester), in Grant County, Oklahoma, under WNG's blanket certificate issued in Docket No. CP82-479–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

WNG proposes to install the facilities to deliver gas to Manchester to fill its storage facility and to receive gas from the storage facility. WNG states that the annual volume is estimated to be approximately 13,200,000 Dth with a peak day volume of 80,000 Dth. WNG states further that the total volume would not exceed the total volume currently authorized. The total construction cost, it is said, would be reimbursed by Manchester.

WNG states further that this change is not prohibited by an existing tariff and that WNG has sufficient capacity to accomplish the deliveries specified without detriment or disadvantage to WNG's other customers.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 95–2668 Filed 2–2–95; 8:45 am]

BILLING CODE 6717–01–M

Office of Arms Control and Nonproliferation; Proposed Subsequent Arrangements

Pursuant to Section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of proposed ''subsequent arrangements'' under the Agreement for Cooperation between the Government of the United States of America and the Government of Canada concerning Civil Uses of Atomic Energy, as amended, and the Agreement for Cooperation between the Government of the United States of America and the Government of the Republic of Korea concerning Civil Uses of Atomic Energy, as amended.

The subsequent arrangements to be carried out under the above-mentioned agreements involves approval of the following retransfers: RTD/KO(CA)–3, for the transfer from Canada to the

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rehearing, 59 FR 65707 (December 21, 1994); 69 FERC ¶ 61,334 (December 14, 1994); *appeal docketed sub nom. Conoco, Inc.* v. *FERC,* D.C. Cir. No. 94–1745 (December 13, 1994).

Republic of Korea of 3,127.4 grams of uranium containing 617.7 grams of the isotope uranium–235 (19.75 percent enrichment) for use as fuel in the KMRR research reactor. RTD/KO(CA)–4, for the transfer from Canada to the Republic of Korea of 51,955.2 grams of uranium containing 10,250.8 grams of the isotope uranium–235 (19.73 percent enrichment) for use as fuel in the KMRR research reactor.

In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that these subsequent arrangements will not be inimical to the common defense and security.

These subsequent arrangements will take effect no sooner than fifteen days after the date of publication of this notice.

Issued in Washington, D.C. on January 27, 1995.

Edward T. Fei,

Acting Director, International and Regional Security Division, Office of Arms Control and Nonproliferation.

[FR Doc. 95–2716 Filed 2–2–95; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–4719–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared January 2, 1995 through January 6, 1995 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1994 (59 FR 16807).

Draft EISs

ERP No. D–AFS–E65047–MS, Rating EC1, G. F. Erambert and Black Creek Seed Orchards Pest Management Plan, Implementation, Southern Region, National Forests in Mississippi, Forrest and Perry Counties, MS.

Summary: EPA expressed environmental concerns regarding the impact of pesticides and recommended that mitigation measures and pest damage thresholds be carefully followed.

Final EISs

ERP No. F–USN–E11031–NC, Camp Lejeune Marine Corps Base, Disposal of Non-Hazardous Solid Waste Project, Implementation, COE Section 404 and NPDES Permits, Onslow County, NC.

Summary: EPA had no objections to the proposed action.

Dated: January 30, 1995.

William D. Dickerson,

Director, Federal Agency Liaison Division, Office of Federal Activities.

[FR Doc. 95–2685 Filed 2–2–95; 8:45 am]

BILLING CODE 6560–50–U

[ER–FRL–4719–8]

Environmental Impact Statements; Availability

Responsible: Office of Federal Activities, General Information (202) 260–5076 OR (202) 260–5075.

Weekly receipt of Environmental Impact Statements Filed January 23, 1995 Through January 27, 1995 Pursuant to 40 CFR 1506.9.

EIS No. 950025, Draft EIS, AFS, UT, Jacob/Swale Vegetation Management Project, Implementation, Dixie National Forest, Escalante Ranger District, Garfield County, UT, Due: March 20, 1995, Contact: Kevin R. Schulkoski (801) 826–5400.

EIS No. 950026, Draft EIS, AFS, MT, Wagner-Atlanta Vegetation Treatment Project, Implementation, Helena National Forest, Townsend Ranger District, Meagher County, MT, Due: March 20, 1995, Contact: George Weldon (406) 266–3425.

EIS No. 950027, Final EIS, FHW, NC, US 421 Highway Improvements, East of Secondary Road 2433 to West of I–77, Funding and Possible COE 404 Permit, Wilkes and Yadkin Counties, NC, Due: March 06, 1995, Contact: Nicholas L. Graf (919) 856–4346.

EIS No. 950028, Final EIS, FHW, OR, New Eugene Transfer Station, Site Selection and Construction, Funding, McDonald Site or IHOP Site, Lane County, OR, Due: March 06, 1995, Contact: Terry L. Ebersole (206) 220–7954.

EIS No. 950029, Draft SUPPLEMENT, AFS, WA, East Curlew Creek Analysis Area, Harvesting Timber and Road Construction, Updated Information, Portion of Profanity Roadless Area, Colville National Forest, Republic Ranger District, Ferry County, WA, Due: March 20, 1995, Contact: Patricia Egan (509) 775–3305.

EIS No. 950030, Draft EIS, AFS, OR, Sandy River Delta Plan, Implementation, Special Management Area (SMA), Columbia River Gorge National Scenic Area (NSA), Several Permits for Approval, US Coast Guard Bridge Permit and COE Section 404 Permit, Multnomah County, OR, Due: March 20, 1995, Contact: Virginia Kelly (503) 386–2333.

EIS No. 950031, Draft EIS, USN, CA, Long Beach Naval Hospital Disposal and Reuse, NPDES Permit, City Long Beach, CA, Due: March 20, 1995, Contact: Jo Ellen Anderson (619) 532–3912.

EIS No. 950032, Final EIS, IBR, UT, Narrows Multi-Purpose Water Development Project, Construction and Operation, Funding, Gooseberry Creek, Manti-La Sal National Forest, Sanpete County, UT, Due: March 06, 1995, Contact: Ron Willhite (303) 236–9336.

EIS No. 950033, Final EIS, FHW, MN, I–35 W/Washington Avenue South in Minneapolis to I–35E in Burnsville Improvements, Construction and Reconstruction, Funding, COE Section 404 and 10 Permits, U.S. CGD Permit, Cities of Minneapolis and Burnsville, Hennepin and Dakota Counties, MN, Due: March 06, 1995, Contact: Stephen Bahler (612) 290–3259.

EIS No. 950034, Draft EIS, AFS, AZ, Carlotta Open-Pit Copper Mine Project, Construction and Operation, Plan of Operations and COE Section 404 Permit, Tonto National Forest, Gila and Pinal Counties, AZ, Due: March 27, 1995, Contact: Paul M. Stewart (602) 225–5200.

Amended Notices

EIS No. 940525, Draft EIS, DOD, HI, Kauai Acoustic Thermometry of Ocean Climate (ATOC) Project and Marine Mammal Research Program (MMRP), Funding, Marine Manual Research Permit and COE Section 10 Permit Issuance, Kauai, HI, Due: March 09, 1995, Contact: Marilyn Cox (619) 534–3860. Published FR 16–95—Review period extended.

Dated: January 31, 1995.

William D. Dickerson,

Director, Federal Agency Liaison Division, Office of Federal Activities.

[FR Doc. 95–2686 Filed 2–2–95; 8:45 am]

BILLING CODE 6560–50–U

[FRL–5150–S]

Interagency Working Group on Environmental Justice; Notification of Availability of Federal Agency Environmental Justice Strategies for Comment

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations'' (February 11, 1994) requires Federal agencies to develop Environmental Justice strategies for carrying out the requirements of the Executive Order. The Order also permits public input ''relating to the incorporation of environmental justice principles into Federal agency programs or policies.''

As part of its effort to seek public input, the Interagency Working Group will make available to the public, the drafts of the Federal agency strategies. The following draft strategies are available for distribution at this time:

Publication No. and Agency or Department

200–D–95–900—Agriculture
200–D–95–901—Defense
200–D–95–902—Energy
200–D–95–001—Environmental Protection Agency
200–D–95–903—Health, Human Services
200–D–95–904—Housing and Urban Development
200–D–95–905—Interior
200–D–95–906—Justice
200–D–95–907—Nuclear Regulatory Commission

These strategies may be obtained, free of charge, by contacting: The National Center for Environmental Publications and Information, P.O. Box 42419, Cincinnati, Ohio 45202; Phone: 513/489–8190; FAX: 513/489–8695 (Please include publication number).

The following draft strategies should be available shortly; for information about their availability please contact: Department of Commerce—Paul Taggart (202) 482–4115; Department of Labor—Stephen Mallinger (202) 219–7031; Department of Transportation—Antonio Califa (202) 366–4640; and National Aeronautics and Space Administration—Robert Hammond (202) 358–0230.

Comments—Send any comments on the strategies to the appropriate agency contact listed below *by March 1, 1995.*

Agency of Department, Contact, and Fax

Agriculture—Velma Charles-Shannon, Office of Civil Rights Enforcement, 14 and Independence Ave., SW., Room 39A, Washington, DC 20250, (202) 205–2891
Defense—Len Richeson, Environmental Security, 3000 Defense Pentagon, Washington, DC 20301–3000, (703) 604–5396
Energy—Georgia Johnson, Room 5B110, Dept. of Energy, Washington, DC 20585, (202) 586–3075
Environmental Protection Agency—Clarice Gaylord, Office of Environmental Justice, 3103, 401 M St., SW., Washington, DC, 20460, (202) 260–0852
Health and Human Services—DHHS Environmental Justice Strategic Plan, c/o Office of Minority Health Resource Center, P.O. Box 37337, Washington, DC 20013–7337, (301) 589–0884
Housing and Urban Development—Richard Broun, Dept. of HUD, Room 7240, 451 7th St, SW., Washington, DC 20410, (202) 708–3363
Interior—Robert Faithful, Office of Environmental Policy and Compliance, Dept. of Interior MS 2340, 1849 C Street, NW., Washington, DC 20240, (202) 208–6970
Justice—Cathy Sheafor, Director of Environmental Justice, DOJ, Office of the Associate Attorney General, Room 5214, 10th and Constitution, NW., Washington, DC 20530, (202) 307–3904
Nuclear Regulatory Commission—Maria Lopez-Otin, NRC, Federal Liaison, Office of State Programs, Washington, DC 20555, (301) 504–3502

Dated: January 31, 1995.

Jonathan Z. Cannon,

Assistant Administrator for Administration and Resources Management.

[FR Doc. 95–2845 Filed 2–2–95; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

January 25, 1995.

The Federal Communications (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. For further information contact Shoko B. Hair, Federal Communications Commission, (202) 418–1379.

Federal Communications Commission

OMB Control No.: 3060–0620.

Title: Universal Service Fund Data Request.

Expiration Date: 10/31/95.

Estimated Annual Burden: 125,193 total annual hours; 87 hours per response.

Description: The Federal Communications Commission has issued a Notice of Inquiry to evaluate various means of providing financial assistance to support telephone service in areas with high costs of service. The Universal Service Fund Data Request will give the Commission, State regulatory agencies, local exchange carriers (LECs), and interexchange carriers, and other interested parties, the ability to compare the effects of various assistance mechanisms on the telecommunications industry as a whole, as well as on an individual LECs. The importance of the Universal Service Fund goals and the substantial amount of money involved require thorough analysis of those financial effects and their implications, if any, for reasonably-priced local telephone service. The respondents consist of approximately 1439 LECs.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–2677 Filed 2–2–95; 8:45 am]

BILLING CODE 6712–01–M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

January 26, 1995.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW, Suite 140, Washington, DC 20037, (202) 857–3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 418–0214. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, Room 10214 NEOB, Washington, DC 20503, (202) 395–3561.

OMB Number: 3060–0536.

Title: Rules and Requirements for Telecommunications Relay Services (TRS) Interstate Cost Recovery.

Form Number: FCC Form 431.

Action: Revision of a currently approved collection.

Respondents: Businesses or other for-profit.

Frequency of Response: Annually and on occasion reporting requirements

Estimated Annual Burden: 5,000 responses, 9.266 hours average burden per response, 46,330 hours total annual burden.

Needs and Uses: The Americans with Disabilities Act of 1990 (ADA) was enacted with the purpose of providing a clear and comprehensive national mandate to end discrimination against individuals with disabilities and to bring persons with disabilities into the economic and social mainstream of American life; to provide enforceable standards addressing discrimination against individuals with disabilities, and to ensure that the Federal government plays a central role in enforcing these standards on behalf of individuals with disabilities. On February 19, 1993, the Commission adopted an Order on Reconsideration, Second Report and Order and Further Notice of Proposed Rulemaking in this proceeding (hereinafter referred to as TRS II). In TRS II, the Commission adopted a shared-funding mechanism to

implement interstate TRS cost recovery pursuant to Title IV of the ADA, and sought further comments on its proposed rules and requirements outlining the specifics of the shared-funding cost recovery plan. See 47 CFR 64.604(c)(4) (iii). Pursuant to Section 64.604(c)(4)(iii)(A), every carrier providing interstate telecommunications services must contribute to the TRS Fund on the basis of its relative share of gross interstate revenues. The types of interstate services for which contributions must be made include, but are not limited to, cellular telephone and paging, mobile radio, operator services, personal communication service (PCS), interstate access, alternative access and special access, packet-switched, WATS, 800, 900, message telephone service, interstate private line, telex, telegraph, video, satellite, international, interstate intraLATA and resale services. The FCC Form 431 has been revised to include PCS and mobile services. Also, where two carriers have merged during the year, the successor company should report total revenues for the year for both the predecessor and successor operations. However, the two carriers would continue to report separately if each maintained separate corporate identities and continued to operate. Additionally, the calculation of contribution rate changed for the 1995 filing year.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–2679 Filed 2–2–95; 8:45 am]

BILLING CODE 6712–01–F

[Gen Docket No. 88–476; DA 94–1329]

Private Land Mobile Radio Services; New York Metropolitan Area Public Safety Plan Amendment

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Acting Chief, Land Mobile and Microwave Division and the Acting Chief, Spectrum Engineering Division released an Order amending the Public Safety Radio Plan for the New York Metropolitan Area (Region 8). As a result of accepting the amendment for the Plan for Region 8, the interests of the eligible entities within the region will be furthered.

EFFECTIVE DATE: December 9, 1994.

FOR FURTHER INFORMATION CONTACT: Betty Woolford, Private Radio Bureau, Policy and Planning Branch, (202) 418-0620.

Federal Communications Commission.

Rosalind K. Allen,

Acting Chief, Land Mobile and Microwave Division.

[FR Doc.95–2678 Filed 2–2–95; 8:45 am]

BILLING CODE 6712–01–F

FEDERAL RESERVE SYSTEM

ESB Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than February 28, 1995.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. ESB Bancorp, Inc., Enfield, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Enfield Savings Bank, Inc., SSB, Enfield, North Carolina.

B. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Hibernia Corporation, New Orleans, Louisiana; to merge with Progressive Bancorporation, Inc., Houma, Louisiana, and thereby indirectly acquire Progressive Bank & Trust Company, Houma, Louisiana.

Board of Governors of the Federal Reserve System, January 30, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–2675 Filed 2–2–95; 8:45 am]

BILLING CODE 6210–01–F

Regions Financial Corporation; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 21, 1995.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Regions Financial Corporation, Birmingham, Alabama; to acquire Fidelity Federal Savings Bank, Dalton, Georgia, and thereby engage in the

operation of a federal savings bank, pursuant to § 225.25(b)(9) of the Board's Regulation Y. The proposed activity will be conducted throughout the State of Georgia.

Board of Governors of the Federal Reserve System, January 30, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–2676 Filed 2–2–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95G–0009]

American Dairy Products Institute; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the American Dairy Products Institute has filed a petition (GRASP 1G0371), proposing to affirm that whey protein isolate and dairy product solids are generally recognized as safe (GRAS) as direct human food ingredients and to broaden the specifications for reduced lactose whey, reduced minerals whey, and whey protein concentrate.

DATES: Written comments by April 4, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFS–207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that the American Dairy Products Institute, 130 North Franklin St., Chicago, IL., (c/o Keller and Heckman, Washington, DC) has filed a petition (GRASP 1G0371), proposing that whey protein isolate and dairy product solids be affirmed as GRAS for use as direct human food ingredients, and to broaden the specifications for reduced lactose whey, reduced minerals whey, and whey protein concentrate.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Interested persons may, on or before April 4, 1995, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 26, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–2629 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0004]

Vaginal Contraceptive Drug Products; Guidance on Content of New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for manufacturers of vaginal contraceptive drug products entitled, ''Guidance for Development of Vaginal Contraceptive Drugs.'' This guidance document is intended to facilitate the development of data in support of new drug applications (NDA's), which FDA has proposed to require for all over-the-counter (OTC) vaginal contraceptives.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Development of Vaginal Contraceptive Drugs'' to the Division of Metabolism and Endocrine Drug Products (HFD–510), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The guidance document is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Lisa Stockbridge, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3520.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Guidance for Development of Vaginal Contraceptive Drugs'' on content of NDA's for manufacturers of vaginal contraceptive drug products. As part of FDA's ongoing review of OTC drug products, the agency is publishing elsewhere in this issue of the **Federal Register** a proposed rule that addresses OTC vaginal contraceptive drug products. The preamble to that proposed rule sets forth FDA's determination that the effectiveness of OTC vaginal contraceptives is highly variable and is dependent on final formulation. Because in vitro testing does not adequately predict the effectiveness of these products, FDA is proposing to call for the submission of product-specific marketing applications for vaginal contraceptives, including effectiveness data obtained from clinical studies of the products in their final formulations.

The guidance document is intended to assist manufacturers in the preparation of NDA's for vaginal contraceptive drug products. It describes the chemistry, pharmacology,

biopharmaceutic, and clinical information required in support of these applications for vaginal contraceptive drug products.

Like other guidance issued by FDA, this document states practices or procedures that may be useful, but are not legal requirements. Such guidance represents the agency's position at the time of issuance. A person may follow the guidance or may choose to follow alternate practices or procedures. If a person chooses to use alternate practices or procedures, that person may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA.

A guidance such as this does not bind FDA, and it does not create or confer any rights, privileges, or benefits for or on any person. When a guidance states a requirement imposed by statute or regulation, however, the requirement is law, and its force and effect are not changed in any way by virtue of inclusion in the guideline.

Dated: January 13, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 95–2630 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

AGENCY: Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96–511).

1. *Type of Information Collection:* Reinstatement, without change, of a previously approved collection; *Type of Review Requested:* Regular submission; *Title of Information Collection:* Medicaid Eligibility Quality Control (MEQC) Statistical Tables; *Form No.:* HCFA–302–309; *Use:* The MEQC statistical tables yield information concerning Medicaid eligibility payment error rates, which enable the HCFA to identify patterns that can lead to the misspending of Medicaid dollars; *Respondents:* State or local governments; *Obligation to Respond:* Required to obtain or retain benefit; *Number of Respondents:* 54; *Total Annual Responses:* 108; *Total Annual Hours Requested:* 175.5.

2. *Type of Information Collection:* Reinstatement, without change, of a previously approved collection; *Type of Review Requested:* Regular submission; *Title of Information Collection:* Transmittal and Notice of Approval of State Plan Material; *Form No.:* HCFA–179; *Use:* The HCFA–179 is used by State agencies to transmit State plan material to HCFA for approval prior to amending their State plans; *Respondents:* State or local governments; *Obligation to Respond:* Required to obtain or retain benefit; *Number of Respondents:* 57; *Total Annual Responses:* 22; *Total Annual Hours Requested:* 1254.

Additional Information or Comments: Call the Reports Clearance Office on (410) 966–5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 26, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95–2636 Filed 2–2–95; 8:45 am]

BILLING CODE 4120–03–P

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

AGENCY: Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services (HHS), has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96–511).

1. *Type of Information Collection:* New; *Type of Review Requested:* Regular Submission; *Title of Information Collection:* Criteria for Medicare Coverage of Lung Transplants; *Form No.:* HCFA–R–170; *Use:* Medicare participating hospitals must file an application to be approved for coverage and payment of lung transplants performed on Medicare beneficiaries; *Respondents:* Business or other for profit; *Total Annual Responses:* 15; *Number of Respondents:* 15; *Total Annual Hours Requested:* 1,800.

2. *Type of Information Collection:* New; *Type of Review Requested:* Regular Submission; *Title of Information Collection:* Evaluation of the Drug Use Review Demonstrations Projects; *Form No.:* HCFA–R–171; *Use:* The Omnibus Budget Reconciliation Act of 1990 mandated drug utilization review demonstration projects to test the cost-effectiveness of both on-line prospective drug utilization review and payment to pharmacists for cognitive services. The survey will determine the attitudes, perceptions, and behavior of pharmacists relative to the two services mentioned. The survey is necessary to evaluate complex behavorial interactions; *Respondents:* Business or other for profit; *Total Annual Responses:* 670 (owner/manager) and 1,710 (pharmacist); *Number of Respondents:* 670 (owner/manager) and 1,710 (pharmacist); *Total Annual Hours Requested:* 55.61 (owner/manager) and 342.0 (pharmacist).

3. *Type of Information Collection:* New; *Type of Review Requested:* Regular Submission; *Title of Information Collection:* Evaluation of the Community Supported Living Arrangements Program (CSLA); *Form No.:* HCFA–R–172; *Use:* This survey will collect data on a sample of 240 persons receiving Medicaid CSLA services and about the agencies and individuals providing those services to them, in order to describe the nature, adequacy, cost, and quality of CSLA services, and the extent to which these contribute to community inclusion, desired lifestyles, health and safety, self-determination, and choice; *Respondents:* Business or other for profit; *Total Annual Responses:* 720; *Number of Respondents:* 240; *Total Annual Hours Requested:* 560.

Additional Information or Comments: Call the Reports Clearance Office on (410) 966–5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503

Dated: January 26, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95–2724 Filed 2–2–95; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Correction for Program Announcement and Proposed Review Criteria for Grants for Geriatric Education Centers for Fiscal Year 1995

The Health Resources and Services Administration (HRSA) announced, in the **Federal Register** on January 9, 1995 at 60 FR 2396, that applications are being accepted for fiscal year (FY) 1995 Grants for Geriatric Education Centers funded under the authority of section 777(a) of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408. This announcement also proposed two additional review criteria. Following is information regarding where to send public comments on the review criteria. This information was inadvertently omitted from the original notice.

Interested persons are invited to comment on the proposed review criteria. The comment period is 30 days. All comments received on or before March 6, 1995 will be considered before the final review criteria are established. Written comments should be addressed to: Neil Sampson, Director, Division of Associated, Dental, and Public Health Professions, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8–101, 5600 Fishers Lane, Rockville, Maryland 20857

All comments received will be available for public inspection and copying at the Division of Associated, Dental, and Public Health Professions, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

Dated: January 27, 1995.

Ciro V. Sumaya,

Administrator.

[FR Doc. 95–2626 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–15–P

Maternal and Child Health Services; Federal Set-Aside Program; Research and Training Grants

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The Maternal and Child Health Bureau (MCHB), HRSA, announces that fiscal year (FY) 1995 funds are available for Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS) research and training grants. Awards will be made under the program authority of section 502(a) of the Social Security Act, the MCH Federal Set-Aside Program. MCH research and training grants improve the health status of mothers and children through: development and dissemination of new knowledge; demonstration of new or improved ways of delivering care or otherwise enhancing Title V program capacity to provide or assure provision of appropriate services; and preparation of personnel in MCH-relevant specialties. Grants for SPRANS genetic services and special MCH improvement projects (MCHIP), which contribute to the health of mothers, children, and children with special health care needs (CSHCN), are being announced in a separate notice. No new SPRANS hemophilia program grants will be funded in FY 1995.

Of the approximately $7.3 million available for SPRANS research and $35.6 million for training in FY 1995, about $1.0 million will be available to support approximately 8 new and competing continuation MCH research projects and about $19.5 million will be available for 47 new and competing training projects. About $6.5 million will be used to support continuation of existing MCH research and $16.3 million will support continuation of existing training. The actual amounts available for awards and their allocation may vary depending on unanticipated program requirements and the volume and quality of applications. Awards are made for grant periods which generally run from 1 up to 5 years in duration. Funds for research and training grants under the MCH Federal Set-Aside Program are appropriated by Public Law 103–333. A revised regulation implementing the Federal Set-Aside Program (42 CFR part 51a) was published in the July 19, 1994, issue of the **Federal Register** at 59 FR 36703.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The MCH Block Grant Federal Set-Aside Program addresses issues related to the Healthy People 2000 objectives of improving maternal, infant, child and adolescent health and developing service systems for children with special health care needs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office Washington, DC 20402–9325 (telephone: 202 783–3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

ADDRESS: Grant applications for MCH research and training grants must be obtained from and submitted to: Chief, Grants Management Branch, Office of Program Support, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1440. Applicants for research projects will use Form PHS 398, approved by the Office of Management and Budget (OMB) under control number 0925–0001. Applicants for training projects will use Form PHS 6025–1, approved by OMB under control number 0915–0060. Requests should specify the category or categories of activities for which an application is requested so that the appropriate forms, information and materials may be provided.

DATES: Potential applicants are invited to request application packages for the particular program category in which they are interested, and to submit their applications for funding consideration. Deadlines for receipt of applications differ for the several categories of grants. These deadlines are as follows:

MCH FEDERAL SET-ASIDE COMPETITIVE RESEARCH AND TRAINING GRANTS ANTICIPATED DEADLINE, AWARD, FUNDING, AND PROJECT PERIOD INFORMATION, BY CATEGORY; FY 1995

Category	Application deadline	Estimated number of awards	Estimated amounts available	Project period
Grants in the following areas:				
1. Research	Cycle 1: 3/1/95* ..... Cycle 2: 8/1/95*	up to 8	$1.0 million	up to 5 years.
2. Long Term Training:				
2.1. Pediatric Pulmonary Centers	4/3/95	up to 9	$1.5 million	up to 5 years.
2.2. Neuro developmental Disabilities	4/3/95	up to 30 ...	$18 million	up to 5 years.
3. Continuing Education	7/3/95	up to 8	$400,000	1–3 years.

* Approximately one-half of the available funds are allocated to each cycle. Applications approved but not funded in one cycle are automatically carried forward to the next.

Applications will be considered to have met the deadline if they are either: (1) received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants should request a legibly dated receipt from a commercial carrier or the U.S. Postal Service, or obtain a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications or those sent to an address other than specified in the **ADDRESS** section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information should be directed to the contact persons identified below for each category covered by this notice. Requests for information concerning business management issues should be directed to: Dorothy M. Kelley, Acting Grants Management Officer (GMO), Maternal and Child Health Bureau, at the address specified in the **ADDRESS** section.

SUPPLEMENTARY INFORMATION: To facilitate the use of this announcement, information in this section has been organized, as outlined in the Table of Contents below, into a discussion of: Program Background, Special Concerns, Overall Review Criteria, SPRANS Program, and Eligible Applicants. In addition, for each research and training funding category or subcategory, information is presented under the following headings:

- Application Deadline
- Purpose
- Priorities
- Special Eligibility Considerations
- Grants/Amounts
- Contact

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1. Program Background and Objectives

Under Section 502 of the Social Security Act, as amended by the Omnibus Budget Reconciliation Act (OBRA) of 1989, 12.75 percent of amounts appropriated for the MCH Block Grant in excess of $600 million are set aside by the Secretary of Health and Human Services (HHS) for special Community Integrated Service Systems projects under Section 501(a)(3) of the Act. Of the remainder of the total appropriation, 15 percent of the funds are to be retained by the Secretary to support (through grants, contracts, or otherwise) special projects of regional and national significance, research, and training with respect to maternal and child health and children with special health care needs (including early intervention training and services development); for genetic disease testing, counseling, and information development and dissemination programs; for grants (including funding for comprehensive hemophilia diagnostic treatment centers) relating to hemophilia without regard to age; and for the screening of newborns for sickle cell anemia, and other genetic disorders and follow-up services. The MCH SPRANS set-aside was established in 1981. Support for projects covered by this announcement will come from the SPRANS set-aside. Availability of FY 1995 funds for MCH research and training grants is being announced separately from other SPRANS grants this year in order to reduce confusion to potential applicants from announcement of grants in very large numbers of SPRANS categories and subcategories. The research and training grants covered in this notice are intended to improve the health status of mothers and children.

Research programs focus on the development of new knowledge for application in health care promotion and prevention efforts directed at pregnant women, women of childbearing age, infants, children, adolescents, and children with special health care needs and their families. Findings are expected to have potential for application in health care delivery programs for mothers and children.

Training programs focus on development of professionals for leadership roles, in combination with advanced professional preparation. Training is intended to accomplish the dual objectives of developing high levels of clinical competence and developing leadership attributes which extend beyond clinical acumen and skills. To achieve the latter objective, emphasis is placed on those curriculum and practicum areas which relate to: populations as well as individuals; systems of care as well as specific services; community-based services as well as institution-based; program administration in addition to clinical expertise; public policy in addition to practice policy; and research in addition to putting new knowledge into practice. In addition, leadership training emphasizes cultural and linguistic competence in serving the end user; trainees, however, are not end users. With an understanding of and appreciation for these broader issues and aspects of health care, professionals are more adequately prepared to deliver care and to provide leadership in advancing the field to better serve mothers and children.

''Continuing Education'' (CE) is any short-term, non-degree program offered by an institution of higher learning. Continuing Education focuses on increasing leadership skills of MCH health professionals; facilitating timely transfer and application of new information, research findings, and technology related to MCH; and updating and improving the knowledge and skills of health and related professionals in programs serving mothers and children, including children with special health care needs (CSHCN). As a result of the CE, professionals are more adequately prepared to deliver comprehensive services and to provide leadership in advancing the field to better serve mothers and children.

2. Special Concerns

In its administration of the MCH Services Block Grant, the MCHB places special emphasis on improving service delivery to women and children from racial and ethnic minority populations who have had limited access to accessible care. This means that SPRANS projects are expected to serve and appropriately involve in project activities individuals from the populations to be served, unless there are compelling programmatic or other justifications for not doing so. The MCHB's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB.

3. Project Review and Funding

Within the limit of funds determined by the Secretary to be available for the activities described in this announcement, the Secretary will review applications for funds under the specific project categories in section 4 below as competing applications and may award Federal funding for projects which will, in her judgment, best promote the purpose of title V of the Social Security Act, with special emphasis on improving service delivery to women and children from culturally distinct populations; best address achievement of Healthy Children 2000 objectives related to maternal, infant, child and adolescent health and service systems for children at risk of chronic and disabling conditions; and otherwise best promote improvements in maternal and child health.

3.1 Criteria for Review

The criteria which follow are used, as pertinent, to review and evaluate applications for awards under all SPRANS grants and cooperative agreement project categories announced in this notice. Further guidance in this regard is supplied in application guidance materials, which may specify variations in these criteria.

—The quality of the project plan or methodology.
—The need for the research or training.
—The extent to which the project will contribute to the advancement of maternal and child health and/or improvement of the health of children with special health care needs;
—The extent to which the project is responsive to policy concerns applicable to MCH grants and to program objectives, requirements, priorities and/or review criteria for specific project categories, as published in program announcements or guidance materials.
—The extent to which the estimated cost to the Government of the project is reasonable, considering the anticipated results.
—The extent to which the project personnel are well qualified by training and/or experience for their roles in the project and the applicant organization has adequate facilities and personnel.
—The extent to which, insofar as practicable, the proposed activities, if well executed, are capable of attaining project objectives.
—The strength of the project's—plans for evaluation.
—The extent to which the project will be integrated with the administration of the MCH Block Grant, State primary care plans, public health, and prevention programs, and other related programs in the respective State(s).
—The extent to which the application is responsive to the special concerns and program priorities specified in this notice.

3.2 Funding of Approved Applications

Final funding decisions for SPRANS research and training grants are the responsibility of the Director, MCHB. In considering scores for the ranking of approved applications for funding, preferences may be exercised for groups of applications; for example, new projects may be funded ahead of competing continuations, or vice versa. Within any category of approved projects, the score of an individual project may be favorably adjusted if the project addresses specific priorities identified in this notice. In addition, special consideration in assigning scores may be given by reviewers to individual applications that address areas identified in this notice as special concerns.

4. Special Projects of Regional and National Significance

Three categories of SPRANS grants are discussed below: Research, Long Term Training, and Continuing Education:

4.1. Research Grants

- Application Deadlines: March 1 and August 1, 1995.
- Purpose: To encourage research in maternal and child health which has the potential for ready transfer of findings to health care delivery programs. Research grants may be made only to public or nonprofit institutions of higher learning and public or nonprofit private agencies and organizations engaged in research or in maternal and child health or programs for CSHCN.

Special consideration will be given to projects which address the factors and processes that lead to disparities in health status and use of services among minority and other disadvantaged groups as well as health promoting behaviors, quality outcome measures, and systems integration/reform.

- Grants/Amounts: Approximately $1.0 million will be available to support up to 8 new or competing renewal research projects at an average of $125,000 per award for one year. Project periods are generally 3 years but may be up to 5 years.
- Contact: For programmatic or technical information, contact Gontran Lamberty, Dr.P.H., telephone: 301 443–2190.

4.2. Long Term Training Grants

- Application Deadline: April 3, 1995.
- Purpose: Awards to institutions of higher learning to support and strengthen MCH programs through long term training of health professionals at the graduate and postgraduate levels, with a special focus on family-centered, community-based care. The programs are designed to develop leadership personnel to provide for comprehensive health, including health promotion and disease prevention, and related services to mothers and children; and to address special issues, such as HIV; injury; minority health concerns; and substance abuse. Training is provided to a wide range of health professionals who serve mothers and children.

Contact: For programmatic and technical information, contact Elizabeth

Brannon, M.S., R.D., telephone: 301 443–2190.

The following subcategories have been identified for competition in FY 1995 under the MCH long term training program:

4.2.1. Pediatric Pulmonary Centers

- Application Deadline: April 3, 1995.
- Purpose: To support the development, enhancement, or improvement of community-based care for children with chronic respiratory diseases and their families in a wide geographic area by providing interdisciplinary training of a range of professional personnel and by working with State and local health agencies and providers—public, private, or voluntary. The centers are expected to be models of excellence in training, service and research related to chronic respiratory diseases in infants and children.
- Special Qualifications: Applicant qualifications include meeting the special requirements for Training Programs in Pediatric Pulmonology of the Accreditation Council for Graduate Medical Education (ACGME) Residency Review Committee.
- Grants/Amounts: About $1.5 million will be available to support up to 6 new or competing renewal projects in this subcategory. Grant awards average $250,000 for one year. Project periods are up to five years.
- Contact: For programmatic and technical information, contact Elizabeth Brannon, M.S., R.D., telephone 301 443–2190.

4.2.2. MCH Interdisciplinary Leadership Education/Training in Neurodevelopmental and Related Disabilities

- Application Deadline: April 3, 1995.
- Purpose: To support and strengthen MCH programs through long term training of a wide range of health professionals at the graduate and post-graduate levels, with a special focus on family-centered, community-based care. The programs are designed to develop leadership personnel to provide for comprehensive health, including health promotion and disease prevention, and related services to children (infants through adolescents) with, or at risk for, neurodevelopmental delays, developmental disabilities, mental retardation, or multiple systems disabilities, through interdisciplinary clinical training, and through provision of continuing education, technical assistance and consultation.
- Special Qualifications: Universities with an accredited medical school which has defined working relationships/agreements with academic (i.e., degree granting) schools or departments providing graduate training in all requisite core disciplines identified in the program elements and requirements for this category. Such agreements may be either with components of the applicant institution or with one or more other institutions of higher learning through formal affiliation agreements. Although multiple institutions and programs may, and are encouraged to participate, the application must be submitted by the university at which the major medical and other health profession schools/departments are located. All training components must have their primary locus in, or proximal to, the applicant institution.
- Grants/Amounts: Approximately $18 million will be available to support up to 30 new or competing renewal projects in this subcategory. Grant award amounts will vary depending upon budget requirements. Project periods are up to 5 years.
- Contact: For programmatic and technical information, contact Elizabeth Brannon, M.S., R.D., telephone 301 443–2190.

4.3. Continuing Education

- Application Deadline: July 3, 1995.
- Purpose: To support and strengthen MCH programs and improve MCH systems of care through short term, non-degree related training of health professionals and others providing health and related services for mothers and children; workshops; seminars; institutes; and other related activities intended to develop or improve standards, practices, curriculum or delivery of health care for the MCH population. Continuing Education grants may be made only to public or nonprofit private institutions of higher learning.
- Priorities: Priority for funding in this category will be given to continuing education projects in the following areas:

—Emergency Medical Services for Children.
—Violence Prevention in Schools.
—Core Public Health.

- Grants/Amounts: Approximately $400,000 will be available to support up to 8 new or competing renewal continuing education training projects. Project periods range from 1 to 3 years.
- Contact: For programmatic or technical information, contact Stephanie Bryn, M.P.H., telephone: 301 443–2190.

The categories, priorities, special considerations and preferences described above are not being proposed for public comment this year. In July 1993, following publication of the Department's Notice of Proposed Rulemaking to revise the MCH special project grant regulations at 42 CFR 51a, the public was invited for a 60-day period to submit comments regarding all aspects of the SPRANS application and review process. Public comments regarding SPRANS priorities received during the comment period were considered in developing this announcement. In responding to those comments, the Department noted the practical limits on Secretarial discretion in establishing SPRANS categories and priorities owing to the extensive prescription in both the statute and annual Congressional directives.

Comments on this SPRANS notice which members of the public wish to make are welcome at any time and may be submitted to: Director, Maternal and Child Health Bureau, at the address listed in the **ADDRESS** section. Suggestions will be considered when priorities are developed for the next solicitation.

5. Eligible Applicants

In general, MCH training grants may be made only to public or nonprofit private institutions of higher learning. Research grants may be made only to public or nonprofit private institutions of higher learning and public or nonprofit private agencies and organizations engaged in research in maternal and child health or programs for CSHCN. As noted above, applicants for certain grant categories or subcategories are expected to have additional qualifications.

6. Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 424).

(b) A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State and local health agencies.

7.Executive Order 12372

The MCH Federal set-aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

The OMB Catalog of Federal Domestic Assistance number is 93.110.

Dated: January 31, 1995.

Ciro V. Sumaya,

Administrator.

[FR Doc. 95–2738 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–15–P

Final Funding Preference for Centers of Excellence in Minority Health Professions Education for Fiscal Year 1995

The Health Resources and Services Administration (HRSA) announces the final funding preference for fiscal year (FY) 1995 Grants for Centers of Excellence (COE) in Minority Health Professions Education funded under the authority of section 739, title VII of the Public Health Service Act (the Act), as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992.

Purposes

Grants for eligible Historically Black Colleges and Universities (HBCUs), Hispanic, Native American and Other Centers of Excellence must be used by the schools for the following purposes:

l. To establish, strengthen, or expand programs to enhance the academic performance of minority students attending the school;

2. To establish, strengthen, or expand programs to increase the number and quality of minority applicants to the school;

3. To improve the capacity of such school to train, recruit, and retain minority faculty;

4. With respect to minority health issues, to carry out activities to improve the information resources and curricula of the school and clinical education at the school; and

5. To facilitate faculty and student research on health issues particularly affecting minority groups.

Applicants must address the five legislative purposes. In addition, grants for eligible HBCUs as described in section 799(l)(A) and which have received a contract under section 788B of the Act (Advanced Financial Distress Assistance) for FY 1987 may also be used to develop a plan to achieve institutional improvements, including financial independence, to enable the school to support programs of excellence in health professions education for minority individuals, and to provide improved access to the library and informational resources of the school.

Eligibility

Section 739 authorizes the Secretary to make grants to schools of medicine, osteopathic medicine, dentistry and pharmacy for the purpose of assisting the schools in supporting programs of excellence in health professions education for Black, Hispanic and Native American individuals, as well as for HBCUs as described in section 799(l)(A) and which have received a contract under section 788B of the Act (Advanced Financial Distress Assistance) for FY 1987.

To qualify as a COE, a school is required to:

l. Have a significant number of minority individuals enrolled in the school, including individuals accepted for enrollment in the school;

2. Demonstrate that it has been effective in assisting minority students of the school to complete the program of education and receive the degree involved;

3. Show that it has been effective in recruiting minority individuals to attend the school, including providing scholarships and other financial assistance to such individuals, and encouraging minority students of secondary educational institutions to attend the health professions school; and

4. Demonstrate that it has made significant recruitment efforts to increase the number of minority individuals serving in faculty or administrative positions at the school.

These entities must be located in any of the several states, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, and the Federated States of Micronesia.

Final Funding Preference

A funding preference for this program was proposed in the **Federal Register** on November 1, 1994, at 59 FR 54617. One comment was received during the comment period. The respondent recommended that preference be given to previously funded COE programs which have completed only one grant cycle. We have proposed that preference be given to competing continuation applications (renewals) to direct assistance to quality COE programs that have documented sustained or increased accomplishments under this program. Therefore, the preference will remain as proposed.

A funding preference will be given to competing continuation (renewal) applications for Centers of Excellence programs whose current project periods end in fiscal year 1995.

Additional Information

To obtain information regarding the programmatic aspects of this grant program, direct inquiries to: A. Roland Garcia, Ph.D., Chief, Centers of Excellence Section, Program Coordination Branch, Division of Disadvantaged Assistance, Bureau of Health Professions, HRSA, Parklawn Building, Room 8A–09, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–4493, FAX: (301) 443–5242.

This program is listed at 93.157 in the *Catalog of Federal Domestic Assistance.* It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

This program is not subject to the Public Health System Reporting Requirements.

Dated: January 30, 1995.

Ciro V. Sumaya,

Administrator.

[FR Doc. 95–2625 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–15–P

Health Resources and Services Administration Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of March 1995.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 1, 1995; 9:00 am–5:00 pm; March 2, 1995; 9:00 am–12:00 noon.

Place: Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

Purpose: The Commission: (1) Advises the Secretary on the implementation of the Program, (2) on its own initiative or as the result of the filing of a petition, recommends changes in the Vaccine Injury Table, (3) advises the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions, (4) surveys Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advises the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and (5) recommends to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

Agenda: Agenda items will include, but not be limited to: a vaccine safety update from the Centers for Disease Control and Prevention and the Food and Drug Administration; a report on Children with Special Needs; a report on the National Vaccine Program; and routine Program reports.

Public comment will be permitted before noon and at the end of the full Commission meeting on March 1; and before the Commission adjourns on the second day on March 2. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to Mr. Jerry Anderson, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–35, 5600 Fishers Lane, Rockville, MD 20852; Telephone (301) 443–1533.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation, but desire to make an oral statement, may sign up in Conference Rooms G & H before 10:00 a.m. on March 1 and 2. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Mr. Anderson, Division of Vaccine Injury Compensation, Bureau of Health Professions, Room 8A–35, 5600 Fishers Lane, Rockville, Maryland 20852; Telephone (301) 443–1533.

Agenda Items are subject to change as priorities dictate.

Dated: January 30, 1995.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 95–2624 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications
Name of SEP: Biological and Physiological Sciences
Date: February 13–14, 1995
Time: 8:30 a.m.
Place: Holiday Inn, Chevy Chase, MD
Contact Person: Dr. Sherry Dupere, Scientific Review Administrator, 5333 Westbard Ave., Room 225A, Bethesda, MD 20892, (301) 594–7097

Name of SEP: Clinical Sciences
Date: February 22, 1995
Time: 8:30 a.m.
Place: River Inn, Washington, DC
Contact Person: Dr. Mushtag Khan, Scientific Review Administrator, 5333 Westbard Ave., Room 354B, Bethesda, MD 20892, (301) 594–7168

Name of SEP: Behavioral and Neurosciences
Date: March 3, 1995
Time: 8:30 a.m.
Place: Holiday Inn, Bethesda, MD
Contact Person: Dr. Peggy McCardle, Scientific Review Administrator, 5333 Westbard Ave., Room 305, Bethesda, MD 20892, (301) 594–7293

Name of SEP: Microbiological and Immunological Sciences
Date: March 8, 1995
Time: 2:00 p.m.
Place: NIH, Westwood Building, Room 1A03 Telephone Conference
Contact Person: Dr. Garrett Keefer, Scientific Review Administrator, 5333 Westbard Ave., Room 1A03, Bethesda, MD 20892, (301) 594–7253

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 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: January 27, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–2632 Filed 2–2–95; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Microbiological and Immunological Sciences.

Date: February 3, 1995.

Time: 9:30 a.m.

Place: NIH, Westwood Building, Room 236A Telephone Conference.

Contact Person: Dr. William Branche, Scientific Review Admin., 5333 Westbard Ave., Room 236A, Bethesda, MD 20892, (301) 594–7297.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 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: January 31, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–2874 Filed 2–1–95; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

Agency Forms Undergoing Paperwork Reduction Act Review

Each Friday the Public Health Service (PHS) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call

the PHS Reports Clearance Office on 202–690–7100.

The following requests have been submitted for review since the list was last published on Friday, January 27.

1. Nominations for ATSDR Community Assistance Panels—0923–0007 (Extension, no change)—This information collection mechanism allows the Agency for Toxic Substances and Disease Registry (ATSDR) to assist local communities in the nomination of members of the community to become members of Community Assistance Panels. The panels provide for a two-way exchange of information between ATSDR and the concerned public regarding the public health activities planned for the area. Respondents: Individuals or households; Number of Respondents: 1350; Number of Responses per Respondent: 1; Average Burden per Response: 0.16 hour; Estimated Annual Burden: 225 hours. Send comments to James Scanlon, Office of the Assistant Secretary for Health, Room 737–F, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

2. AIDS Education and Training Centers Program: National Program and Service Record Reporting Form—0915–0154 (Revision)—Information will be obtained from AIDS Education and Training Centers to determine compliance with terms of cooperative agreements and specific project requirements. The National Program and Service Record Data Reporting Form will be used by ETCs to provide standardized reporting of project activities for Federal program monitoring. Respondents: Not-for-profit institutions; Number of Respondents: 17; Number of Responses per Respondent: 4; Average Burden per Response: 30.15 hours; Estimated Annual Burden: 2,050 hours. Send comments to James Scanlon, Office of the Assistant Secretary for Health, Room 737–F, Humphrey Building, 200 Independence Ave. SW., Washington, DC 20201.

3. National Donor Research and Education Study (REDS) 0925–0383 (Revision)—This is a mail survey of a random sample of blood donors from five Blood Centers participating in the REDS program. Data will be used to monitor the safety of the U.S. blood supply and facilitate development, evaluation and refinement of donor recruitment and education strategies. Seven additional items will be asked of a subset of respondents to guide development of the next major round of the survey. Respondents: Individuals or households. Send comments to James Scanlon, Office of the Assistant Secretary for Health, Room 737–F, Humphrey Building, 200 Independence Ave. SW., Washington, DC 20201.

Title	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Currently approved	72,000	1	.33
Additional burden—5 minutes more for a subset of 15,600 donors	.....	.....	1,295

Estimated total annual burden: 25,295 hours

4. Survey of Rural Hospitals on Telemedicine—New—This survey of rural hospitals will identify all rural telemedicine systems in the United States. The information will be used to design a followup study, which will provide baseline data on the systems, a minimum data set for future studies, and evaluation methodologies for future evaluations of these systems. Respondents: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 2,400; Number of Responses per Respondent: 1; Average Burden per Response: .1 hour; Estimated Annual Burden: 250 hours. Send comments to Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

5. Survey of NIH Extramural Shared Instrumentation Activities 0925–0318 (Extension, no change)—It is generally accepted that the capabilities of expensive state-of-the art biomedical instruments can be made available to the largest number of researchers in the most cost-effective manner by awarding them on the condition that they be shared. This study will examine the extent to which such instruments are shared; and how fully they are utilized, by whom, and for what. Respondents: Not-for profit institutions, Business or other for-profit; Number of Respondents: 9,870; Number of Responses Per Respondent: 1; Average Burden per Response: .286 hour; Estimated Annual Burden: 2,819 hours. Send comments to James Scanlon, Office of the Assistant Secretary for Health, Room 737–F, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

6. Study of Consequences of Being Accused of Scientific Misconduct—New—42 CFR Part 50 specifies certain treatment of accused individuals, including restoration of reputation of those when allegations are not confirmed. This voluntary survey will provide background information to assure institutional compliance with regulation and other information. Respondents: Individuals or households; Number of Respondents: 112; Number of Responses per Respondent: 1; Average Burden per Response: .5 hour; Estimated Annual Burden: 56 hours. Send comments to Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

7. X-Ray Examination Program/Federal Mine Safety and Health Act 1977 (42 CFR Part 37)—0920–0020 (Reinstatement)—Information is utilized for early identification of incidence and/or treatment. Identification is followed by clinical management on miners' health, through appropriate notification of medical findings and applicable dust transfer rights. Public affected includes underground coal miners and operators, physicians and x-ray facilities. Respondents: Individuals or households, Business or other for-profit. Send comments to Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

Title	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Roentgenographic Interpretation: 42 CFR 37.40(b) ...	20,000	1.05	.02
Miner Identification Title 42 CFR 37.20	10,000	1	.3
Coal Mine Operator Plan 42 CFR 37.4(a)	500	1	.33
Facility Certification 42 CFR 37.42(c) ...	100	20	.17
Interpreting Physical Certification 42 CFR 37.51(c) ...	300	1	.05

Estimated total annual Burden: 3,940 hours.

Written comments and recommendations concerning the

proposed information collections should be sent within 30 days of this notice directly to the individual designated.

Dated: January 30, 1995.

James Scanlon,

Director, Division of Data Policy, Office of Health Planning and Evaluation.

[FR Doc. 95–2703 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–17–M

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443-6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACCU–LAB, Inc., 405 Alderson St., Schofield, WI 54476, 800–627–8200 (formerly: Alpha Medical Laboratory, Inc., Employee Health Assurance Group, ExpressLab, Inc.)

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615–331–5300

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/205–263–5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–227–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414–355–4444/800–877–7016

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5810

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020

Clinical Reference Lab, 11850 West 85th St., Lenexa, KS 66214, 800–445–6917

CORNING Clinical Laboratories, 2320 Schuetz Rd., St. Louis, MO 63146, 800–288–7293 (formerly: Metropolitan Reference Laboratories, Inc.)

CORNING Clinical Laboratories, 8300 Esters Blvd., Suite 900, Irving, TX 75063, 800–526–0947 (formerly: Damon Clinical Laboratories, Damon/MetPath)

CORNING MetPath Clinical Laboratories, 1355 Mittel Blvd., Wood Dale, IL 60191, 708–595–3888 (formerly: MetPath, Inc.)

CORNING MetPath Clinical Laboratories, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5000 (formerly: MetPath, Inc.)

CORNING National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–1485 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science)

CORNING Nichols Institute, 7470–A Mission Valley Rd., San Diego, CA 92108–4406, 800–446–4728/619–686–3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT))

Cox Medical Centers, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–836–3093

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, Building 38–H, Great Lakes, IL 60088–5223, 708–688–2045/708–688–4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 813–936–5446/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468

Drug Labs of Texas, 15201 I–10 East, Suite 125, Channelview, TX 77530, 713–457–3784

DrugProof, Division of Laboratory of Pathology of Seattle, Inc., 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180/206–386–2672, (formerly: Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969 , 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310

Eagle Forensic Laboratory, Inc., 950 N. Federal Highway, Suite 308, Pompano Beach, FL 33062, 305–946–4324

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267

Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784/915–563–3300, (formerly: Harrison & Associates Forensic Laboratories)

HealthCare/MetPath, 24451 Telegraph Rd., Southfield, MI 48034, 800–444–0106 ext. 650 (formerly: HealthCare/Preferred Laboratories)

Holmes Regional Medical Center Toxicology Laboratory, 5200 Babcock St., N.E., Suite 107, Palm Bay, FL 32905, 407–726–9920

Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051
LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913–888–3927 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.)
Laboratory Specialists, Inc., 113 Jarrell Dr., Belle Chasse, LA 70037, 504–392–7961
Marshfield Laboratories, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–222–5835
MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38175, 901–795–1515
Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43699–0008, 419–381–5213
Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302–655–5227
MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800–832–3244/612–636–7466
Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317–929–3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800–752–1835/309–671–5199
MetPath Laboratories, 4900 Perry Hwy., Pittsburgh, PA 15229, 412–931–7200, (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon)
National Health Laboratories Incorporated, 2540 Empire Dr., Winston-Salem, NC 27103–6710, Outside NC: 919–760–4620/800–334–8627 / Inside NC: 800–642–0894
National Health Laboratories Incorporated, d.b.a. National Reference Laboratory, Substance Abuse Division, 1400 Donelson Pike, Suite A–15, Nashville, TN 37217, 615–360–3992/800–800–4522
National Health Laboratories Incorporated, 13900 Park Center Rd., Herndon, VA 22071, 703–742–3100
National Psychopharmacology Laboratory, Inc., 9320 Park W. Blvd., Knoxville, TN 37923, 800–251–9492
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805–322–4250
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361
Occupational Toxicology Laboratories, Inc., 2002 20th St., Suite 204A, Kenner, LA 70062, 504–465–0751
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 503–687–2134
Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400
PDLA, Inc. (Princeton), 100 Corporate Court, So. Plainfield, NJ 07080, 908–769–8500/800–237–7352
PharmChem Laboratories, Inc., 1505–A O'Brien Dr., Menlo Park, CA 94025, 415–328–6200/800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–595–0294 (formerly: Harris Medical Laboratory)
Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–338–4070/800–821–3627 (formerly: Physicians Reference Laboratory Toxicology Laboratory)
Poisonlab, Inc., 7272 Clairemont Mesa Rd., San Diego, CA 92111, 619–279–2600/800–882–7272
Puckett Laboratory, 4200 Mamie St., Hattiesburg, MS 39402, 601–264–3856/800–844–8378
Regional Toxicology Services, 15305 N.E. 40th St., Redmond, WA 98052, 206–882–3400
Roche Biomedical Laboratories, Inc., 1120 Stateline Rd., Southaven, MS 38671, 601–342–1286
Roche Biomedical Laboratories, Inc., 69 First Ave., Raritan, NJ 08869, 800–437–4986
Roche CompuChem Laboratories, Inc., A Member of the Roche Group, 3308 Chapel Hill/Nelson Hwy., Research Triangle Park, NC 27709, 919–549–8263/800–833–3984 (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory)
Roche CompuChem Laboratories, Inc., Special Division, A Member of the Roche Group, 3308 Chapel Hill/Nelson Hwy., Research Triangle Park, NC 27709, 919–549–8263 (Formerly: CompuChem Laboratories, Inc. - Special Division)
Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130
Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 800–749–3788
S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505–848–8800
Sierra Nevada Laboratories, Inc., 888 Willow St., Reno, NV 89502, 800–648–5472
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91045, 818–376–2520
SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 32748, 904–787–9006 (formerly: Doctors & Physicians Laboratory)
SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 404–934–9205 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 708–885–2010 (formerly: International Toxicology Laboratories)
SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800–523–5447 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301 (formerly: SmithKline Bio-Science Laboratories)
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176
Southwest Laboratories, 2727 W. Baseline Rd., Suite 6, Tempe, AZ 85283, 602–438–8507
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee St., Oklahoma City, OK 73102, 405–272–7052
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 314–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260
TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818–226–4373 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)
UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800–492–0800/818–343–8191 (formerly: MetWest-BPL Toxicology Laboratory)

Richard Kopanda,

Acting Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 95–2548 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–95–1917; FR–3778–N–22]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

ADDRESSES: For further information, contact William Molster, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Judy Breitman, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A–10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to William Molster at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: U.S. Navy: John J. Kane, Deputy Division Director, Dept. of Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–0474; Dept. of Transportation: Ronald D. Keefer, Director, Administrative Services & Property Management, DOT, 400 Seventh St. SW., room 10319, Washington, DC 20590; (202) 366–4246; (These are not toll-free numbers).

Dated: January 27, 1995.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program Federal Register Report for 02/03/95

Suitable/Available Properties

Buildings (by State)

Hawaii

Bldg. S900, Naval Station
Pearl Harbor Co: Honolulu HI 96860–
Landholding Agency: Navy
Property Number: 779510018
Status: Unutilized
Comment: 1980 sq. ft. fall out shelter, possible asbestos and lead base paint, termite damage, off-site use only

Bldg. S902, Naval Station
Pearl Harbor Co: Honolulu HI 96860–
Landholding Agency: Navy
Property Number: 779510019
Status: Unutilized
Comment: 1416 sq. ft., most recent use—storage, possible asbestos and lead base paint, termite damage, off-site use only

Unsuitable Properties

Buildings (by State)

Hawaii

Bldg. 7
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510002
Status: Unutilized
Reason: Extensive deterioration

Bldg. 8
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510003
Status: Unutilized
Reason: Extensive deterioration

Bldg. 9
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510004
Status: Unutilized
Reason: Extensive deterioration

Bldg. 10
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510005
Status: Unutilized
Reason: Extensive deterioration

Bldg. 11
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510006
Status: Unutilized
Reason: Extensive deterioration

Bldg. 12
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510007
Status: Unutilized
Reason: Extensive deterioration

Bldg. 13
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510008
Status: Unutilized
Reason: Extensive deterioration

Bldg. 14
Naval Magazine Lualualei

Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510009
Status: Unutilized
Reason: Extensive deterioration
Bldg. 15
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510010
Status: Unutilized
Reason: Extensive deterioration
Bldg. 39
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510011
Status: Unutilized
Reason: Extensive deterioration
Bldg. 40
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510012
Status: Unutilized
Reason: Extensive deterioration
Bldg. 43
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510013
Status: Unutilized
Reason: Extensive deterioration
Bldg. 44
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510014
Status: Unutilized
Reason: Extensive deterioration
Bldg. 45
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510015
Status: Unutilized
Reason: Extensive deterioration
Bldg. 46
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510016
Status: Unutilized
Reason: Extensive deterioration
Bldg. 101
Naval Magazine Lualualei
Waipio Peninsula Co: Oahu HI
Landholding Agency: Navy
Property Number: 779510017
Status: Unutilized
Reason: Extensive deterioration

Puerto Rico

Bldg. 115
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510001
Status: Unutilized
Reason: Secured Area
Bldg. 117
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510002
Status: Unutilized
Reason: Secured Area
Bldg. 118
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510003
Status: Unutilized
Reason: Secured Area
Bldg. 119
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510004
Status: Unutilized
Reason: Secured Area
Bldg. 120
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510005
Status: Unutilized
Reason: Secured Area
Bldg. 122
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510006
Status: Unutilized
Reason: Secured Area
Bldg. 128
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510007
Status: Unutilized
Reason: Secured Area
Bldg. 129
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510008
Status: Unutilized
Reason: Secured Area

[FR Doc. 95–2350 Filed 2–2–95; 8:45 am]
BILLING CODE 4210–29–M

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N–95–3714; FR–3397–N–08]

Announcement of Funding Awards for the Family Investment Centers Program—Fiscal Year 1994

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for Fiscal Year 1994 Public and Indian Housing Authority applicants under the Family Investment Centers (FIC) Program. The purpose of this document is to announce the names and addresses of the award winners and the amount of the awards to be used to further the Department's commitment to provide families living in public and Indian housing with better access to employment and training opportunities to achieve self-sufficiency and independence, and to rescind scores announced in an amendment published July 29, 1994 (59 FR 38617) regarding the score achievable under the ranking factor that addressed the evidence of need for supportive services by eligible residents.

FOR FURTHER INFORMATION CONTACT: Marcia Y. Martin, Office of Community Relations and Involvement (OCRI), or Dom Nessi, Director, Office of Native American Programs (ONAP), Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, DC 20410; telephone numbers: OCRI (202) 708–4214; and ONAP (202) 755–0032 (these are not toll-free numbers). Hearing- or speech-impaired persons may use the Telecommunications Devises for the Deaf (TDD) by contacting the Federal Information Relay Services on 1–800–877–TDDY (1–800–877–8339) or 202–708–9300 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Section 22 of the United States Housing Act of 1937 (42 U.S.C. 1437t) provides for the establishment of Family Investment Centers. The stated purpose of Section 22 is to provide families living in public housing with better access to educational and employment opportunities to achieve self-sufficiency and independence by: (a) Developing facilities in or near public housing for training and supportive services; (b) mobilizing public and private resources to expand and improve the delivery of such services; (c) providing funding for such essential training and support services that cannot otherwise be funded; and (d) improving the capacity of management to access the training and service needs of families, coordinate the provision of training and services that meet such needs, and ensure the long-term provision of such training and services.

Although section 22 is phrased in terms of families living in public housing, the program is also available to Indian Housing Authorities (IHAs), because of section 527 of the National Affordable Housing Act (104 Stat. 4216: 42 U.S.C. 1437aa note) (NAHA). Section 527 extends the applicability of many NAHA provisions affecting Title I of the 1937 Act (including section 515, which added Section 220 to housing operated by an IHA.

Applicants under FIC receive funding to conduct: Supportive Services (Only), Renovation/Conversion/New Construction (Only), and Combination Supportive Services/Renovation/Conversion/Construction Activities.

On February 28, 1994 (59 FR 9592), HUD published a Notice of Funding Availability (NOFA) that announced $75 million in FIC funds, and stated the Department's intention to use $1 million of FIC funds to undertake a Neighborhood Demonstration Program. The Notice of Demonstration was announced in the **Federal Register** on July 21, 1994 (59 FR 37338). The NOFA was amended four times as follows:

- April 19, 1994 (59 FR 18570). Extended the eligible activities to include new construction and acquisition; and extended the application submission deadline to Friday, July 22, 1994. In addition, the Department announced it's intention to use $5 million of FIC funds for a Youth Development Initiative to address the problems of violence in low-income communities. The Demonstration was announced in the **Federal Register** on May 13, 1994 (59 FR 25262).
- June 9, 1994 (59 FR 29816). Revised the NOFA to include language regarding the Comprehensive Improvement Assistance Program (CIAP). In addition, the Department announced the award of $2 million to the Chicago Housing Authority (CHA) on an emergency basis for FIC eligible purposes.
- July 14, 1994 (59 FR 35945). Announced new application submission requirements for applicants applying to undertake renovation/conversion/new construction activities (only). This amendment was issued subsequent to the Notice of Demonstration published June 21, 1994. In addition, the amendment determined that section 957 of the National Affordable Housing Act (NAHA) was subject to appropriations and not applicable at this time.
- Published July 29, 1994 (59 FR 38617). Announced the change of the explanation of the award of funds and increased the number of points available in the ranking factor that addresses the need for services by eligible residents under the categories for renovation/conversion/supportive services and supportive services (only) from ''10'' points to ''30'' points. In addition, maximum points achievable under Renovation/Conversion/Supportive Services activities were changed from ''135'' to ''155''. Maximum points achievable for Supportive Services (Only) were changed from ''140'' to ''160.''

Accordingly, this announcement further amends the NOFA for Public and Indian Family Investment Centers as published on February 28, 1994 (59 FR 9592), and specifically the Amendment published on July 29, 1994 (59 FR 38617), which increased the points achievable in the ranking factor that addressed the need for services by eligible residents. The Department announces that applications were reviewed and evaluated in accordance with the ranking factors set forth in the original NOFA published February 28, 1994, and did not include the increased number of points specified in the July 29, 1994 amendment. Applications were selected in accordance with ranking guidance set forth in the July 29, 1994 NOFA amendment that allowed that grants may be awarded out of rank order based on project size and geographical diversity. The final ranking list was compiled from lists that included the four top applications (per funding category) per HUD Region; the top applications in states not represented in the former category; and a mix of small, medium and large housing authorities nationwide.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101–235, approved December 15, 1989), the Department is publishing details regarding the recipients of funding awards. This information is provided in Appendix A to this document.

Dated: January 30, 1995.

Joseph Shuldiner,

Assistant Secretary for Public and Indian Housing.

Appendix A

Public Housing Authorities

Lynn Housing Authority
174 South Common Street
Lynn, MA 01905–2513
(617) 598–1225
Contact: Norm Cole
Grant Amount: $985,000

Salem Housing Authority
27 Charter Street
Salem, MA 01970
(508) 744–4432
Contact: Elayne Hart
Grant Amount: $1,000,000

Housing Authority City of Hartford
475 Flatbush Avenue
Hartford, CT 06106
(203) 275–8487
Contact: Paul Capra
Grant Amount: $970,000

Portland Housing Authority
14 Baxter Boulevard
Portland, ME 04101–4935
(207) 773–4753
Contact: John Hodge
Grant Amount: $1,000,000

Manchester Housing & Redevelopment Authority
198 Hanover Street
Manchester, NH 03104
(603) 624–2100
Contact: Grace Grogan
Grant Amount: $710,637

Providence Housing Authority
100 Broad Street
Providence, RI 02903–4129
(401) 751–6400
Contact: Stephen O'Rourke
Grant Amount: $997,500

Van Buren Housing Authority
16 Champlain Street
Van Buren, ME 04785–0158
(207) 868–5441
Contact: Steve La Pierre
Grant Amount: $1,000,000

Municipal Housing Authority of Schenectady
375 Broadway
Schenectady, NY 12305–2595
(518) 372–3346
Contact: Sharron Jordan
Grant Amount: $944,995

Rochester Housing Authority
140 West Avenue
Rochester, NY 14611–2744
(716) 328–6200
Contact: Thomas McHugh
Grant Amount: $1,000,000

Geneva Housing Authority
P.O. Box 153
Geneva, NY 14456–2319
(315) 789–8010
Contact: Andrew Tyman
Grant Amount: $732,626

New York City Housing Authority
250 Broadway
New York, NY 10007–2516
(212) 306–3440
Contact: Jacqueline Barley
Grant Amount: $950,000

Poughkeepsie Housing Authority
P.O. Box 630
Poughkeepsie, NY 12601–0632
(914) 485–8862
Contact: Evelyn Bayon
Grant Amount: $284,282

Atlantic City Housing Authority
227 N. Vermont Avenue
Atlantic City, NJ 08404–7549
(609) 344–1107
Contact: Ron Lewis
Grant Amount: $392,000

Morristown Housing Authority
31 Early Street
Morristown, NJ 07960–3883
(201) 583–6343
Contact: Lawrence Jackson
Grant Amount: $893,440

Housing Authority of Baltimore City
417 E. Fayette Street
Baltimore, MD 21202
(410) 396–3232
Contact: Ralph Multhopp
Grant Amount: $1,000,000

Housing Authority of the City of Clarksburg
916 W. Pike Street
Clarksburg, WV 26301–2250
(304) 623–3322
Contact: Alice Limbers
Grant Amount: $450,802

Dover Housing Authority
1266–76 White Oak Road
Dover, DE 19901–3437

(302) 678–1965
Contact: David Buches
Grant Amount: $1,000,000

Pittsburgh Housing Authority
200 Ross Street
Pittsburgh, PA 15219–2068
(412) 456–5000
Contact: Steven Tyson
Grant Amount: $933,517

Newport News Redevelopment & Housing Authority
P.O. Box 77
Newport News, VA 23607–0077
(804) 247–9701
Contact: Judy Coleman
Grant Amount: $1,000,000

Richmond Redevelopment & Housing Authority
P.O. Box 26887
Richmond, VA 23261–6887
(804) 644–9881
Contact: Joan Seldon
Grant Amount: $999,860

Wise County Redevelopment & Housing Authority
P.O. Box 630
Coeburn, VA 70339–5587
(703) 395–6104
Contact: Charles McConnell
Grant Amount: $979,719

Suffolk Redevelopment & Housing Authority
P.O. Box 3079
Suffolk, VA 23439
(804) 925–6343
Contact: James Armstrong
Grant Amount: $426,318

D.C. Department of Public and Assisted Housing
1133 North Capitol Street, NE
Washington, DC 20002–7599
(202) 535–1500
Contact: Joi Yeldell
Grant Amount: $1,000,000

Housing Opportunity Commission, Montgomery County
10400 Detrick Avenue
Kensington, MD 20895
(301) 933–9750
Contact: Lillian Durham
Grant Amount: $1,000,000

Housing Authority of the City of Macon
P.O. Box 4928
Macon, GA 31208–4928
(912) 752–5070
Contact: John Hiscox
Grant Amount: $1,000,000

Florence Housing Authority
303 North Pine Street
Florence, AL 35630
(205) 764–3030
Contact: Shaler Roberts
Grant Amount: $997,296

Columbia Housing Authority
1917 Harden Street
Columbia, SC 29204–1015
(803) 254–3886
Contact: George Ray
Grant Amount: $638,488

Housing Authority of the City of Charlotte
P.O. Box 36795
Charlotte, NC 28236
(704) 336–5221
Contact: John Hayes
Grant Amount: $999,118

Northwestern Regional Housing Authority
P.O. Box 2510
Boone, NC 28607
(704) 264–6683
Contact: E. Fowler
Grant Amount: $259,700

Housing Authority of the City of McComb
P.O. Box 469
McComb, MS 39648
(601) 684–7291
Contact: Dorothy Jones
Grant Amount: $638,610

Palatka Housing Authority
400 N. 15th Street
Palatka, FL 32077
(904) 329–0132
Contact: Larry Shoeman
Grant Amount: $596,242

Clearwater Housing Authority
P.O. Box 960
Clearwater, FL 34617
(813) 441–3643
Contact: Deborah Vincent
Grant Amount: $999,349

Housing Authority of Louisville
420 South Eighth Street
Louisville, KY 40203
(502) 574–3420
Contact: Kevin Fields
Grant Amount: $1,000,000

Knoxville Community Development Corporation
P.O. Box 3550
Knoxville, TN 39727
(615) 521–8600
Contact: Becky Wade
Grant Amount: $1,000,000

Franklin County Housing Authority
P.O. Box 68
West Frankfurt, IL 62896–0068
(618) 932–2124
Contact: Monica Stewart
Grant Amount: $999,625

Lucus Metropolitan Housing Authority
P.O. Box 477
Toledo, OH 43692–0477
(419) 259–9400
Contact: Arlene Hinson
Grant Amount: $1,000,000

Inkster Housing Commission
4500 Inkster Road
Inkster, MI 48141–1871
(313) 561–2600
Contact: Floyd Simmons
Grant Amount: $999,990

Benton Township Housing Commission
1216 Blossom Lane
Benton Harbor, MI 49022
(616) 927–3541
Contact: Sammie Smith
Grant Amount: $1,000,000

South Bend Housing Authority
P.O. Box 11057
South Bend, IN 46634–0057
(219) 235–9346
Contact: Barbara Lawson
Grant Amount: $1,000,000

Indianapolis Housing Authority
410 North Meridian
Indianapolis, IN 46204–1790
(317) 634–2361
Contact: Marcia Pierce
Grant Amount: $995,794

Public Housing Agency of the City of Saint Paul
480 Cedar Street
St. Paul, MN 55101–2240
(612) 298–5664
Contact: Jon Gutzman
Grant Amount: $1,000,000

Housing Authority of the City of Santa Fe
P.O. Box 4039
Santa Fe, NM 87502–4039
(505) 988–2859
Contact: Michael Varela
Grant Amount: $646,500

Housing Authority of El Paso
P.O. Box 9895
El Paso, TX 79989–9895
(915) 532–5678
Contact: Sharon Busch
Grant Amount: $997,648

Housing Authority of Fort Worth
P.O. Box 430
Fort Worth, TX 76101–0430
(817) 336–2419
Contact: Barbara Holston
Grant Amount: $1,000,000

Housing Authority of San Angelo
P.O. Box 1751
San Angelo, TX 76902–1751
(915) 657–4226
Contact: Fred Contreras
Grant Amount: $248,614

Housing Authority of the City of Galveston
920 53rd Street
Galveston, TX 77551–1099
(409) 744–3641
Contact: Walter Norris
Grant Amount: $1,000,000

Housing Authority of the City of Dumas
Box 115
Dumas, AR 71639–0115
(901) 382–5457
Contact: Margaret Weaver
Grant Amount: $1,000,000

Housing Authority of New Iberia
325 North Street
New Iberia, LA 70560
(318) 364–5515
Contact: Ernest Wilson
Grant Amount: $999,887

Low Rent Housing Agency of Clinton
215 6th Aevenue South
Clinton, IA 52732
(319) 243–1280
Contact: Jayne Jochem
Grant Amount: $571,934

Southern Iowa Regional Housing Authority
219 North Pine Street
Creston, IA 50801–2413
(515) 782–8585
Contact: Harold Riedel
Grant Amount: $449,200

Eastern Iowa Regional Housing Authority
P.O. Box 1140
Dubuque, IA 52004–1140
(319) 556–4166
Contact: Jerelyn O'Connor
Grant Amount: $353,000

North Iowa Regional Housing Authority
217 2nd Street, SW
Mason City, IA 50401
(515) 423–0897
Contact: Karen McGreevey
Grant Amount: $997,921

Olathe Housing Authority

P.O. Box 768
Olathe, KS 66061–0768
(913) 782–2600
Contact: Joyce Keys
Grant Amount: $688,121

Scotts Bluff County Housing Authority
89A Woodley Park Road
Gering, NE 69341–1633
(308) 635–3815
Contact: Don Neureuther
Grant Amount: $408,000

Housing Authority of Saint Louis County
8865 Natural Bridge
St. Missouri, MO 63121–0580
(314) 428–7948
Contact: Julia Tibbs
Grant Amount: $1,000,000

Fort Collins Housing Authority
1715 West Mountain
Ft. Collins, CO 80521
(303) 221–5484
Contact: Rochelle Stephens
Grant Amount: $830,495

Helena Housing Authority
812 Abbey Street
Helena, MT 59601
(406) 442–7970
Contact: Joanne Hale
Grant Amount: $1,000,000

Sioux Falls Housing & Redevelopment Commission
804 S. Minnesota Avenue
Sioux Falls, SD 57104
(605) 331–0704
Contact: Gloria Maher
Grant Amount: $342,865

Housing Authority County of Salt Lake
1962 South 200 East
Salt Lake City, UT 84115
(801) 487–5453
Contact: Mary Thompson
Grant Amount: $1,000,000

Housing Authority of Salt Lake City
1776 S.W. Temple
Salt Lake City, UT 84115
(801) 487–2161
Contact: Terry Feveryear
Grant Amount: $1,000,000

Housing Authority of the City of Los Angeles
P.O. Box 17157
Los Angeles, CA 90017
(213) 252–2500
Contact: Milton Patterson
Grant Amount: $1,000,000

State of Hawaii Housing Authority
P.O. Box 17907
Honolulu, HI 96717
(808) 848–3230
Contact: Bella Belmonte
Grant Amount: $1,000,000

Housing Authority of the City of Oxnard
1470 Colonia Road
Oxnard, CA 93030–3714
(805) 385–8089
Contact: M. Bernard Carn
Grant Amount: $1,000,000

Chandler Housing & Redevelopment Division
99 North Delaware Street
Chandler, AZ 85225–5577
(602) 786–2600
Contact: Jennifer Morrison
Grant Amount: $483,372

Housing Authority of the City of Fresno
1833 ''E'' Street
Fresno, CA 93706
(209) 443–8493
Contact: Donna McBrien
Grant Amount: $1,000,000

Housing Authority of the County of Kings
680 North Douty
Hanford, CA 93230
(209) 582–2806
Contact: Tracy Insley
Grant Amount: $177,827

Housing Authority of the City of Las Vegas
420 North 10th Street
Las Vegas, NV 89101
(702) 386–2727
Contact: Paula McDonald
Grant Amount: $999,750

Alaska Housing Finance Corporation
P.O. Box 230329
Anchorage, AK 99523–0329
(907) 562–2813
Contact: James Gurke
Grant Amount: $789,648

Housing Authority of Portland
135 Southwest Ash
Portland, OR 97204
(503) 228–2178
Contact: Paul Parker
Grant Amount: $1,000,000

Housing Authority of the City of Salem
P.O. Box 808
Salem, OR 97308–0808
(503) 588–6443
Contact: Kevin McTeague
Grant Amount: $492,757

Lincoln County Housing Authority
P.O. Box 1470
Newport, OR 97365
(503) 265–5326
Contact: Georgia Stone
Grant Amount: $738,032

Housing Authority of the City of Tacoma
1728 East 44th Street
Tacoma, WA 98404–4699
(206) 479–3694
Contact: Patricia Harrington
Grant Amount: $1,000,000

Spokane Housing Authority
West 55 Mission Street
Spokane, WA 99201–2044
(509) 328–2953
Contact: Ruth Robinson
Grant Amount: $608,783

Indian Housing Authorities

Seminole Tribe of Florida
3101 Northwest 63rd Avenue
Hollywood, FL 33024
(305) 983–6727
Contact: Peggie Reynolds
Grant Amount: $999,209

Choctaw Nation Indian Housing Authority
P.O. Box G
Hugo, OK 74743
(405) 326–7521
Contact: Gary Batton
Grant Amount: $1,000,000

Cherokee Nation Indian Housing Authority
P.O. Box 1007
Tahlequah, OK 74465
(918) 456–5482
Contact: Joel Thompson
Grant Amount: $918,024

White Earth Reservation Indian Housing Authority
P.O. Box 436
White Earth, MN 56591
(218) 983–3285
Contact: Mary Heisler
Grant Amount: $1,000,000

Absentee Shawnee Indian Housing Authority
P.O. Box 425
Shawnee, OK 74802–0425
(405) 273–1050
Contact: Sherry Wilson
Grant Amount: $1,000,000

Cheyenne River Indian Housing Authority
P.O. Box 480
Eagle Butte, SD 57625
(605) 964–4265
Contact: Wayne Ducheneaux
Grant Amount: $430,000

Menominee Tribal Indian Housing Authority
P.O. Box 459
Keshena, WI 54135–0459
(715) 799–3236
Contact: Brian Van Enkenvoort
Grant Amount: $1,000,000

[FR Doc. 95–2692 Filed 2–2–95; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–015–95–1610–00: G5–063]

Proposed Perlite Mining Operation, Lake County, Oregon; Intent to Prepare an Environmental Impact Statement

AGENCY: Bureau of Land Management (BLM), DOI.

ACTION: Notice of Intent to prepare an Environmental Impact Statement (EIS) for a proposed mining operation.

SUMMARY: The Lakeview District is initiating the EIS process to analyze the potential environmental impacts of a proposed perlite mining operation in Lake County, Oregon. Atlas Perlite, Inc. is proposing to develop a 15–20 acre quarry and associated waste rock dump on Tucker Hill located approximately 35 northwest of the town of Lakeview, Oregon. The ore would be hauled from Tucker Hill to Lakeview where it would be crushed and transported via rail to markets mainly in the northwest. This notice has been given so interested or affected people may participate and contribute to the final decision.

DATES: This notice constitutes the beginning of the 30-day public scoping process. Interested individuals, organizations, and other agencies are encouraged to review the proposal and provide written comments on or before March 6, 1995 to the address below.

ADDRESSES: Scott Florence, Area Manager, Lakeview Resource Area, BLM, PO Box 151, Lakeview, OR 97630.

FOR FURTHER INFORMATION CONTACT: Ted Davis, Project Coordinator, at address above or telephone (503–947–2177).

SUPPLEMENTARY INFORMATION: The BLM will consider issues and concerns identified during the scoping process in the preparation of the draft EIS. The preliminary issues identified include potential impacts to traditional Native American uses of the area, archaeological sites, wildlife, visual quality, native plants, noxious weeds, and socio-economics. Those individuals, organizations, and agencies with a known interest in the proposal have been sent a scoping letter requesting comments on the proposal. Persons wishing to be added to the mailing list for this EIS may do so by contacting Ted Davis. At this time there is no formal scoping meeting planned, though one could be scheduled if there is sufficient interest.

The comment period on the draft EIS will last 60 days from the date the U.S. EPA Notice of Availability appears in the **Federal Register** and EIS is expected to be available for review in August 1995. Because of recent court rulings, it is very important that those interested in the proposed action participate during the scoping and draft EIS review processes, so that any substantive comments are provided at a time when the BLM can meaningfully consider them.

Ed Singleton,

District Manager.

[FR Doc. 95–2637 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–33–P

[ID–020–1430–01; I–29055]

Exchange of Public Lands in Blaine County, Idaho; Realty Action

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action; Exchange of Public Lands in Blaine County, Idaho.

SUMMARY: The following described public lands have been determined to be suitable for disposal by exchange under Section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

T. 7 S., R. 26 E., B.M., Blaine County
Sec. 20: ESE;
Sec. 21: SW¼;
Sec. 28: NW¼, SW¼SW¼;
Sec. 29: E½NE¼.
T. 8 S., R. 26 E., B.M., Blaine County
Sec. 4: W½SW¼
Sec. 5: SE¼SE¼

The area described contains 640 acres, more or less.

In exchange for these lands, the United States will acquire the following described lands from Dale Klingler:

T. 7 S., R. 26 E., B.M., Blaine County
Sec. 16: All.

The area described contains 640 acres, more or less.

DATES: The publication of this notice in the **Federal Register** will segregate the public lands described above to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. As provided by the regulations of 43 CFR 2201.1(b), any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed and shall be returned to the applicant. The segregative effect of this notice will terminate upon issuance of patent or in two years, whichever occurs first.

ADDRESSES: Detailed information concerning the exchange is available for review at the Burley District Office, 200 South Oakley Highway, Burley, Idaho 83318.

SUPPLEMENTARY INFORMATION: The purpose of the land exchange is to facilitate more efficient management of the public lands through consolidation of ownership and to benefit the public interest by obtaining important resource values. The public lands to be exchanged are isolated and difficult to manage parcels with limited resource values. The private lands being offered would significantly improve the land ownership pattern in the area and provide key access to a large block of public land. The exchange is consistent with the Bureau of Land Management land use plan for the area which is the Monument Resource Management Plan (approved February, 1986 and amended January, 1992). The public interest will be served by making this exchange.

The value of the lands to be exchanged has been determined through appraisal to be equal.

The exchange will be subject to:

1. All valid existing rights of record, including but not limited to, electric power distribution line rights-of-way, I–29552 and I–14412.

2. A reservation to the United States of a right-of-way for ditches and canals.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the Snake River Area Manager at the above address. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

Dated: January 24, 1995

Ken Knowles,

Environmental Protection Specialist.

[FR Doc. 95–2638 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–66–P

Bureau of Land Management

[ID–014–4210–05; IDI–29418]

Realty Action; Bureau Motion Recreation and Public Purposes (R&PP) Act Classification; Idaho

AGENCY: Bureau of Land Management, Interior.

SUMMARY: The following public lands near the City of Cascade, Valley County, Idaho have been examined and found suitable for classification for lease to the City of Cascade under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*). The City of Cascade proposes to use the lands for a park in connection with their North Fork Payette River Greenway.

Boise Meridian, Idaho

T. 13 N., R. 4 E.,
Section 6: Lot 2
Containing 8.7 acres more or less.

The lands are not needed for Federal purposes. A lease is consistent with current BLM land use planning and would be in the public interest.

The lease, when issued, will be subject to the following terms, conditions, and reservations:

1. Provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior.

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals.

3. Lessee shall adhere to the proposed development plan and shall obtain written approval from the Authorized Officer prior to any changes in the development plan.

4. Lessee shall include the Bureau of Land Management as an interested party on any revisions of the North Fork of the Payette River Greenway Plan.

5. Lessee shall have all proper permits, specifically including but not limited to the permits from the Corps of Engineers and/or the Idaho Department of Water Resources for disturbance of any wetland/riparian areas, prior to any construction activities.

6. All merchantable timber shall be reserved to the BLM. The City of Cascade will reimburse the BLM for the value of the merchantable trees removed or at the Authorized Officer's discretion the BLM will authorize their removal

under a timber sale contract or related authorization.

7. Any signs for the subject park will include a reference that the land was obtained from the Bureau of Land Management. Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Boise District, 3948 Development Avenue, Boise, Idaho.

Upon publication of this notice in the **Federal Register**, the lands will be segregated from all forms of appropriation under the public land laws, including the general mining laws, except for lease or conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. For a period of 45 days from the date of publication of this notice, interested persons may submit comments regarding the proposed lease or classification of the lands to the District Manager, Boise District Office, 3948 Development Avenue, Boise, Idaho 83705.

CLASSIFICATION COMMENTS: Interested parties may submit comments involving the suitability of the lands for a park. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

APPLICATION COMMENTS: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for a park.

Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification will become effective 60 days from the date of publication of this notice.

Dated: January 23, 1995.

David Vail,

Acting District Manager.

[FR Doc. 95–2639 Filed 2–2–95; 8:45 am]

BILLING CODE 4310-gg-p

[NV–930–1430–01; N–59553]

Realty Action: Modified-Competitive Sale of Public Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Modified-Competitive Sale of Public Lands in Clark County, Nevada.

SUMMARY: The following described public land in Henderson, Clark County, Nevada has been examined and found suitable for sale utilizing modified-competitive procedures, at not less than the fair market value. Authority for the sale is Section 203 and Section 209 of the Federal Land Policy and Management Act of 1976 (FLPMA).

Mount Diablo Meridian, Nevada

T. 21 S., R. 62 E.,
Sec. 35: NE¼SW¼.
Containing 40.00 acres, more or less.

Fair Market Value (FMV) $1,020,000.00

This land is not required for any federal purpose. The sale is consistent with current Bureau planning for this area and would be in the public interest.

In the event of a sale, conveyance, of the available mineral interests will occur simultaneously with the sale of the land. The mineral interests being offered for conveyance have no known mineral value. Acceptance of a sale offer will constitute an application for conveyance of those mineral interests. The applicant will be required to pay a $50.00 nonreturnable filing fee for conveyance of the available mineral interests.

The patent, when issued, will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. Oil, gas, sodium, potassium and saleable minerals and will be subject to:

1. Those rights for airport marker purposes which have been granted to the Federal Aviation Administration by Permit No. N–4245 under the authority of (44LD513).

2. Those rights for natural gas pipeline purposes which have been granted to Southwest Gas Corporation by Permit No. NEV–015814 under section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185).

3. Those rights for water pipeline purposes which have been granted to Las Vegas Valley Water District by Permit No. NEV–043457 under the Act of October 21, 1976 (43 U.S.C. 1719).

4. Those rights for a public road which have been granted to the City of Henderson by Permit No. 31767 under the Act of October 21, 1967 (43 U.S.C. 1719).

5. Those rights for highway (Boulder Highway) purposes which have been granted to the Nevada Department of Transportation by Permit No. CC–018944 under the Act of November 9, 1921 (42 U.S.C. 216).

And is also subject to easements for roads, public utilities and flood control purposes in accordance with the transportation plan for Clark County and the City of Henderson.

The land will be offered for sale at public auction beginning at 10:00 am PST on April 19, 1995, at 4765 West Vegas Drive, Las Vegas, Nevada 89108. This sale will be by modified competitive procedures. City of Henderson will be given the opportunity to meet the highest bid received at public auction. Sale will be by sealed bid only. All sealed bids must be submitted to the BLM's Las Vegas District Office at 4765 W. Vegas Drive, Las Vegas, Nevada 89108, no later than 4:15 pm PST, April 18, 1995. Bid envelopes must be marked on the letter front corner with the parcel number and sale date. Bids must be for not less than the appraised FMV specified in this notice. Each sealed bid shall be accompanied by a certified check, postal money order, bank draft or cashier's check made payable to the Department of the Interior, BLM for not less than 20 percent of the amount bid.

Federal law requires that all bidders must be U.S. citizens 18 years old or older, or in the case of corporations, be subject to the laws of any State of the U.S. Proof of these requirements must accompany the bid.

Under modified competitive sale procedures, an apparent high bid will be declared at public auction. The apparent high bidder and the designated bidder, City of Henderson, will be notified. The designated bidder shall have 30 days from the date of the sale to exercise the preference consideration given to meet the high bid. Should the designated bidder fail to submit a bid that matches the apparent high bid with the specified time period, the apparent high bidder, shall be declared high bidder. The total purchase price for the land shall be paid within 180 days of the date of the sale. The purchaser will be required to reimburse the BLM for the costs of publication of this notice.

Upon publication of this notice in the **Federal Register**, the above described land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for sales and disposals under the mineral disposal laws. This segregation will terminate upon issuance of a patent or 270 days from the date of this publication, whichever comes first.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Las Vegas District, 4765 West Vegas Drive, Las Vegas, Nevada 89108. Any adverse comments will be reviewed

by the State Director who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, his realty action will become the final determination of the Department of the Interior. The Bureau of Land Management may accept or reject any or all offers, or withdraw any land or interest in the land from sale, if, in the opinion of the authorized officer, consummation of the sale would not be fully consistent with FLPMA, or other applicable laws. The lands will not be offered for sale until at least 60 days after the date of publication of this notice in the **Federal Register**.

Dated: January 19, 1995.

Lorraine Buck,

Acting District Manager.

[FR Doc. 95–2640 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–HC–M

[ID–942–04–1420–000]

Idaho: Filing of Plats of Survey; Idaho

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m., January 26, 1995.

The plat representing the dependent resurvey of portions of the north boundary and subdivisional lines, the subdivision of section 4, and the survey of a portion of the center line of U.S. Highway No. 93 and lots 9, 14, 15, 18, and 19 in section 4, and of lot 9 in section 5, T. 13 N., R. 19 E., Boise Meridian, Idaho, Group No. 869, was accepted January 24, 1995.

This survey was executed to meet certain administrative needs of the Bureau of Land Management.

All inquiries concerning the survey of the above described land must be sent to the Chief, Branch of Cadastral Survey, Idaho State Office, Bureau of Land Management, 3380 Americana Terrace, Boise, Idaho, 83706.

Dated: January 26, 1995.

Gary T. Oviatt,

Acting Chief Cadastral Surveyor for Idaho.

[FR Doc. 95–2641 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–66–M

[ID–942–04–1420–00]

Idaho: Filing of Plat of Survey; Idaho

The plat of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m., January 26, 1995.

The plat representing the dependent resurvey of portions of the north and west boundaries, subdivisional lines, and the meanders of the left bank of the Snake River in section 8, the subdivision of sections 6, 7, and 8, the survey of the 1994 meanders of the right bank of the Snake river in section 6, and a metes-and-bounds survey in sections 6 and 7, T.4 S., R.2 E., Boise Meridian, Idaho, Group No. 881, was accepted January 20, 1995.

This survey was executed to meet certain administrative needs of the Bureau of Land Management.

All inquiries concerning the survey of the above described land must be sent to the Chief, Branch of Cadastral Survey, Idaho State Office, Bureau of Land Management, 3380 Americana Terrace, Boise, Idaho, 83706.

Dated: January 26, 1995.

Gary T. Oviatt,

Acting Chief Cadastral Surveyor for Idaho.

[FR Doc. 95–2642 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–66–M

National Park Service

Beaver Basin Rim Road, Draft Environmental Impact Statement

AGENCY: National Park Service, Interior.

ACTION: Availability of draft environmental impact statement for the proposed Beaver Basin Rim Road at Pictured Rocks National Lakeshore, Alger County, Michigan; announcement of public meetings for the purpose of receiving public comments on the draft environmental impact statement for the Beaver Basin Rim Road.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the National Park Service (NPS) announces the availability of a draft environmental impact statement (DEIS) for the proposed Beaver Basin Rim Road in Pictured Rocks National Lakeshore. The NPS proposes to construct a paved road in Pictured Rocks National Lakeshore along the Beaver Basin Rim. The action is being proposed in response to a mandate by Congress in section 6 of the Act of October 15, 1966, 16 U.S.C. 460s–5(b)(1), establishing Pictured Rocks National Lakeshore, directing the development of a scenic shoreline drive. The proposed action is also consistent with and would implement the management directions of the 1981 general management plan for the national lakeshore. The DEIS was prepared by the NPS.

The NPS's preferred alternative for the Beaver Basin Rim Road is identified in the DEIS as Alternative B: Shoreline Zone Alignment. Under the preferred alternative, a 13-mile-long paved road would be constructed in the shoreline zone of Pictured Rocks National Lakeshore. The proposed road would connect on both ends with Alger County Road H–58. Two spur roads would be constructed off the main road to two overlooks. These overlooks would provide views of Beaver Basin, Beaver Lake, Grand Portal Point, the Sevenmile Creek area, and Lake Superior. Two other alternatives are also considered: the no action alternative, and an alternative under which a new paved road would be constructed within the inland buffer zone of the national lakeshore.

The impacts of the proposed action on the natural resources of the national lakeshore are expected to be minor. However, significant social impacts could occur, particularly in the Grand Marais area. The proposed action will also result in changes to visitor experience in the affected portion of the national lakeshore.

DATES: Comments on the draft EIS should be received no later than March 20, 1995.

The dates, times and locations of public meetings regarding the DEIS are:

Saturday, February 11, 1995, 3:00–5:00 pm, Sheraton Oaks Hotel, 27000 Sheraton Drive, Novi, Michigan

Sunday, February 12, 1995, 2:00–4:00 pm, Holiday Inn South Convention Center, 6820 South Cedar Street, Lansing, Michigan

Monday, February 13, 1995, 7:00–9:00 pm, Comfort Inn, 4155 28th Street, SE, Grand Rapids, Michigan

Wednesday, February 15, 1995, 7:00–9:00 pm, Grand Marais Recreation Center, Grand Marais, Michigan

Thursday, February 16, 1995, 7:00–9:00 pm, Comfort Inn, M–28 East, Munising, Michigan

Friday, February 17, 1995, 7:00–9:00 pm, Ramada Inn, 2750 Ramada Way, Green Bay, Wisconsin

ADDRESSES: Comments on the DEIS should be submitted to: Superintendent, Pictured Rocks National Lakeshore, P.O. Box 40, Munising, MI 49862, 906–387–2607.

SUPPLEMENTARY INFORMATION: Public reading copies of the DEIS will be available for review at the Department of Interior Natural Resources Library, 1849 C Street, NW., Washington, DC 20240; Pictured Rocks National Lakeshore, Sand Point Road, Munising, Michigan 49862; Burt Township Office, Grand Marais, Michigan 49839; Munising Public Library, Munising, Michigan 49862; Peter White Public Library, Marquette, Michigan 49855;

and selected public libraries in cities where public meetings will be held.

FOR FURTHER INFORMATION CONTACT: Superintendent, Pictured Rocks National Lakeshore at the address or phone number listed above.

Dated: January 20, 1995.

Catherine A. Damon,

Acting Regional Director, Midwest Region, National Park Service.

[FR Doc. 95–2713 Filed 2–2–95; 8:45 am]

BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

[Investigation 332–358]

General Agreement on Trade in Services: Examination of Major Trading Partners' Schedules of Commitments

AGENCY: International Trade Commission.

ACTION: Institution of investigation and scheduling of public hearing.

EFFECTIVE DATE: January 26, 1995.

SUMMARY: Following receipt on January 4, 1995, of a request from the Office of the United States Trade Representative (USTR), the Commission instituted investigation No. 332–358, General Agreement on Trade in Services: Examination of Major Trading Partners' Schedules of Commitments.

FOR FURTHER INFORMATIONCONTACT: Information on service industries may be obtained from Mr. Richard Brown, Office of Industries (202–205–3438) and Ms. Julie Throne, Office of Industries (202–205–3390); economic aspects, from Mr. Joseph Flynn, Office of Economics (202–205–3251); and legal aspects, from Mr. William Gearhart, Office of the General Counsel (202–205–3091). The media should contact Ms. Margaret O'Laughlin, Office of Public Affairs (202–205–1819). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on (202–205–1810).

BACKGROUND: The USTR in his letter dated December 28, 1994, requested that the Commission, pursuant to section 332(g) of the Tariff Act of 1930, conduct an investigation to (1) examine the content of foreign schedules of commitments under the General Agreement on Trade in Services, explaining the commitments in non-technical language; and (2) identify the potential benefits (e.g., improved market access, national treatment, MFN treatment, greater regulatory transparency, etc.) and limitations of foreign commitments agreed upon in April 1994.

The Commission will seek to provide such information in its report. As requested by the USTR, the Commission, in its examination of foreign schedules, will focus on sector-specific commitments pertaining to the following service sectors of the European Union, Japan, Canada, and Mexico:

- Distribution services (defined as wholesaling, retailing, and franchising services);
- Education services;
- Communications services (e.g., enhanced telecommunication services, courier services, and audiovisual services);
- Health care services;
- Professional services (e.g. accounting, engineering, construction, architectural, and advertising services, and lawyers);
- Transportation services (defined as rail and trucking services); and
- Travel and tourism.

In addition, as requested by the USTR, the Commission will examine horizontal commitments regarding the temporary entry and stay of certain foreign workers.

As requested by the USTR, the Commission plans to deliver its report to the USTR by December 15, 1995.

PUBLIC HEARING: A public hearing in connection with the investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC, beginning at 9:30 a.m. on June 7, 1995. All persons shall have the right to appear, by counsel or in person, to present information and to be heard. Requests to appear at the public hearing should be filed with the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436, no later than 5:15 p.m., May 24, 1995. Any prehearing briefs (original and 14 copies) should be filed no later than 5:15 p.m., May 24, 1995. The deadline for filing posthearing briefs or statements is 5:15 p.m., June 21, 1995.

In the event that, as of the close of business on May 24, 1995, no witnesses are scheduled to appear at the hearing, the hearing will be cancelled. Any person interested in attending the hearing as an observer or non-participant may call the Secretary to the Commission (202–205–2000) after May 24, 1995 to determine whether the hearing will be held.

WRITTEN SUBMISSIONS: In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements concerning the matters to be addressed by the Commission in its report on this investigation. Commercial or financial information that a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked ''Confidential Business Information'' at the top. All submissions requesting confidential treatment must conform with the requirements of section § 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). All written submissions, except for confidential business information, will be made available in the Office of the Secretary of the Commission for inspection by interested parties. To be assured of consideration by the Commission, written statements relating to the Commission's report should be submitted to the Commission at the earliest practical date and should be received no later than the close of business on June 21, 1995. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202- 205–2000).

By order of the Commission.

Issued: January 27, 1995

Donna R. Koehnke,

Secretary.

[FR Doc. 95–2684 Filed 2–2–95; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant to the Clean Water Act

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a consent decree in *United States of America* v. *Commonwealth of Massachusetts, Executive Office for Administration and Finance, Division of Capital Planning and Operations; and Dimeo Construction Company*, Civ. Act. No. 93–10280 WD (D. Mass.), was lodged with the United States District Court for the District of Massachusetts on January 13, 1995. The proposed decree concerns alleged violations of the Clean Water Act, 33 U.S.C. 1311, as a result of the discharge of fill materials onto approximately 11.6 acres of wetlands by the Commonwealth of Massachusetts (''Commonwealth'') and its general contractor, Dimeo Construction Company (''Dimeo''),

during the construction of the Bristol County House of Corrections on Faunce Corner Road in Dartmouth, Massachusetts, without a permit issued pursuant to 33 U.S.C. 1344.

The Consent Decree requires that the Commonwealth pay a civil penalty of $50,000; perform a $1.5 million off-site compensatory mitigation project; pay $378,000 in the event the Commonwealth sells the undeveloped area around the House of Corrections; and provide a $150,000 endowment to the Massachusetts Audubon Society (''MAS'') for the management of 264 acres of wetlands that will be conveyed to MAS pursuant to a settlement agreement in another Clean Water Act enforcement matter. Dimeo is required to offer a comprehensive wetlands training course to Dimeo's employees and to members of the Associated General Contractors of Massachusetts.

The Department of Justice will receive written comments relating to the consent decree for a period of thirty (30) days from the date of this notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, Attention: Daniel W. Pinkston, 10th St. and Pennsylvania Ave., NW., Room 7303—Main Building, Washington, DC 20530, and should refer to *United States* v. *Commonwealth of Massachusetts and Dimeo Construction Co.*, DJ Reference No. 90–5–1–1–3710.

The proposed consent decree may be examined at the Office of the United States Attorney for the District of Massachusetts, 1107 John W. McCormack Federal Bldg., U.S. P.O. & Courthouse, Boston, MA 02109, the Region I Office of the United States Environmental Protection Agency, Office of Regional Counsel, 1 Congress Street, 10th Floor, Boston, MA and at the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005 (202–624–0892). A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005. In requesting a copy, please enclose a check in the amount of $9.75 for a copy of the consent decree only, or $36.25, for both the consent decree and exhibits, payable to the Consent Decree Library.

Letitia J. Grishaw,

Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 95–2643 Filed 2–2–95; 8:45 am]

BILLING CODE 4410–01–M

[AAG/A Order No. 97–95]

Privacy Act of 1974 as Amended by the Computer Matching and Privacy Protection Act of 1988

This notice is published in the **Federal Register** in accordance with the requirements of 5 U.S.C. 552a(e)(12). The Immigration and Naturalization Service (INS), Department of Justice (the source agency), is participating in a computer matching program with the Massachusetts Department of Employment and Training (MA–DET) (the receipt agency). The matching program entitled ''Systematic Alien Verification for Entitlements (SAVE)'' will permit MA–DET to confirm the immigration status of alien applicants for, or recipients of, Federal benefits assistance (i.e., unemployment compensation insurance) as required by section 121 of the Immigration Reform and Control Act (IRCA) of 1986 (Pub. L. 99–603).

Section 121(c) of IRCA amends section 1137 of the Social Security Act and requires agencies which administer the Federal benefit programs designated within IRCA to use the INS verification system to determine eligibility. Accordingly, through the use of user identification codes and passwords, authorized persons from MA–DET may electronically access the data base of an Immigration and Naturalization Service Privacy Act system of records entitled ''Alien Status Verification Index, JUSTICE/INS–009.'' From its automated records system, MA–DET may enter electronically into the INS data base the alien registration number of the applicant or recipient. This action will initiate a search of the INS data base for a corresponding alien registration number. Where such number is located, MA–DET will receive electronically from the INS data base the following data upon which to determine eligibility: Alien registration number; last name; first name; date of birth; country of birth; Social Security number (if available); date of entry; immigration status data; and employment eligibility data. In accordance with 5 U.S.C. 552a(p), MA–DET will provide the alien applicant with 30 days' notice and an opportunity to contest any adverse finding before final action is taken against that alien because of ineligible immigration status as established through the computer match.

The original effective date of the matching program was February 28, 1990, for which notice was published in the **Federal Register** on January 29, 1990 (55 FR 2890). The program has continued to date under the authority of a series of new approvals as required by the CMPPA. The CMPPA provides that based upon approval by agency Data Integrity Boards of a new computer matching agreement, computer matching activities may be conducted for 18 months and, contingent upon specific conditions, may be similarly extended by the Board for an additional year without the necessity of a new agreement. The most recent one-year extension for this program will expire March 9, 1995. Therefore, the Department's Data Integrity Board has approved a new agreement to permit the continuation of the above-named computer matching program for another 18-month period from the effective date (described below).

Matching activity under the new agreement will be effective (1) 30 days after publication of a computer matching notice in the **Federal Register**, or (2) 40 days after a report concerning the computer matching program has been transmitted to the Office of Management and Budget and transmitted to Congress along with a copy of the agreement, whichever is later. The agreement (and matching activity) will continue for 18 months from the effective date—unless within 3 months prior to the expiration of the agreement, the Data Integrity Board approves a one-year extension pursuant to 5 U.S.C. 552a(o)(2)(D).

In accordance with 5 U.S.C. 552a(o)(2)(A) and (r), the required report has been provided to the Office of Management and Budget, and to Congress together with a copy of the agreement.

Inquiries may be addressed to Patricia E. Neely, Staff Assistant, Systems Policy Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 850, WCTR Building).

Dated: January 27, 1995.

Michael J. Roper,

Acting Assistant Attorney General for Administration.

[FR Doc. 95–2623 Filed 2–2–95; 8:45 am]

BILLING CODE 4410–10–M

Antitrust Division

United States v. New England Fish Exchange, et al.; Proposed Termination of Final Decree

Notice is hereby given that defendant New England Fish Exchange (''NEFE'') has filed with the United States District Court for the District of Massachusetts a motion to terminate the Final Decree entered in *United States* v. *New England Fish Exchange, et al.*, No. 810 Equity, and the Department of Justice (''government''), in a stipulation also

filed with the Court, has consented to termination of the Final Decree, but has reserved the right to withdraw its consent based on public comments and for other reasons.

The Original Petition in this case was filed on June 21, 1917, and charged the NEFE, and 49 other businesses and individuals, with combining and conspiring to monopolize and restrain interstate trade and commerce in the fresh fish industry in New England, in violation of Sections 1 and 2 of the Sherman Act and Section 7 of the Clayton Act. Specifically, the Petition alleged that of the 40 member dealers of the NEFE, 28 were owned by defendant dealer Boston Fish Pier Co. and 8 were owned by defendant dealer Boston Fish Pier Co. and 8 were owned by defendant dealer Bay State Fishing Co. Because of their monopoly power, Boston Fish Pier Co. and Bay State Fishing Co. were able to impose rules and regulations upon the NEFE that made it impossible for boat captains to get fair prices for their fish when it was auctioned off at the NEFE. It was also virtually impossible for non-NEFE members to purchase fish in Boston.

The Final Decree: (i) prohibited the NEFE's practice of restricting its membership to only those dealers having offices on the Boston Fish Pier; (ii) ordered Boston Fish Pier Co. to divest and dissolve; (iii) ordered Bay State Fishing Co. to divest; (iv) prohibited the defendants from ''splitting trips'', that is, entering into action pools when lots of fish were being bid on. They were also enjoined from ''agreeing among themselves to raise or depress the price of fish; (v) limited the NEFE's annual return on capital to 8%; and (iv) prohibited the NEFE from accumulating capital in excess of $36,000, plus a safety fund of an additional $15,000.

The government has filed with the Court a memorandum setting forth the reasons why the government believes that termination of the Final Decree would serve the public interest. Copies of the Petition, Final Decree, the Government's Memorandum, motion papers and all further papers filed with the Court in connection with this motion will be available for inspection at Room 3233, Antitrust Division, Department of Justice, 10th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20530 (telephone 202–633–2481), and at the Office of the Clerk of the United States District Court for the District of Massachusetts, United States Courthouse, John W. McCormack Post Office and Courthouse Building, Boston, Massachusetts 02109. Copies of any of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Interested persons may submit comments regarding the proposed termination of the Final Decree to the government. Such comments must be received within the sixty-day period established by Court order, and will be filed with the Court by the government. Comments should be addressed to Ralph T. Giordano, Chief, New York Office, Antitrust Division, Department of Justice, New York, New York 10278 (telephone 212–264–0390).

Constance K. Robinson,

Director of Operations.

[FR Doc. 95–2644 Filed 2–2–95; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–30,216]

AEG Transportation Systems, Incorporated Pittsburgh, PA; Affirmative Determination Regarding Application for Reconsideration

On November 30, 1994, the company requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers at the subject firm. The Department's Negative Determination was issued on October 17, 1994 and was published in the **Federal Register** on November 1, 1994 (59 FR 54631).

The company submitted additional information showing a lost major bid that caused worker separations in 1994.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C., this 24th day of January 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–2696 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–30,317]

Exxon Company, U.S.A., A/K/A Exxon Corporation; Southeastern Production Division, New Orleans, Louisiana (Formerly Known as Eastern Division Production Department, New Orleans, Louisiana Under TA–W–26,798); A/K/A New Orleans Production Organization New Orleans, Louisiana; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility To Apply for Worker Adjustment Assistance on November 8, 1994, applicable to all workers of the subject firm engaged in employment related to the production of crude oil and condensate.

The certification notice was published in the **Federal Register** on December 9, 1994 (59 FR 63823).

At the request of the State Agency, the Department again reviewed the certification for workers of the subject firm. New finding show a series of corporate and divisional name changes. On December 31, 1989, the employer account number for unemployment insurance (UI) for the Exxon Company, U.S.A., went inactive when a new UI account number bearing the name of the Exxon Corporation becoming the successor account.

Further, the workers of Exxon Corporation's Eastern Division Production Department in New Orleans certified earlier under TA–W–26,798 is the same group of workers certified under this certification as Exxon Corporation's Southeastern Production Division in New Orleans with the name changing to the Exxon Corporation's New Orleans Production Organization on September 1, 1994.

Other findings show a coverage overlap between the Eastern Division Production Department of Exxon Corporation in New Orleans, Louisiana from January 21, 1991 to February 11, 1994 (TA–W–26,798) and the Southeastern Production Division of Exxon Corporation, New Orleans, Louisiana from August 30, 1993 to November 8, 1994 (TA–W–30,317). Accordingly, the Department is deleting the August 30, 1993 impact date for TA–W–30,317 and inserting a new impact date of February 11, 1994.

The amended notice applicable to TA–W–30,317 is hereby issued as follows:

''All workers of the Southeastern Production Division of Exxon Company, U.S.A., A/K/A Exxon Corporation, New

Orleans Louisiana and its successor appropriate subdivision New Orleans Production Organization of Exxon Corporation, New Orleans, Louisiana who became totally or partially separated from employment on or after February 11, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed in Washington, D.C., this 23rd day of January 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–2697 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–28,220]

M.C.M. Coats Incorporated, Hoboken, New Jersey; Revised Determination on Reopening

On January 18, 1995, the Department, on its own motion, reopened its investigation for the former workers of the subject firm. The initial investigation resulted in a negative determination on February 24, 1993 because the ''contributed importantly'' test of the Group Eligibility Requirements of the Trade Act was not met. The denial notice was published in the **Federal Register** on March 22, 1993 (58 FR 15383).

A late response to the Department's customer survey shows that a major customer accounting for a substantial portion of the sales decline for M.C.M. Coats' switched its purchases from the subject firm to imports.

Other findings show that the plant closed on December 15, 1992 when all production workers were laid off.

U.S. imports of women's suits and coats increased in 1993 compared to 1992 and in 1992 compared to 1991.

Conclusion

After careful consideration of the new facts obtained on reopening, it is concluded that increased imports of articles like or directly competitive with the women's suits and coats produced by the subject firm contributed importantly to the decline in production and to the total or partial separation of workers at the subject firm. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

''All former workers of M.C.M., Incorporated, Hoboken, New Jersey who became totally or partially separated from employment on or after January 5, 1992 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, DC, this 23rd day of January 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–2698 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–30,508; TA–W–30,509]

Marathon Oil Company, Anchorage, Alaska and Kenai, Alaska; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on November 21, 1994 in response to a worker petition which was filed on behalf of workers and former workers at locations of Marathon Oil Company, located in Anchorage, Alaska (TA–W–30, 508) and Kenai, Alaska, (TA–W–30, 509).

Workers at the above locations of Marathon Oil Company are currently covered under an existing certification (TA–W–30, 455B). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C. this 20th day of January 1995.

James D. Van Erden,

Administrator, Office of Work-Based Learning.

[FR Doc. 95–2700 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–30,517]

Miles Chemical Laboratories, Haledon, NJ; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on November 28, 1994 in response to a worker petition which was filed on behalf of workers at Miles Chemical Laboratories, Haledon, New Jersey.

All workers were separated from the subject firm more than one year prior to the date of the petition. Section 223 of the Act specifies that no certification may apply to any worker whose last separation occurred more than one year before the date of the petition. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C. this 18th day of January, 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–2701 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than February 13, 1995.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than February 13, 1995.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 17th day of January, 1995.

Victor J. Trunzo,

Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition No.	Articles produced
Uarco, Inc (Wkrs)	Adrian, MI	01/17/95	01/09/95	30,643	Continuous stock computer forms.
Energizer Power Systems (Wkrs)	El Paso, TX	01/17/95	01/06/95	30,644	Rechargable batteries.
Mitchell Energy Corp (Co)	Columbus, OH	01/17/95	01/03/95	30,645	Crude oil.
Enterra Oilfield Rental Co (Wkrs)	Odessa, TX	01/17/95	12/29/94	30,646	Oilfield equipment rental.
Amerada Hess Corp (Wkrs)	Houston, TX	01/17/95	01/04/95	30,647	Oil and gas.
Seagull Mid-South, Inc (Wkrs)	Shreveport, LA	01/17/95	01/06/95	30,648	Oil and gas.
Dee Exploration, Inc (Co)	Whitesboro, TX	01/17/95	01/04/95	30,649	Crude oil exploration and drilling.
Lynn Alison Manufacturing Co (Wkrs)	Pittston, PA	01/17/95	01/05/95	30,650	Ladies' dresses.
Elbit Ft. Worth (Wkrs)	Ft. Worth, TX	01/17/95	01/04/95	30,651	Cables and harnesses for F–16 planes.
The Coach Factory (LGPN)	Carlstadt, NJ	01/17/95	01/03/95	30,652	Leather handbags and accessories.
Licensed Clothing (Co)	Saddle Brook, NJ	01/17/95	01/04/95	30,653	Tee shirts.
Guardian Manufacturing Co, Inc (Wkrs).	Woodstock, IL	01/17/95	01/03/95	30,654	Relays, switches and aerospace grip assem.
LaVelle Powder Co (Wkrs)	Butte, MT	01/17/95	03/27/94	30,655	Truck transportation.
Becton Dickinson & Co (Wkrs)	Franklin Lakes, NJ	01/17/95	12/26/94	30,656	Ship merchandise to Latin America.
JPS Converter and Industrial Corp (Wkrs).	Laurens, SC	01/17/95	01/06/95	30,657	Griege goods.

[FR Doc. 95–2695 Filed 2–2–95; 8:45 am]
BILLING CODE 4510–30–M

[TA–W–30,277; TA–W–30,277A–J]

Union Oil Company of California (d.b.a. UNOCAL) Sugar Land, Texas, et al.

Union Oil Company of California (d.b.a. UNOCAL) Operating at various locations in the following States: TA–W–30,277A Alabama, TA–W–30,277B Illinois, TA–W–30,277C Louisiana, TA–W–30,277D Michigan, TA–W–30,277E Montana, TA–W–30,277F New Mexico, TA–W–30,277G Texas, TA–W–30,277H Utah, TA–W–30,277I Wyoming, TA–W–30,277J Oklahoma; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance.

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) as amended by the Omnibus Trade and Competitiveness Act of 1988 (P.L. 100–418), the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is determined in this case that all of the requirements have been met.

The investigation was initiated in response to a petition received on September 6, 1994 and filed on behalf of workers at Union Oil Company of California, d.b.a. UNOCAL, headquartered in Sugar Land, Texas (TA–W–30,277) and all operations in the following states: (1) Alabama (TA–W–30,277A); (2) Illinois (TA–W–30,277B); (3) Louisiana (TA–W–30,277C); (4) Michigan (TA–W–30,277D); (5) Montana (TA–W–30,277E); (6) New Mexico (TA–W–30,277F); (7) Texas (TA–W–30,277G); (8) Utah (TA–W–30,277H); (9) Wyoming (TA–W–30,277I); and (10) Oklahoma (TA–W–30,277J). Workers at Union Oil Company of California (UNOCAL), headquartered in Sugar Land, Texas (TA–W–30,277) and operating in various locations in the following states of this entity of the Company (TA–W–30,277A–J) are engaged in employment related to the exploration and production of crude oil, natural gas, and natural gas liquids.

Workers are not separately identifiable between crude oil, natural gas, and natural gas liquids exploration or production. Crude oil represents an important portion of sales at Union Oil Company of California (UNOCAL).

Workers at various locations of UNOCAL Corporation were certified eligible to apply for trade adjustment assistance benefits on September 30, 1992 (TA–W–27,538; TA–W–27,542–27,544; and TA–W–27,544A–D).

Workers at various other locations of UNOCAL Corporation were certified eligible to apply for trade adjustment assistance benefits on November 3, 1992.

U.S. imports of crude oil and natural gas increased absolutely and relative to domestic shipments and consumption in the latest twelve month period of September 1993 through August of 1994 compared to a year earlier.

Corporate-wide sales and production of crude oil at Union Oil Company of California (UNOCAL) declined in 1993 compared to 1992 and in the first six months of 1994 compared to the same period in 1993.

Corporate-wide sales of natural gas liquids at Union Oil Company of California (UNOCAL) declined in 1993 compared to 1992 and in the first six months of 1994 compared to the same period in 1993. Corporate-wide production of natural gas liquids of the subject firm declined in 1993 compared to 1992.

Employment of workers at Union Oil Company of California (UNOCAL) declined in 1993 compared to 1992 and in the first six months of 1994 compared to the same period in 1993 (TA–W–30,277 and TA–W–30,277A–J).

Company imports of import purchases of crude oil in 1993 compared to 1992.

The Department conducted a survey of major customers of Union Oil Company of California (UNOCAL). The survey revealed that respondents increased purchases of imported crude oil in 1993 compared to 1992, and that these respondents continued their reliance of imported crude oil in the first nine months of 1994 compared to the same period in 1993.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with crude oil and natural gas produced at Union Oil Company of California, d.b.a. UNOCAL contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

''All workers of Union Oil Company of California, d.b.a. UNOCAL, headquartered in Sugar Land, Texas (TA–W–30,277) and at all locations in the following states listed below (TA–W–30,277A–J) engaged in employment related to the exploration and

production of crude oil, natural gas, and natural gas liquids who became totally or partially separated from employment on or after September 6, 1993 through two years from the date of certification are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

TA–W–30,277A Alabama
TA–W–30,277B Illinois
TA–W–30,277C Louisiana
TA–W–30,277D Michigan
TA–W–30,277E Montana
TA–W–30,277I Wyoming
TA–W–30,277J Oklahoma

and

''All workers of Union Oil Company of California, d.b.a. UNOCAL, located New Mexico (TA–W–30,277F); Texas (TA–W–30,277G); and Utah (TA–W–30,277H) engaged in employment related to the exploration and production of crude oil, natural gas, and natural gas liquids who became totally or partially separated from employment on or after September 30, 1994 through two years from the date of certification are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

TA–W–30,277F New Mexico
TA–W–30,277G Texas
TA–W–30,277H Utah

Signed in Washington, D.C. this 9th day of December 1994.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–2699 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–30–M

Employment Standards Administration

Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Age Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delaying the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued must be made a party of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or general agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determination, 200 Constitution Ave., N.W., Room S–3014, Washington, D.C. 20210.

Modification to General Wage Determinations Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I:
None
Volume II:
None
Volume III:
None
Volume IV:
None
Volume V:
None
Volume VI:
None

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from:

Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which included all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 27th day of January 1995.

Alan L. Moss,

Director, Division of Wage Determination.

[FR Doc. 95–2452 Filed 2–2–95; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL SCIENCE FOUNDATION

Privacy Act of 1974; New System of Records

AGENCY: National Science Foundation.

ACTION: Notice of new system of records and routine uses.

New System of Records

Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), the National Science Foundation is providing notice of a new system of records—NSF–58, ''National Survey of Recent College Graduates and Follow-up File.'' This system is established and maintained by the National Science Foundation, the U.S. Department of Energy and their present and future contractors (present contractors include the U.S. Bureau of Census and Westat, Inc.). The system is used as a source for measuring the new entrants into the science and engineering workforce and for providing information on indicators related to the science and engineering workforce, as required by congressional mandate. The system is also used to report on the participation rates of women and minorities in scientific and technical fields, as required by congressional mandate.

Effective date: Section 552a(e) (4) and (11) of Title 5 of the U.S. Code provides the public thirty days to comment on the routine uses of systems of records. The new system of records and its routine uses will become effective 30 days after publication of this notice, unless comments are received on or before that date that would result in a contrary decision. In this case a notice will be published to that effect.

Comments: Written comments should be addressed to the NSF Privacy Act Officer, Office of Information and Resource Management, National Science Foundation, Room 485, 4201 Wilson Blvd., Arlington, VA 22230.

Dated: January 30, 1995.

Herman G. Fleming,

Privacy Act Officer.

NSF–58

SYSTEM NAME:

National Survey of recent College Graduates and Follow-up File.

SECURITY CLASSIFICATIONS:

None.

SYSTEM LOCATION:

Record that make up this system may be kept in multiple locations: National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230: U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, U.S. Bureau of Census, Washington, DC 20233, and Westat, Inc., 1550 Research Blvd., Rockville, MD 20850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system includes a sample of individuals holding bachelor's and master's degrees from U.S. institutions in science and engineering degree fields.

CATEGORIES OF RECORDS IN THE SYSTEM:

Educational, professional, and demographic characteristics of degree holders including name, age, race, ethnicity, sex, disability, and country of birth, social security number, occupational information, labor force status, professional activities, academic degrees, earlier education, continuing education, marital status, spouse's employment status, number and ages of children living at home, parent's educational attainment, citizenship.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Science Foundation Act of 1950, as amended, 42 U.S.C. 1862(a)(6), 1863(j)(1), 1885d.

PURPOSES:

This system is used as a source of information on the characteristics of individuals with bachelor's and master's degrees in science and engineering in the United States. The system is used as a source for measuring the new entrants into the science and engineering workforce. The system is used to provide information on indicators related to the science and engineering workforce, as required by congressional mandate. The system is also used to report on the participation rates of women and minorities in scientific and technical fields, as required by congressional mandate. It is also used by researchers interested in policy issues related to the scientific and engineering workforce.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure of the records may be made to the Federal sponsors listed under ''System location'' above, their contractors and collaborating researchers and their staff for the purpose of analyzing data, preparing reports, writing articles, and preparing public use data tapes in order to accomplish the research purpose for which the records are collected. Disclosure of certain data on records (including name, address, phone number, academic institution, degree type) are also made to present and future contractors to conduct longitudinal surveys of individuals included in the system. All users of the data are required to comply by the requirements of the Privacy Act with respect to such records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer tapes with identifying information on individuals and questionnaires are kept by the National Science Foundation, the U.S. Department of Energy, U.S. Bureau of Census, and Westat, Inc.

RETRIEVABILITY:

Alphabetically by last name of individual.

SAFEGUARDS:

Data are kept in secured areas with access limited to authorized personnel. Questionnaires in paper copy are kept in locked cabinets. Published findings and computer tapes are in formats which preclude individual identification.

RETENTION AND DISPOSAL:

Computer tapes are kept indefinitely by the U.S. Bureau of Census and Westat, Inc. and the other sponsors in fulfilling the responsibilities described under ''Purposes''.

SYSTEM MANAGER(S) AND ADDRESS

Division Director, Science Resources Studies, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

NOTIFICATION PROCEDURE:

The NSF Privacy Act Officer should be contacted in accordance with procedures found at 45 CFR part 613.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Most information was obtained voluntarily from individuals. Initial identifying information was also voluntarily obtained from colleges and/or universities and individuals.

SYSTEM EXEMPTIONS FROM CERTAIN PROVISION OF THE ACT:

None.

[FR Doc. 95–2661 Filed 2–2–95; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

All U.S. Pressurized Water Reactors; Issuance of Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has taken action with regard to a Petition for action under 10 CFR 2.206 received from John Willis of Greenpeace International with respect to all pressurized water reactors (PWRs) in the United States. The Petitioner requested that all U.S. PWRs be examined for cracks in control rod drive mechanism (CRDM) vessel head penetrations (VHP) and that any reactors found containing VHP cracking be shut down, repaired, and ''relicensed'' before restarting.

The Director of the Office of Nuclear Reactor Regulation has determined to deny the Petition. The reasons for this denial are explained in the ''Director's Decision under 10 CFR 2.296,'' (DD–95–02) which is available for public inspection in the Commission's Public Document Room, Gelman Building, 2120 L St., N.W., Washington, DC 20037. A copy of this decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR 2.206(c) of the Commission's regulations. As provided by this regulation, the decision will constitute the final action of the Commission 25 days after the date of issuance of the decision unless the Commission on its own motion institutes a review of the decision within that time.

Dated at Rockville, Maryland this 26th day of January, 1995.

For the Nuclear Regulatory Commission.

William T. Russell,

Director, Office on Nuclear Reactor Regulation.

[FR Doc. 95–2728 Filed 2–2–95; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–461]

Illinois Power Company; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–62, issued to the Illinois Power Company (the licensee), for operation of the Clinton Power Station, Unit 1, located in DeWitt County, Illinois.

The proposed amendment would modify the Technical Specifications (TSs) to eliminate selected response time testing requirements. The affected TSs are TS 3.3.1.1, ''Reactor Protection System (RPS) Instrumentation,'' TS 3.3.5.1, ''Emergency Core Cooling System (ECCS) Instrumentation,'' TS 3.3.6.1, ''Primary Containment and Drywell Isolation Instrumentation,'' and TS 3.5.1, ''ECCS—Operating.''

The proposed changes are supported by analyses performed by the Boiling Water Reactor Owners Group (BWROG) in their topical report, NEDO–32291, ''System Analyses for Elimination of Selected Response Time Testing Requirements,'' submitted on January 14, 1994. NEDO–32291 demonstrated that other periodic tests required by TSs, such as channel calibrations, channel checks, channel functional tests, and logic system functional tests, in conjunction with the actions taken in response to NRC Bulletin 90–01, ''Loss of Fill-Oil in Transmitters Manufactured by Rosemount,'' and Supplement 1, are adequate to ensure that instrument response times are within acceptable limits.

The staff has reviewed NEDO–32291 and, by letter dated December 28, 1994 (B. Boger to R. Pinelli), issued its Safety Evaluation. Based on a review of the information presented by the BWROG, the staff concluded that significant degradation of instrument response times, i.e., delays greater than about 5 seconds, can be detected during the performance of other surveillance tests, principally calibration, if properly performed. Accordingly, the staff concluded response time testing can be eliminated from TSs for the selected instrumentation identified in the topical report and accepted NEO–32291 for reference in license amendment applications for all boiling water reactors provided that certain conditions are met. These conditions were specified in the staff's letter to the BWROG dated December 28, 1994.

In a letter dated January 27, 1995, the licensee submitted an application to amend their technical specifications based on the BWROG topical report. In their submittal, the licensee confirmed the applicability of the generic analysis of NEDO–32291 to their plant, and provided the supplemental information demonstrating compliance with the conditions specified in the staff's Safety Evaluation. In addition, the licensee identified their submittal as a cost beneficial licensing action (CBLA) and requested prompt approval by the staff so that they could implement the changes prior to their refueling outage scheduled for March 1995.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of Safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) The purpose of the proposed Technical Specification (TS) change is to eliminate response time testing requirements for selected components in the Reactor Protection System (RPS), Containment and Reactor Vessel Isolation Control System (CRVICS) instrumentation, and Emergency Core Cooling System (ECCS) actuation instrumentation. The Boiling Water Reactor Owners' Group (BWROG) has completed an evaluation which demonstrates that response time testing is redundant to the other TS-required testing. These other tests, in conjunction with actions take in response to NRC Bulletin 90–-01, ''Loss of Fill-Oil in Transmitters Manufactured by Rosemount,'' and Supplement 1, are sufficient to identify failure modes or degradations in instrument response time and ensure operation of the associated systems within acceptable limits.There are no known failure modes that can be detected by response time testing that cannot also be detected by the other TS-required testing. This evaluation was documented in NEDO–32291, ''System Analyses for Elimination of Selected Response Time Testing Requirements,'' January 1994. Illinois Power (IP) has confirmed the applicability of this evaluation to Clinton Power Station (CPS). In addition, IP will complete the actions identified in the NRC staff's safety evaluation of NEDO–32291.

Because of the continued application of other existing TS-required tests such as channel calibrations, channel checks, channel functional tests, and logic system functional tests, the response time of these systems will be maintained within the acceptance limits assumed in plant safety analyses and required for successful mitigation of an initiating event. The proposed changes do not affect the capability of the associated systems to perform their intended function within their required response time, nor do the proposed changes themselves affect the operation of any equipment. As a result, IP has concluded that

the proposed changes do not involve a significant increase in the probability or the consequences of an accident previously evaluated.

(2) The proposed changes only apply to the testing requirements for the components identified above and do not result in any physical change to these or other components or their operation. As a result, no new failure modes are introduced. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) The current TS-required response times are based on the maximum allowable values assumed in the plant safety analyses. These analyses conservatively establish the margin of safety. As described above, the proposed changes do not affect the capability of the associated systems to perform their intended function within the allowed response time used as the basis for the plant safety analyses. The potential failure modes for the components within the scope of this request were evaluated for impact on instrument response time. This evaluation confirmed that, with the exception of loss of fill-oil of Rosemount transmitters, the remaining TS-required testing is sufficient to identify failure modes or degradations in instrument response times and ensure operation of the instrumentation within the scope of this request is within acceptable limits. The actions taken in response to NRC Bulletin 90–01 and Supplement 1 are adequate to identify loss of fill-oil failures of Rosemount transmitters. As a result, it has been concluded that plant and system response to an initiating event will remain in compliance with the assumptions of the safety analyses.

Further, although not explicitly evaluated, the proposed changes will provide an improvement to plant safety and operation by reducing the time safety systems are unavailable, reducing the potential for safety system actuations, reducing plant shutdown risk, limiting radiation exposure to plant personnel, and eliminating the diversion of key personnel resources to conduct unnecessary testing. Therefore, IP has concluded that this request will result in an overall increase in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The result determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By March 6, 1995, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designed by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary of the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first perhearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later that 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant or a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram identification Number N1023 and the following message addressed to Leif J. Norrholm, Project Director, Project Directorate III–3, petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Leah Manning Stetener, Vice President, General Counsel, and Corporate Secretary, 500 South 27th Street, Decatur, Illinois 62525, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated January 27, 1995, which is available for public inspection the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727.

Dated at Rockville, Maryland, this 31st day of January, 1995

For the Nuclear Regulatory Commission.

Douglas V. Pickett,

Senior Project Manager, Project Directorate III–3, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulations.

[FR Doc. 95–2727 Filed 2–2–95; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 30–16055–ML–Ren; ASLBP No. 95–707–02–ML–Ren

Advanced Medical Systems, Inc.; Cleveland, OH; Designation of Presiding Officer

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 FR 28710 (1972), and Sections 2.105, 2.700, 2.702, 2.714, 2.714a, 2.717 and 2.721 of the Commission's Regulations, all as amended, a presiding officer from the Atomic Safety and Licensing Board Panel is hereby designated to rule on petitions for leave to intervene and/or requests for hearing and, if necessary, to serve as the presiding officer to conduct the hearing in the event that an informal adjudicatory hearing is ordered in the following Materials License Renewal proceeding.

Advanced Medical Systems, Inc., Cleveland, Ohio

Renewal of Material License No. 34–19089–01

The Presiding Officer is being designated pursuant to 10 CFR 2.1207 of the Commission's Regulations, ''Informal Hearing Procedures for Materials Licensing Adjudications,'' published in **Federal Register**, 54 F.R. 8269 (1989). This action is in response to hearing requests submitted by Earth Day Coalition, Northeast Ohio Regional Sewer District, and the City of Cleveland, Ohio. The hearing requests were submitted in response to an application filed with the Commission by Advanced Medical Systems, Inc. for renewal of its license for possession of radioactive materials.

The presiding officer in this proceeding is Administrative Judge Marshall E. Miller.

Following consultation with the Panel Chairman, pursuant to the provisions of 10 CFR 2.722, the Presiding Officer has appointed Dr. Harry Foreman to assist the Presiding Officer in taking evidence and in preparing a suitable record for review.

All correspondence, documents and other materials shall be filed with Judge Miller and Dr. Foreman in accordance with 10 CFR 2.701. Their addresses are; Administrative Judge Marshall E. Miller, Presiding Officer, 1920 South Creek Boulevard, Spruce Creek Fly-In, Daytona Beach, FL 32124; Dr. Harry Foreman, Special Assistance, 1564 Burton Avenue, St. Paul, MN 55108.

Issued at Rockville, Maryland, this 27th day of January 1995.

B. Paul Cotter, Jr.,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 95–2725 Filed 2–2–95; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–35293; File No. SR–MSTC–94–19]

Self-Regulatory Organizations; Midwest Securities Trust Company; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change Implementing New Procedures Regarding the Distribution of Hardcopy Reorganization Offer Notices

January 30, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on December 8, 1994, the Midwest Securities Trust Company (''MSTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared primarily by MSTC. On December 15, 1994, MSTC amended the proposed rule change by requesting that the Commission consider the proposal as being filed under Section 19(b)(2)[2] of the Act instead of Section 19(b)(3)(A)[3] of the Act.[4] The Commission is publishing this notice and order to solicit comments from interested

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 15 U.S.C. 78s(b)(2) (1988).

[3] 15 U.S.C. 78s(b)(3) (1988).

[4] Letter from David T. Rusoff, Foley & Lardner, to Peter R. Geraghty, Division of Market Regulation, Commission (December 15, 1994).

persons and to grant accelerated approval of the proposed rule change.

I. Self-Regulatory Organizations Statement of the Terms and Substance of the Proposed Rule Change

In light of the recent implementation of the Reorganization Processing System (''RPS''),[5] MSTC proposes to introduce new procedures regarding distribution of the hardcopy (*i.e.,* paper) reorganization offer notices to MSTC participants.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MSTC 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. MSTS has prepared summaries, set forth in section (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

The primary purpose of MSTC's proposed rule change is to implement new procedures regarding the distribution of hardcopy reorganization notices to MSTC members. Rule 4 under Article IV of MSTC's rules describes MSTC's activities with respect to reorganization information disseminated by MSTC. Pursuant to these rules, MSTC provides daily to all MSTC participates detailed written notices, termed ''Goldenrod Notices,'' of each newly announced or updated corporate reorganization offer. MSTC recently implemented RPS, an on-line computer system available to participants for accessing reorganization information; therefore, MSTC proposes to discontinue providing detailed written notices to all participants. Under the proposal, MSTC will provide hardcopy notices only to those participants with a Midwest Clearing Corporation (''MCC'') or MSTC position [6] in the security to which the notice relates on the date the RPS notice is produced by MSTC. Every participant will continue to have available information regarding every reorganization offer, but unless the participant has a position in the subject security, the information will be provided over RPS rather than in hardcopy reorganization notices. Consequently, MSTC participants that do not have a position in the affected security on the date MSTC produces the reorganization notices will have to use RPS to access the information.[7]

Following this rule change, two hardcopy reports that summarize offer information will be provided daily to all participants: the ''Offer Information Report'' and the ''Active Offers with Position Report.'' The Offer Information Report will identify new, updated, and closed RPS offers, and indicate whether the participant has a position with MSTC in the relevant CUSIPs. The Active Offers with Position Report will list all active RPS offers in which the participant has a MCC/MSTC position.

Sections 3 and 4 of rule 2 of Article IV set forth MSTC's responsibility with respect to reorganization information disseminated by MSTC. Consistent with MSTC's current policy, MSTC continues to disclaim any obligation, responsibility, or liability with respect to these written notices provided to participants.

MSTC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act and the rules and regulations thereunder applicable to MSTC because the proposal will further automate the processing of reorganization offers through the facilities of MSTC.

(B) Self-Regulatory Organization's Statement on Burden on Competition

MSTC believes that no burden will be placed on competition as a result of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

MSTC has not solicited or received any comments. MSTC will notify the Commission of any written comments it receives.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[8] The Commission believes that the proposed rule change is consistent with MSTC's obligations under Section 17A(b)(3)(F) because the rule change should help to reduce the labor and expense associated with distributing reorganization notices to all MSTC participants and thereby increases the efficiency of reorganization processing and advances the prompt and accurate clearance and settlement of securities transactions.

MSTC has requested that the Commission find good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of the filing. The Commission finds good cause for so approving the proposed rule change because the RPS system has been operational for more than six months and accelerated approval will allow MSTC to begin as soon as possible to reduce the amount of paper notices that it must produce.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington DC 20549. Copies of the submissions, 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 inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such

[5] For a complete description of RPS, refer to Securities Exchange Act Release No. 34200 (June 10, 1994), 59 FR 31283 [File No. SR–MSTC–94–8] (notice of filing and immediate effectiveness of a proposed rule change relating to reorganization processing).

[6] A MCC/MSTC position represents securities of a particular CUSIP of an individual participant at either the MCC or MSTC.

[7] Currently, RPS inquiries can be designed by participants to provide offer information regarding any combination of the following: (1) Position only, (2) selected date or date ranges, (3) offer status, (4) specific offer groups or types, (5) CUSIP or CUSIP ranges, and (6) critical date types. Participants subsequently can create customized reports containing this information. RPS represents offers classified as either nonmandatory, mandatory, or redemption. These offer classifications will be expanded to include nonexpiring offers. Nonmandatory offers include tenders, exchanges, puts, rights, and warrants. Mandatory offers include mergers, reverse splits, liquidations, bankruptcies, and name and CUSIP changes. Currently redemptions include partial prefundings, and convertible partial calls. Full calls, partial calls, and maturities are not yet included in RPS. Notably, MSTC anticipates that in the future participants will be able to use RPS for processing reorganization offer instructions in a real-time environment.

[8] 15 U.S.C. 78q–1(b)(3)((F) (1988).

filing will also be available for inspection and copying at the principal office of MSTC. All submissions should refer to File No. SR–MSTC–94–19 and should be submitted by February 24, 1995.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–MSTC–94–19) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–2694 Filed 2–2–95; 8:45 am]

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[Release No. 34–35287; File No. SR–NYSE–39; SR–Phlx–94–29; SR–PSE–94–34; SR–BSE–94–15; SR–CHX–94–28; SR–NASD–94–67; SR–CBOE–94–55]

Self-Regulatory Organizations; New York Stock Exchange, Inc., Philadelphia Stock Exchange, Inc., Pacific Stock Exchange, Inc., Boston Stock Exchange, Inc., Chicago Stock Exchange, Inc., National Association of Securities Dealers, Inc., and Chicago Board Options Exchange; Order Granting Accelerated Approval to Proposed Rule Change Adopting Rules for Short Position Reporting

January 27, 1995.

On October 27, 1994, the New York Stock Exchange, Inc. (''NYSE''), October 20, 1994, the Philadelphia Stock Exchange, Inc. (''Phlx''), November 23, 1994, the Pacific Stock Exchange, Inc. (''PSE''), November 28, 1994, the Boston Stock Exchange, Inc. (''BSE''), December 12, 1994, the Chicago Stock Exchange, Inc. (''CHX''), December 2, 1994, the National Association of Securities Dealers, Inc. (''NASD''),[1] and on January 3, 1995, the Chicago Board Options Exchange (''CBOE'') (collectively, the ''SROs'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] proposed rule changes to facilitate uniform short position reporting requirements.[4]

The proposed rule change filed by the CBOE was published for comment in Securities Exchange Act Release No. 35227 (January 13, 1995), 60 FR 4208 (January 20, 1995). In addition, all of the other proposed rule changes were published for comment in Securities Exchange Act Release No. 35147 (December 23, 1994), 60 FR 518 (January 4, 1995). No comments were received on the proposal from either notice publication.

The proposed rule changes emanated from an initiative by the SROs, as Intermarket Surveillance Group (''ISG'')[5] members, to ensure uniform short position reporting in U.S. traded securities.[6] Although the specific language of each proposed rule change differs slightly, the goal of the SROs is uniform in proposing the adoption of the above referenced rules. Generally, the SROs' goal is to ensure that a broker-dealer registered in the United States reports its open short positions to the SRO that is the broker-dealer's Designated Examining Authority (''DEA''). If the particular broker-dealer's DEA does not have rules governing the reporting of short interest positions, then the broker-dealer is to report to another SRO of which it is a member. Non-self-clearing broker-dealers, however, will be considered to have satisfied their reporting requirements by making the appropriate arrangements with their respective clearing organizations.

Substantively, the new reporting requirements will continue to include stocks and warrants, including odd lots, in each such security traded on a United States securities exchange or association. Further, the reports will continue to include both customer and proprietary positions, and for those broker-dealers with more then one ''account'' with a short position in the same stock or warrant, the combined aggregate should be reported. In this regard, the Commission notes that like accounts should be netted, and then multiple accounts should be aggregated.[7]

The format, time, and method of reporting will be prescribed by each SRO receiving short interest data.[8] Each such SRO will electronically send the data to the Securities Industry Automation Corporation (''SIAC'').[9] With respect to listed securities, SIAC will in turn consolidate all data in each security to generate a number representing the national short position in each such security. The NASD, however, will be performing this function with respect to Nasdaq securities. All Nasdaq short interest will be reported to the NASD by its members. Firms not members of the NASD will report their short interest positions in Nasdaq securities to an SRO, which will forward it to SIAC, which will then forward Nasdaq data to the NASD. The NASD will compile all short interest data in Nasdaq securities and send it, along with a consolidated national short interest position for each security, to SIAC for dissemination purposes.

Several exceptions to the general requirements outlined above are clarified in the ISG circular to members entitled ''Consolidated Reporting of Short Interest Positions.'' First, members and member organizations for which the CHX is the DEA, and who are self-clearing members of the Midwest Clearing Corporation (''MCC''), will have their reporting requirement satisfied automatically through the CHX's ability to capture the required information from the MCC. Further,

[9] 17 CFR 200.30–3(a)(12) (1994).

[1] In addition, the NASD filed Amendment No. 1 on January 11, 1995, to clarify who must report to the NASD, what the entities must report, and the mechanics of how to transmit such report. Because the Amendment does not substantively change the proposal, the Commission is not publishing it for comment. *See* letter from Joan C. Conley, Secretary, NASD, to Mark Barracca, Attorney, SEC, dated January 11, 1995.

[2] 15 U.S.C. 78s(b)(1) (1988).

[3] 17 CFR 240.19b–4 (1991).

[4] ''Short'' positions to be reported are those resulting from ''short'' sales as defined in SEC Rule 3b–3, but excludes positions resulting from sales specified in clauses (1), (6), (7), (8), (9) and (10) of paragraph (e) of SEC Rule 10a–1. Also to be excluded are ''short'' positions carried for other members and member organizations reporting for themselves.

[5] ISG was formed on July 14, 1983 to, among other things, coordinate more effectively surveillance and investigative information sharing arrangements. *See* Intermarket Surveillance Group Agreement, July 14, 1983.

[6] Specifically: (1) The BSE is adding § 38 to Chapter II of its Rules; (2) the CBOE is adopting interpretation and policy .02 to its Rule 15.1; (3) the CHX is adopting Article XI, Rule 9, and an interpretation thereto; (4) the NASD is amending Article III, Section 41; (5) the NYSE is amending Rule 421; (6) the PSE is adopting Rule 2.6(f); and (7) the Phlx is adopting Rule 786.

[7] The aggregation requirement, however, does not include the netting of short interest against long in a given security across ''non-like'' accounts. For example, if a broker dealer has three accounts for different customers, and account 1 has short interest of 100 shares, account 2 has short interest of 225 shares, and account 3 is long 150 shares, the broker dealer shall report short interest of 325, not 175. *See* CHX proposed Article XI, Rule 9, Interpretation and Policy .01. If, however, in the above example account 1 was the firm's customer account, and accounts 2 and 3 were the firm's proprietary accounts, then the firm would net accounts 2 and 3 to ascertain its proprietary account position (in this case short 75 shares). The firm would then report the aggregate of its customer account short interest position of 100 shares and its proprietary short interest position of 75 shares—175 shares short in total—for the firm in the particular security.

[8] Monthly reporting will remain in effect for the present but more frequent reporting might be initiated in the future. *See* Circular sent by the ISG to all members and member organizations titled ''Consolidated Reporting of Short Interest Positions.''

[9] SIAC is a jointly owned subsidiary of the NYSE and the Amex. Among other things, it handles the majority of the automation needs of the ISG.

certain CHX members which trade Nasdaq National Market System securities as specialists may be required by the CHX to report their short interest positions in those securities directly to the NASD.

Second, short interest position information for member organizations which act as specialists on the BSE, PSE or Phlx, will be processed by the clearing corporations utilized by these organizations.

Third, pursuant to an amendment of CBOE Rule 15.1, clearing members of the CBOE for which the CBOE is the DEA, will be required to report any short interest positions to another exchange or the NASD, even if solely a member of the CBOE. The CBOE will designate an exchange or the NASD to receive such reports on a case-by-case basis.[10]

Fourth, the Amex will be sending out a circular to its members informing them of the new requirements. The Amex did not submit a new filing because it is relying on the general language in its Rule 30 to encompass the proposal at hand.[11]

The new reporting requirements being approved herein will be tested by SIAC and the ISG members during the months of March and April, 1995. Testing will be conducted to ensure the reliability of the new reporting requirements, but the new figures will not be reported to the public. During the test period, broker-dealers currently subject to a reporting requirement must report open short interest positions under both the new reporting requirements and such current reporting requirement. After this test period, the new reporting requirements will be the only reporting requirements, and will be mandatory for all short positions. Thus, beginning in May, 1995, all broker-dealers will be reporting open short positions to an SRO under the new requirements. The national numbers generated as of that date will be reported to the public.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Sections 6(b) and 15A.[12] In particular, the Commission believes the proposal is consistent with the Section 6(b)(5) and 15A(b)(6) requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, and, in general, to protect investors and the public, in that the proposal should enhance the ability of the SROs, both collectively and individually, to monitor short interest reporting, and to reinforce their regulatory and surveillance capabilities in this area. In this regard, the Commission commends the ISG in recognizing that consolidated short interest figures, that would include the regional exchanges, would serve as an important surveillance tool to monitor trading activity. Further, the Commission believes that uniform short interest reporting requirements, and subsequent aggregation and reporting by SIAC, will enable the public to make more informed investment decisions in the United States market.

Finally, the Commission finds good cause for approving the proposed rule changes prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission believes that accelerated approval of the proposal is appropriate in order to allow the SROs to inform their members about the new short interest reporting rules and how the new reporting requirements will be tested and implemented. Further, shortly after the approval date hereof, a circular will be sent out by the ISG, as indicated above, which will contain some additional clarifying information. The Commission notes that the new procedures were noticed in the **Federal Register** for the full statutory period and the Commission did not receive any comments on it. Although the CBOE filing was not published for the full period, the Commission notes that the intent of all of the proposals encompassed herein is the same. To facilitate the orderly implementation of the changes in short interest reporting requirements, the Commission is approving all filings simultaneously.

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[13] that the proposed rule changes (SR–NYSE–94–39; SR–Phlx–94–29; SR–PSE–94–34; SR–BSE–94–15; SR–CHX–94–28; SR–NASD–94–67; SR–CBOE–94–55) are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–2653 Filed 2–2–95; 8:45 am]

BILLING CODE 8010–01–M

[10] The CBOE and NASD have represented to the Commission that currently this exception applies to only one firm. That firm will be reporting to the NASD pursuant to an agreement between the CBOE and the NASD. Conversations between Amy Bilbija, Attorney, SEC, and Jim Cangiano, NASD, on January 23, 1995; and Jeff Schroer, CBOE, on January 23, 1995.

[11] *See* Amex Rule 30 requiring every member to file with the Amex such periodic reports or special reports as the Board of Governors may authorize. The Amex currently requires short interest position reporting of its membership pursuant to this Rule, and will continue to rely on this Rule to require the new reporting.

[12] 15 U.S.C. §§ 78f(b), 78o–3 (1988).

[13] 15 U.S.C. § 78s(b)(2) (1988).

[14] 17 CFR 200.30–3(a)(12) (1991).

[Rel. No. IC–20867; File No. 812–9320]

G.T. Global Growth Series; Notice of Application

January 27, 1995.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (''the Act'').

APPLICANTS: G.T. Global Growth Series (''Growth Series''), G.T. Investment Funds, Inc. (''Investment Funds''), G.T. Investment Portfolios, Inc. (''Investment Portfolios''), G.T. Capital Management, Inc. (the ''Adviser''), and G.T. Global Financial Services, Inc. (''Distributor'').

RELEVANT ACT SECTIONS: Order requested under section 6(c) of the Act exempting applicants from sections 2(a)(32), 2(a)(35), 18(f)(1), 18(g), 18(i), 22(c), and 22(d) of the Act and rule 22c–1 thereunder.

SUMMARY OF APPLICATION: Applicants request an order that would permit certain investment companies to issue multiple classes of shares representing interests in the same portfolios of securities and assess, and under certain circumstances waive, a contingent deferred sales charge (''CDSC'') on redemptions of shares.

FILING DATES: The application was filed on November 4, 1994, and amended on January 5, 1995.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 21, 1995, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street NW., Washington, DC 20549.

Applicants, 50 California Street, San Francisco, California 94111.

FOR FURTHER INFORMATION CONTACT: Bradley W. Paulson, Staff Attorney, at (202) 942–0147 or Robert A. Robertson, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC's Public Reference Branch.

Applicants' Representations

A. Multi-Class Distribution System

1. Growth Series, Investment Funds, and Investment Portfolios are open-end management investment companies registered under the Act. Applicants request relief on behalf of themselves and any future open-end management investment company for which G.T. Capital (or any person controlling, controlled by, or under common control with G.T. Capital) serves as investment adviser or G.T. Global (or any person controlling, controlled by, or under common control with G.T. Global) serves as principal underwriter. These future companies, together with Growth Series, Investment Funds, and Investment Portfolios, are referred to as the ''Companies.'' Existing and future series of each Company are referred to as the ''Portfolios.'' The Adviser is the investment adviser and administrator for each existing Portfolio, and the Distributor serves as principal underwriter for each existing Portfolio.

2. The existing Portfolios currently offer multiple classes of shares in accordance with existing exemptive orders.[1] Under those orders, shares are offered subject to either a front-end sales charge in accordance with the applicable provisions of rule 22d–1 under the Act and a distribution plan adopted in accordance with rule 12b–1 under the Act or a CDSC and a rule 12b–1 plan. Applicants request an order amending and superseding their prior orders to permit them to offer unlimited classes of shares in accordance with a ''Multiple Class System.''

3. Under this system, each class of shares of a Portfolio would be identical in all respects to any other class of shares of that Portfolio except: (1) Each class would have different class designations; (2) each class may have a different sales charge; (3) each class would bear the expense of any payments made under a rule 12b–1 plan and/or shareholder services plan (collectively, the ''Plans''), if any, entered into with respect to such class; (4) each class could bear certain other expenses directly attributable only to that class described in condition one, below (''Class Expenses''); (5) only the holders of a class of shares would be entitled to vote on matters pertaining to a Plan, related agreements, or other matters relating to such class; and (6) exchange privileges could vary among the classes.

4. With respect to each class, a Company (on behalf of a Portfolio) could enter into one or more rule 12b–1 plan agreements and/or shareholder services plan agreements (''Plan Agreements'') concerning the provision of certain services to shareholders of a particular class by the Adviser, the Distributor, other groups, organizations or institutions.

5. The gross income of each Portfolio will be allocated to each class based upon the relative daily net assets of the class. Expenses of a company that cannot be attributed directly to any one Portfolio (''Company Expenses'') will be allocated to each Portfolio based on the relative daily net assets of those Portfolios. Expenses attributable to a particular Portfolio, but not a particular class of shares (''Portfolio Expenses''), will be allocated to each class based upon the relative daily net assets of the class. Class Expenses will be charged directly to the net assets of the particular class and will be borne on a pro rata basis by the outstanding shares of such class. Accordingly, the net income and net asset value per share of (and dividends and other distributions payable to) each class may differ from other classes in the same Portfolio.

6. The shares of different classes of a Portfolio will have different exchange privileges. Applicants anticipate that shares of each class of a Portfolio will be exchangeable for shares of the corresponding class of one or more other Portfolios. Such exchanges will be based on the respective net asset values of the shares being exchanged. All exchange privileges will comply with rule 11a–3 under the Act.

B. The CDSC

1. Applicants also request an exemption to allow the Portfolios to impose a CDSC on redemptions of certain classes of shares (''CDSC Shares'') and to waive or reduce the CDSC on redemptions under certain circumstances. The sum of any initial sales charge, asset-based sales charge, and CDSC imposed on shares of a class will not exceed the maximum sales charge provided for in Article III, Section 26(d) of the Rules of Fair Practice of the National Association of Securities Dealers, Inc.

2. A Portfolio's CDSC may be imposed at a constant or declining rate over a specified period of years (''CDSC Period''). No CDSC would be imposed on any redemption of CDSC Shares representing reinvestment of dividends or other distributions. As presently contemplated, no CDSC would be imposed on any redemption of CDSC Shares that were purchased more than six years prior to the redemption.

3. The amount of the CDSC would be the lesser of the amount representing a specified percentage of the net asset value of the CDSC Shares at the time of purchase or the amount representing such percentage of the net asset value at the time of redemption. As a result, no CDSC would be imposed on amounts representing an increase in the value of the shareholder's account resulting from capital appreciation above the amount paid for CDSC Shares purchased in the CDSC Period. In determining the applicability and rate of any CDSC, it would be assumed that a redemption is made first of shares representing reinvestment of dividends and capital gain distributions, next of shares held by the shareholder for a period equal to or greater than the CDSC Period, and finally of other shares held by the shareholder for the longest period of time. This would result in a charge, if any, imposed at the lowest possible rate.

4. Applicants request relief to permit each Portfolio to waive or reduce the CDSC under certain circumstances. Any waiver or reduction will comply with the conditions contained in paragraphs (a) through (d) of rule 22d–1.

5. Applicants also request the ability to provide a credit for any CDSC paid in connection with a redemption of Shares followed by a reinvestment effected within a specified period not exceeding 365 days of the redemption. If an investor redeems CDSC Shares and pays a CDSC, then subsequently reinvests all of his redemption proceeds in CDSC Shares of the same or a different Fund within 365 days, the investor will be credited for the full amount of the CDSC paid. If the investor chooses instead to invest less than the full amount of the redemption proceeds, the investor will be credited a pro rata amount of the CDSC. The credit will be paid by the principal underwriter.

Applicants' Legal Analysis

1. Applicants request an exemption under section 6(c) of the Act from

[1] *G.T. Global Growth Series*, Investment Company Act Release No. 19022 (Feb. 4, 1994) (notice) and 20101 (Mar. 1, 1994) (order); and *G.T. Global Growth Series*, Investment Company Act Release No. 18961 (Sept. 17, 1992) (notice) and 19022 (Oct. 14, 1992) (order).

sections 18(f)(1), 18(g), and 18(i) of the Act to the extent that the proposed issuance and sale of multiple classes of shares representing interests in a Fund's Portfolios could be deemed: (A) to result in a ''senior security'' within the meaning of section 18(g) and to be prohibited by section 18(f)(1), and (B) to violate the equal voting provisions of section 18(i). Applicants believe that the proposed allocation of expenses and voting rights in the manner described above is equitable and would not discriminate against any group of shareholders. The proposed arrangement does not involve borrowings, and does not affect the Funds' existing assets or reserves. The proposed arrangement also will not increase the speculative character of the shares of a Fund.

2. Applicants also request an exemption under section 6(c) from sections 2(a)(32), 2(a)(35), 22(c), and 22(d) of the Act and rule 22c–1 thereunder to permit the Funds to assess, and under certain circumstances waive, a CDSC in connection with the redemption of shares.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the conditions set forth below.

1. Each class of shares of a Portfolio will represent interests in the same portfolio of investments, and be identical in all respects, except as set forth below. The only differences between the classes of shares of a Portfolio will relate solely to one or more of the following: (a) Expenses assessed to a class pursuant to a Plan, if any, with respect to such class; (b) sales charges applicable to a class of shares, if any (c) the impact of Class Expenses, which are limited to any or all of the following: (i) Transfer agent fees identified as being attributable to a specific class of shares, (ii) stationery, printing, postage, and delivery expenses related to preparing and distributing materials such as shareholder reports, prospectuses, and proxy statements to current shareholders of a specific class of shares, (iii) Blue Sky registration fees incurred by a specific class of shares, (iv) SEC registration fees incurred by a specific class of shares, (v) expenses of administrative personnel and services as required to support the shareholders of a specific class of shares, (vi) directors' fees or expenses incurred as a result of issues relating to a specific class of shares, (vii) accounting expenses relating solely to a specific class of shares, (viii) auditors' fees, litigation expenses, and legal fees and expenses relating to a specific class of shares, (ix) expenses incurred in connection with shareholders meetings as a result of issues relating to a specific class of shares, (x) organizational expenses related to a specific class of shares and (xi) any other incremental expenses subsequently identified which should be properly allocated to a specific class of shares and which, as such, are approved by the SEC pursuant to an amended order or by rule or regulation; (d) the fact that the classes will vote separately with respect to matters relating to the applicable distribution plan and related agreements, if any, or any other matters appropriately limited to such class(es); (e) the different exchange privileges of the classes of shares, if any; and (f) the designation of each class of shares of a Portfolio.

2. The board of directors of each Company, including a majority of the directors who are not interested persons of the Company (''Independent Directors''), will have approved the Multiple Class System with respect to a particular Portfolio of the Company prior to the implementation of the system by that Portfolio. The minutes of the meetings of the board of the Company regarding the deliberations of the directors with respect to the approvals necessary to implement the Multiple Class System will reflect in detail the reasons for the determination by the board that the proposed Multiple Class System is in the best interests of each Portfolio and its shareholders.

3. The initial determination of the Class Expenses that will be allocated to a particular class and any subsequent changes thereto will be reviewed and approved by a vote of the appropriate board of directors, including a majority of the Independent Directors. Any person authorized to direct the allocation and disposition of monies paid or payable by a Portfolio to meet Class Expense shall provide to the applicable board and the directors shall review, at least quarterly, a written report of the amounts so expended and the purposes for which such expenditures were made.

4. If any class will be subject to a shareholder services plan, the plan(s) will be adopted and operated in accordance with the procedures set forth in rule 12b–1 (b) through (f) as if the expenditures made thereunder were subject to rule 12b–1, except that shareholders need not enjoy the voting rights specified in rule 12b–1.

5. On an ongoing basis, the board of each Company, pursuant to its fiduciary responsibilities under the Act and otherwise, will monitor each Portfolio, as applicable, for the existence of any material conflicts among the interests of the classes of its shares, if there is more than one class. The board, including a majority of the Independent Directors, shall take such action as is reasonably necessary to eliminate any such conflicts that may develop. Each Portfolio's principal underwriter and investment adviser will be responsible for reporting any potential or existing conflicts to the appropriate board. If such a conflict arises, the Portfolio's principal underwriter and investment adviser, at their own expense, will take such actions as are necessary to remedy such conflict, including establishing a new registered management investment company, if necessary.

6. The principal underwriter of each Portfolio implementing a Multiple Class System will adopt compliance standards with respect to when each class of shares may be appropriately sold to particular investors. Applicants will require all persons selling shares of the Portfolios to agree to conform to such standards.

7. The board of directors of each Company will receive quarterly and annual statements concerning the amounts expended under the Company's Plans in compliance with paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time. In the statements, only expenditures properly attributable to the sale or servicing of a particular class of shares will be used to justify and fee for services charged to that class. Expenditures not related to the sale or servicing of a particular class will not be presented to the board to justify any fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review and approval of the Independent Directors in the exercise of their fiduciary duties.

8. Dividends and other distributions paid by a Portfolio with respect to each class of its shares, to the extend any dividends and other distributions are paid, will be declared and paid on the same day and at the same time, and will be determined in the same manner and will be in the same amount, except that the amount of the dividends and other distributions declared and paid by a particular class may be different from that of another class because payments made under a Plan or Plan Agreement by a class and Class Expenses will be borne exclusively by that class.

9. The methodology and procedures for calculating the net asset value and dividends and other distributions of the classes and the proper allocation of expenses among the classes have been reviewed by an expert (''Expert'') who has rendered a report to applicants,

which has been provided to the staff of the SEC, stating that such methodology and procedures are adequate to ensure that such calculations and allocations will be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, will render at least annually a report to the Portfolios that the calculations and allocations are being made properly. The reports of the Expert will be filed as part of the periodic reports filed with the SEC pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following request by the Portfolios (which the Portfolios agree to provide), will be available for inspection by the SEC staff upon written request to the Portfolios for such work papers by a senior member of the Division of Investment Management, limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, an Assistant Director, and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert is a ''Special Purpose'' report on ''policies and procedures placed in operation'' in accordance with Statement on Auditing Standards (''SAS'') No. 70, ''Reports on the Processing of Transactions by Service Organizations,'' of the American Institute of Certified Public Accountants (''AICPA''). Ongoing reports will he on ''policies and procedures placed in operation and tests of operating effectiveness'' prepared in accordance with SAS No. 70 of AICPA, as it may be amended from time to time, or similar auditing standards as may be adopted by the AICPA from time to time and any such other then applicable auditing standards as may be adopted by the AICPA.

10. Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends and other distributions of the classes of shares and the proper allocation of expenses among the classes of shares and this representation has been concurred with by the Expert in the initial report referred to in the preceding condition and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in the preceding condition. Applicants will take immediate corrective action if the Expert, or appropriate substitute Expert, does not so concur in the ongoing reports.

11. The prospectuses of each class of shares will contain a statement to the effect that a salesperson and any other person entitled to receive compensation for selling or servicing shares may receive different compensation with respect to one particular class of shares over another in the Portfolios.

12. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the board of each Portfolio with respect to the Multiple Class System will be set forth in guidelines which will be furnished to the directors.

13. Each Portfolio implementing a Multiple Class System will disclose the respective expenses, performance data, distribution arrangements, services, fees, sales charges (if any), and exchange privileges applicable to each class of its shares in every prospectus, regardless of whether all classes of its shares are offered pursuant to each prospectus. Each Portfolio will disclose the respective expenses and performance data applicable to all classes of its shares in every shareholder report. The shareholder reports will contain, in the statement of assets and liabilities and statements of operations, information related to the Portfolio as a whole generally and not on a per class basis. Each Portfolio's per share data, however, will be prepared on a per class basis with respect to all classes of shares of such Portfolio. To the extent that any advertisement or sales literature describes the expenses or performance data applicable to any class of its shares, each Portfolio will also disclose the respective expenses and/or performance data applicable to all classes of that Portfolio's shares. The information provided by an applicant or other Portfolio for publication in any newspaper or similar listing of a Portfolio's net asset value or public offering price will present each class of that Portfolio's shares separately.

14. Applicants acknowledge that the grant of the exemptive order requested by this application will not imply SEC approval of, authorization of, or acquiescence in any particular level of payments that any Portfolio may make pursuant to a Plan in reliance on the exemptive order.

15. Applicants will comply with the provisions of proposed rule 6c–10 under the Act, Investment Company Act Release No. 16619 (November 2, 1988), as such rule is currently proposed and as it may be reproposed, adopted or amended.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–2656 Filed 2–2–95; 8:45 am]

BILLING CODE 8010–01–M

Issuer Delisting; Notice of Application to Withdraw From Listing and Registration; (Health-Mor Inc., Common Stock, $1 Par Value) File No. 1–6220

January 30, 1995.

Health-Mor Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified security (''Security'') from listing and registration on the American Stock Exchange, Inc. (''Amex'').

The reasons alleged in the application for withdrawing the Security from listing and registration include the following:

According to the Company, its Board of Directors (''Board'') unanimously approved a resolution on October 19, 1994, to withdraw the Security from listing on the Amex and, instead, list the Security on the National Association of Securities Dealers Automated Quotation/National Market System (''NASDAQ/NMS''). According to the Company, the decision of the Board followed a lengthy study of the matter and was based upon the belief that listing of the Security on NASDAQ/NMS will be more beneficial to its stockholders than the present listing on the Amex because:

(a) There will be advantage (potential for research coverage and other financial services for example) of the support of Market Makers (currently there are an average of 11 Market Makers on the average NASDAQ company) versus the single specialist;

(b) The nature of the trading activity and pattern of the Amex specialist, in essence being the buyer and seller of last resort, will be eliminated;

(c) There is greater visibility of the NASDAQ exchange as compared to the Amex through various media;

(d) The history of NASDAQ being a successful promoter of growth companies more appropriately addresses the Company's current position;

(e) There is potentially more capital support for the Company through NASDAQ as each Market Maker is

responsible to purchase 5,000 shares; and

(f) The services offered through the NASDAQ, which have been reviewed, are more likely to assist the Company in understanding the market and communicating with its shareholders.

Any interested person may, on or before February 21, 1995, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–2651 Filed 2–2–95; 8:45 am]

BILLING CODE 8010–01–M

Issuer Delisting; Notice of Application to Withdraw From Listing and Registration; (NuMed Home Health Care, Inc., Common Stock, $.001 Par Value) File No. 1–12992

January 30, 1995.

NuMed Home Health Care, Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified security (''Security'') from listing and registration on the American Stock Exchange, Inc. (''Amex'').

The reasons alleged in the application for withdrawing the Security from listing and registration include the following:

According to the Company, its Board of Directors (''Board'') unanimously approved a resolution on January 10, 1995, to withdraw the Security from listing on the Emerging Company Marketplace of the Amex (''Amex/ECM'') and, instead, list the Security on the National Association of Securities Dealers Automated Quotation Small Cap Market System/National Market System (''NASDAQ/NMS''). The Company believes that:

(1) The NASDAQ SmallCap Market system of competing market-makers will result in increased visibility and sponsorship for the Security than is presently the case with the single specialist assigned to the Security on the Amex/ECM;

(2) The NASDAQ SmallCap Market system will offer the Company's shareholders more liquidity than presently available on the Amex/ECM and less volatility in quoted price per share when trading volume is slight;

(3) The NASDAQ SmallCap Market system will offer the opportunity for the Company to more effectively consummate its proposed offering of 1,100,000 Units; and

(4) Firms making a market in the Company's Security on the NASDAQ SmallCap Market system will be inclined to issue research reports concerning the Company, thereby increasing the number of firms providing institutional research and advisory reports.

Any interested person may, on or before February 21, 1995, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–2652 Filed 2–2–95; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–26223]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

January 27, 1995.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 21, 1995, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

EUA Energy Investment Corporation (70–8283)

EUA Energy Investment Corporation (''EEIC''), P.O. Box 2333, Boston, Massachusetts 02107, a wholly owned subsidiary company of Eastern Utilities Associates, a registered holding company, has filed a post-effective amendment under Section 12(b) of the Act and Rule 45 thereunder to its application-declaration filed under Section 6(a), 7, 9(a), 10 and 12(b) of the Act and Rule 45 thereunder.

By order dated January 24, 1994 (HCAR No. 25976), EEIC was authorized, among other things, to provide up to $1 million of capital contributions and up to $2 million of open account advances and/or loans to TransCapacity L.P. for the research, development and commercialization of an energy-related computer software and hardware system for the collection, compilation and distribution of an information database composed of information regarding natural gas pipeline capacity and capacity rights. As of December 31, 1994, EEIC has provided TransCapacity L.P. with $2.275 million in funding for its working capital, leaving EEIC with unexercised authorization to contribute $725,000 to TransCapacity L.P.

EEIC now proposes to make additional capital contributions to TransCapacity L.P., through December 31, 1996 up to an aggregate principal amount of $2 million. The partners for TransCapacity L.P. project that they will require up to $2 million of additional funding from EEIC for working capital purposes due to unavoidable delays in achieving their target date for full

operation of the Energy Bulletin Board system.

New England Electric Resources, Inc. et al. (70–8513)

New England Electric System (''NEES''), a registered holding company, and its nonutility subsidiary company, New England Electric Resources, Inc. (''NEERI''), both located at 25 Research Drive, Westborough, Massachusetts 01582, have filed an application-declaration under Sections 6(a), 7, 9(a), 10, and 12(b) of the Act and Rules 40 and 45 thereunder.

By orders dated September 4, 1992, April 1, 1994 and May 25, 1994 (HCAR Nos. 25621, 26017 and 26057, respectively), NEES was authorized to capitalize NEERI in amounts of up to $2.5 million. By the same orders, NEERI was authorized to: (1) Enter into the business of performing consulting services on electric utility matters for nonaffiliates; (2) provide electrical related services for nonaffiliates; and (3) invest in a start-up company formed to develop, manufacture and market a low harmonic distortion uninterruptible power supply.

NEERI now seeks authority, through 1998, to invest up to $10 million in research and development activities in connection with environmental, new electrical generation and transmission technologies, and electric end-use technologies, NEERI will not acquire any securities in connection with its research and development activities without further Commission approval. NEES seeks authority for the same period to provide additional financing for NEERI in an amount not to exceed $10 million through non-interest bearing subordinated loans or capital contributions. NEES' request to capitalize NEERI is in addition to its pending request to provide additional financing to NEERI in amounts of up to $11.7 million in S.E.C. File No. 70–8475.

Further, in order to allow NEERI to acquire securities in local enterprises pursuant to Rule 40(a)(5) under the Act, NEES also seeks authority to provide additional financing for NEERI in an annual aggregate amount not to exceed $1 million through non-interest bearing subordinated loans or capital contributions, also through 1998.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–2654 Filed 2–2–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20866; No. 812–9336]

State Mutual Life Assurance Company of America, et al.

January 27, 1995.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice of Application for an Order under the Investment Company Act of 1940 (the ''1940 Act'').

APPLICANTS: State Mutual Life Assurance Company of America (''State Mutual''), Separate Account VA–P of State Mutual Life Assurance Company of America (''State Mutual Account''), SMA Life Assurance Company (''SMA Life,'' together with State Mutual, the ''Insurance Companies''), Separate Account VA–P of SMA Life Assurance Company (''SMA Life Account'') and other separate accounts established by the Insurance Companies in the future to support certain deferred variable annuity contracts issued by the Insurance Companies (''Other Accounts,'' together with the State Mutual Account and the SMA Life Account, the ''Accounts'').

RELEVANT 1940 ACT SECTIONS: Order requested under Section 6(c) granting exemptions from the provisions of Sections 26(a)(2)(C) and 27(c)(2).

SUMMARY OF APPLICATION: Applicants seek an order permitting the deduction of a mortality and expense risk charge from the assets of: (a) The Accounts in connection with the offer and sale of certain variable annuity contracts (''Annuity Contracts''); (b) the Accounts in connection with the issuance of variable annuity contracts that are substantially similar in all material respects to the Contracts (''Future Contracts,'' together with Annuity Contracts, the ''Contracts''); and (c) any other separate account established in the future by the Insurance Companies in connection with the issuance of Contracts.

FILING DATE: The application was filed on November 22, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving the 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 February 21, 1995, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, c/o Joseph W. MacDougall, Jr., State Mutual Life Assurance Company of America, 440 Lincoln Street, Worcester, Massachusetts, 01653.

FOR FURTHER INFORMATION CONTACT: Kevin Kirchoff, Senior Attorney, or Wendy Friedlander, Deputy Chief, at (202) 942–0670, Office of Insurance Products (Division of Investment Management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the Commission's Public Reference Branch.

Applicants' Representations

1. State Mutual is a mutual life insurance company incorporated under the laws of Massachusetts. SMA Life, a wholly-owned subsidiary of State Mutual, is a stock life insurance company organized under the provisions of the Delaware Insurance Code. SMA Life is registered as a broker-dealer under the Securities Exchange Act of 1934 (''1934 Act'') and is a member of the National Association of Securities Dealers (''NASD''). State Mutual is authorized to conduct business as an insurance company in all states and in the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

2. The Accounts are separate investment accounts established by the Insurance Companies for the purpose of investing purchase payments received under the Contracts. Each of the Accounts is a unit investment trust which has filed a registration statement on Form N–4 under the Securities Act of 1933 to register the offering of the Contracts, and the Applicants incorporate such registration statements into the application by reference.

Each Account presently consists of seven Subaccounts, each of which will invest solely in the shares of one of the portfolios of the Pioneer Variable Contracts Trust. Contract owners may invest in any one or more of the Subaccounts, and may also invest in the fixed account, part of the general account of the respective Insurance Companies. The Insurance Companies may, in the future, issue through the Accounts, and through other separate accounts that they may establish in the future, other variable annuity contracts that are substantially similar in all material respects to the Annuity Contracts.

3. Pioneer Variable Contracts Trust is a diversified open-end management investment company which consists of various investment series or portfolios (collectively, ''Portfolios'') with different investment objectives and policies. Shares of the Portfolios are purchased by the Insurance Companies for the corresponding Subaccounts at the net asset value. Shares of the Portfolios also are offered to other affiliated or unaffiliated separate accounts of the Insurance Companies or of other insurance companies offering variable annuity or variable life insurance contracts.

4. Allmerica Investments, Inc., an indirect wholly-owned subsidiary of State Mutual, is registered as a broker-dealer under the 1934 Act and is a member of the NASD. Allmerica Investments, Inc. is the principal underwriter for the Contracts.

5. The Contracts are group and individual combination fixed and variable contracts designed for use in retirement plans which qualify for special federal income tax treatment under sections 401, 403(b), 408 and 457 of the Internal Revenue Code and in retirement plans which do not qualify for special tax treatment under those sections.

6. The Contracts provide for minimum initial purchase payments and permit additional minimum purchase payments and periodic payments, subject to certain limitations. The Contracts provide for the accumulation of values on a variable basis determined by the investment experience of the Portfolios to which the Contract owner allocates payments.

7. The Contracts also provide for the payment of a death benefit. The death benefit, payable in a single sum or under an optional method of settlement, is provided if the annuitant dies before the maturity, surrender, or termination of a Contract. Upon the death of the annuitant, the death benefit is equal to the greatest of (a) the accumulated value under the Contract next determined following receipt of due proof of death at the Insurance Companies' principal office, or (b) the total amount of gross payments made under the Contracts reduced proportionally to reflect the amount of all prior partial withdrawals, or (c) the death benefit that would have been payable on the most recent fifth interval policy anniversary, increased for subsequent purchase payments and reduced proportionally to reflect withdrawals after that date.

8. Various fees and expenses are deducted under the Contracts. Prior to a Contract's maturity, the Insurance Companies assess a Contract Fee of $30, at each Contract anniversary and at full surrender during a contract year for its costs in maintaining each Contract and the Accounts. The Insurance Companies make a daily charge to the Subaccounts of the Accounts equal on an annual basis to 0.15% of the current value of the Subaccounts (''Administrative Service Charge''). The Administrative Service Charge is designed to cover actual administrative expenses which exceed the revenue for the Contract Fee. Applicants represent that the Administrative Service Charge and the Contract Fee have been set at a level that will recover no more that the actual costs associated with administering the Contract and the Accounts. The Insurance Companies do not expect to realize a profit from these charges, and guarantee that the amount of the charges will not increase over the life of the Contract.

9. The Insurance Companies will deduct any premium tax levied by any governmental entity as a result of the Contracts or the Accounts. Applicants state that, where permitted by state law, the premium taxes will be deducted upon annuitization. In all other jurisdictions, the taxes will be deducted upon the death of the annuitant, surrender, or withdrawal, as may be required by the law of the Contract owner's state of residence.

10. Prior to the Annuity Commencement date, amounts held under the Contracts may be transferred among the Subaccounts and the respective Insurance Company's general account. The Insurance Companies currently make no charge for transfers among the accounts, but reserve the right to assess a charge, guaranteed never to exceed $25.

11. Applicants represent that the Insurance Companies will deduct the annual Contract Fee, the annual Administrative Service Charge, and any Transfer Charge in reliance upon and in conformity with all of the requirements of Rule 26a–I under the 1940 Act.

12. No sales charges are deducted from premium payments under the Contracts. The Contracts assess a Contingent Deferred Sales Charge (''CDSC'') which is applied in the case of contract surrender, partial redemptions or annuitization under period certain options during the seven year period from the date the Insurance Companies receive and accept each purchase payment. The CDSC is determined by the number of Contract anniversaries that have passed since the purchase payment that is being withdrawn was made. The CDSC is computed as follows:

Years from date of payment to date of withdrawal	Withdrawal charge (percent)
0–3	7
4	6
5	5
6	4
7	3
More than 7	None

In no event will the Contingent Deferred Sales Charges assessed against a Contract exceed 8% of the gross purchase payments.

The Insurance Companies do not anticipate that the CDSC will generate sufficient revenues to pay the cost of distributing the Contracts. If this charge is insufficient to cover the expenses, the deficiency will be met from the Insurance Companies' general account assets, which may include amounts derived from the charge for mortality and expenses risks, discussed below.

13. A daily charge equal to an effective annual rate of 1.25% of the net asset value of the Accounts will be imposed to compensate the Insurance Companies for bearing certain mortality and expenses risks in connection with the Contracts. Of this amount, approximately 0.80% is allocable to mortality risks and approximately 0.45% is allocable to expense risks. The mortality and expense risk charge is guaranteed never to exceed 1.25%. This charge may be a source of profit for the Insurance Companies which will be added to their surplus and may be used for, among other things, the payment of distribution expenses.

14. The mortality risk arises from the Insurance Companies' (1) Guarantee that they will make annuity payments, in accordance with annuity rate provisions established at the time a Contract is issued for the life of the annuitant or in accordance with the annuity option selected, no matter how long the annuitant or other payee lives and no matter how long all annuitants as a class live, and (2) death benefit guarantees under the Contracts.

15. The expense risk borne by the Insurance Companies is the risk that the charges for administrative expenses, which are guaranteed not to increase for the life of the Contracts, may be insufficient to cover the actual costs of issuing and administering the Contracts.

Applicants' Legal Analysis and Conditions

1. Applicants request an order of the Commission under Section 6(c) for exemptions from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act to the extent necessary to permit the deduction of a maximum charge of

1.25% for the assumption of mortality and expense risks from the assets of: (a) The Accounts in connection with the issuance of the Annuity Contracts; (b) the Accounts in connection with the issuance of any Future Contracts; and (c) any other separate account established in the future by the Insurance Companies in connection with the issuance of Future Contracts. Applicants believe that the requested exemptions are necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

2. Applicants submit that their request for exemptive relief for deduction of the 1.25% mortality and expense risk charge from the assets of the Accounts, or any other separate account established by the Insurance Companies in the future, in connection with the issuance of Future Contracts, would promote competitiveness in the variable annuity contract market by eliminating the need for the Insurance Companies to file redundant exemptive applications, thereby reducing the Insurance Companies' administrative expenses and maximizing the efficient use of their resources. Applicants further submit that the delay and expense involved in having repeatedly to seek exemptive relief would impair the Insurance Companies' ability effectively to take advantage of business opportunities as they arise. Further, if the Insurance Companies were required repeatedly to seek exemptive relief with respect to the same issues addressed in this Application, investors would not receive any benefit or additional protection thereby. Thus, Applicants believe that the requested exemptions are appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the 1940 Act.

3. Section 6(c) of the 1940 Act authorizes the Commission, by order upon application, to conditionally or unconditionally grant an exemption from any provision, rule or regulation of the 1940 Act to the extent that the 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 1940 Act.

4. Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act, in relevant part, prohibit a registered unit investment trust, its depositor or principal underwriter, from selling periodic payment plan certificates unless the proceeds of all payments, other than sales loads, are deposited with a qualified bank and held under arrangements which prohibit any payment to the depositor or principal underwriter except a reasonable fee, as the Commission may prescribe, for preforming bookkeeping and other administrative duties normally performed by the bank itself.

5. Applicants represent that the 1.25% mortality and expense risk charge under the Contracts is within the range of industry practice for comparable annuity contracts. This representation is based upon Applicants' analysis of similar industry products, taking into account such factors as current change levels, existence of charge level guarantees, and guaranteed annuity rates. Applicants represent that the Insurance Companies will maintain at their home offices, available to the Commission, a memorandum setting forth in detail the products analyzed in the course of, and the methodology and results of, their comparative survey.

6. Applicants acknowledge that, if a profit is realized from the mortality and expense risk charge under the Contracts, all or a portion of such profit may be available to pay distribution expenses not reimbursed by the CDSC. The Insurance Companies have concluded that there is a reasonable likelihood that the proposed distribution financing arrangements will benefit the Accounts and the Contract owners. The basis for that conclusion is set forth in a memorandum which will be maintained by the Insurance Companies at their administrative offices and will be made available to the Commission.

7. Applicants also represent that the Accounts will invest only in underlying open-end management investment companies which undertake, in the event they should adopt a plan under Rule 12b–1 to finance distribution expenses, to have a board of directors or trustees, a majority of whom are not ''interested persons'' of such company within the meaning of Section 2(a)(19) of the 1940 Act, formulate and approve any such plan.

Conclusion

For the reasons set forth above, Applicants represent that the exemptions requested are necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–2655 Filed 2–2–95; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Regional Liaison Outreach and Services Program (L.O.S.P.); Announcement of Request for Proposals (RFP)

SUMMARY: The Department of Transportation's Office of Small and Disadvantaged Business Utilization (O.S.D.B.U.) is responsible for the Department's implementation and execution of the functions and duties under sections eight (8) and fifteen (15) of the Small Business Act (15 U.S.C. 637) for developing policies and procedures consistent with Federal statutes to provide policy direction for minority, women-owned, small, and disadvantaged business (S/DBE) participation in the Department's procurement and Federal financial assistance activities. The office is also responsible for implementing and monitoring the Department's goals for minority, women-owned and small and disadvantaged businesses. The Secretary of Transportation has encouraged DOT operating administrations to expand opportunities for these entrepreneurs to participate fully in all DOT-funded procurements and assisted programs. On May 10, 1994 OSDBU published a Notice in the **Federal Register** requesting proposals from organizations classified as minority trade associations and/or Minority Chambers of Commerce to serve as regional representatives for the LOSP. Based upon the nationwide competition an independent panel recommended and OSDBU selected the following as regional representatives: The National Association of Minority Contractors, Washington, D.C. to represent Region 3 (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia and West Virginia); Latin Chamber of Commerce U.S.A., Miami, FL. to represent Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee); Metropolitan Chamber of Commerce, Flint, MI. to represent Region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin); Hispanic Chamber of Greater Kansas City, Kansas City , MO. to represent Region 7 (Iowa, Kansas, Missouri and

Nebraska); Arizona Hispanic Chamber of Commerce, Phoenix, AZ., and Black Business Association, Los Angeles, CA. to represent Region 9 (Arizona, America Samoa, California, Guam, Hawaii and Nevada). This request solicits competitive proposals from organizations classified as minority trade associations and/or minority Chambers of Commerce for participation under the LOSP to represent Regions 1, 2, 6, 8 and 10. The states and territories comprising these Regions are identified in Section 1.4. *Eligible applicants must be registered with the Internal Revenue Service as 501 C(6) tax-exempt organizations.* OSDBU will enter into Cooperative Agreements with these organizations to provide liaison services between the DOT, its grantees, recipients, contractors, subcontractors, and minority, women-owned, and disadvantaged business enterprises. This Request for Proposals contains information concerning: (1) The principal objectives of the competition, eligible applicants, activities and factors for award; (2) the application process, including how to apply and the criteria used for selection; and (3) a checklist of application submission requirements.

FOR GENERAL AND SPECIFIC INFORMATION CONTACT: Ms. Patricia Martin, Staff Associate, David Benton, LOSP Manager or Mr. Art Jackson, LOSP Contracting Officer Technical Representative, Office of Small and Disadvantaged Business Utilization, U.S. Department of Transportation, 400 7th Street, S.W., Room 9410, Washington, D.C., 20590, Tel. (202) 366–2852 or (800) 532–1169.

SEND PROPOSALS TO: Mr. David Benton, LOSP Manager, Office of Small and Disadvantaged Business Utilization (S–40), U.S. Department of Transportation, 400 7th Street, S.W., Room 9410, Washington, D.C. 20590.

DATES: Proposals must be received at the above location by March 3, 1995, 4:00 p.m., Eastern Standard Time. Proposals received after the deadline will be considered non-responsive and not reviewed. DOT plans to give notice of awards on all applications by March 17, 1995.

Dated: January 26, 1995

Luz Hopewell,

Director, Office of Small and Disadvantaged Business Utilization.

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1. Introduction

1.1 Background

The United States Department of Transportation (DOT) established the Office of Small and Disadvantaged Business Utilization (OSDBU) in accordance with Public Law 95–507, an amendment to the Small Business Act and the Small Business Investment Act of 1958. The OSDBU administers the Department's Small and Disadvantaged Business Enterprise (DBE) Program which is designed to ensure that small businesses, including small disadvantaged and minority firms, have an equitable opportunity to participate in DOT's procurement and Federal financial assistance programs and that they receive a fair share of the resulting contract awards. Because DOT's policy is to encourage and increase DBE participation in the contracts and programs that it funds, during FY 1993, DBEs received over $2.6 billion or 14.4 percent of highway, transit, air and rail contracts from DOT-assisted State and local transportation agencies.

OSDBU develops Department-wide policy and administers a number of programs and activities to implement the OSDBU's Congressional mandate of increasing the level of participation of DBEs in the Federal financial assistance and direct contracting programs of all modal administrations of DOT. OSDBU is responsible for the development and implementation of an effective program of activities directed at ensuring DBE participation in the Department's direct procurement and Federal financial assistance activities. This includes the monitoring of all DOT procurement activities that involve the participation of DBEs, including the goal settings and procurement practices of DOT financial assistance recipients, namely, State and local transportation agencies. The OSDBU also serves an important function in assisting firms in their marketing of the Department and all of its operating administrations. OSDBU also is responsible for developing and administering programs to encourage, stimulate, promote and assist DBEs to obtain and manage transportation-related contracts, subcontracts and projects. This includes administering the Short Term Lending Program (STLP) and the Bonding Assistance Program, two financial assistance efforts which provide assistance in obtaining short-term working capital and bonding for DBEs. Under the STLP, lines of credit up to $500,000 are available at prime interest rates to finance accounts receivable for transportation-related contracts. The Bonding Assistance Program enables DBEs to apply for bid, performance and payment bonds on contracts up to $1,000,000.

1.2 Program Description and Goals

An area where the OSDBU has focused considerable efforts has been that of increasing DBE access to DOT financial assistance programs and contracting opportunities through the Liaison Outreach and Services Program (LOSP). This broad-based initiative utilizes Cooperative Agreements with a number of minority Chambers of Commerce and minority trade associations to provide liaison services between DOT, its grantees, recipients, contractors, subcontractors and DBEs. The LOSP includes activities such as information dissemination, outreach services, conference and seminar participation and referrals to technical assistance agencies (i.e., MBDCs, SBDCs and State DOT highway supportive services contractors) which offer management and technical assistance in financial assistance, marketing and other business areas. In addition, the minority organizations include DOT and other transportation-related information in their monthly or quarterly newsletters and provide one-on-one business counseling to DBEs currently doing business or that have the potential for doing business with DOT at the Federal, state or local levels.

Information dissemination and outreach include the distribution of the following DOT marketing materials: DOT Bonding Assistance Program Brochures; DOT Bonding Assistance Fact Sheets; DOT Short-Term Lending Program Brochures; DOT Short-Term Lending Fact Sheets; Procurement Forecasts; DOT Small Business Subcontracting Opportunities Directory; Contracting with the United States Department of Transportation Booklets; DOT Bonding Assistance Program Applications; and DOT Short-Term Lending Program Applications. A compilation of these materials is available in the DOT's Marketing Information Package, a comprehensive document which serves as a resource and reference tool.

Participating LOSP organizations make referrals to technical assistance agencies offering assistance to DBEs in the completion and submission of Short-Term Lending and Bonding Assistance Program applications.

The LOSP was established by the OSDBU in May 1992 in response to the continuing need to outreach to the small and minority business community and increase their participation in DOT contracting and financial assistance programs. To address this need, the LOSP seeks to increase the number of small businesses and DBEs that enter into transportation-related contracts and that receive DOT STLP lines of credit and bonding assistance. This goal is accomplished by the OSDBU working closely with minority Chambers of Commerce and minority trade associations to:

(1) Establish a communications link (network) between DOT, its grantees, recipients, contractors, subcontractors and the small and disadvantaged business community.

(2) Increase awareness of DOT contracting opportunities and financial assistance programs by disseminating DOT marketing materials and relevant information at selected conferences, seminars and marketplace events.

(3) Develop and/or strengthen linkages with State DOTs, local transportation agencies, transportation prime contractors, State highway supportive services contractors, Minority Business Development Centers (MBDCs), Small Business Development Centers (SBDCs) and other minority Chambers of Commerce and minority trade associations to encourage DBE participation in DOT programs.

(4) Stimulate referrals of DBEs to obtain technical assistance from Federal, State and local agencies such as MBDCs, SBDCs and State DOT highway supportive services contractors for management and other business-related assistance including completion and submission of DOT Short-Term Lending Program and Bonding Assistance Program application packages.

(5) Increase awareness of DOT programs by providing DOT representation at selected conferences, seminars and marketplace events and by providing DOT ads and articles in organizations' newsletters.

(6) Develop and maintain databases of transportation-related DBEs as potential participants in DOT procurement and/or financial assistance programs.

1.3 Description of Competition

The purpose of this RFP is to solicit proposals from eligible national and regional minority Chambers of Commerce and minority trade associations to participate in the Liaison and Outreach Services Program (LOSP). The LOSP shall enable the OSDBU to establish a regional presence by assisting small businesses and DBEs in securing information on DOT procurement opportunities, Financial Assistance Programs and the short-term lending and bonding assistance programs to increase the number of DBEs that enter into transportation-related contracts. The LOSP is intended to increase collaboration between OSDBU, minority Chambers of Commerce and minority trade associations to strengthen and enhance their ability to provide liaison services between DOT, its grantees, recipients, contractors, subcontractors and DBEs. As the program requirements and selection criteria indicate, the OSDBU also intends that the LOSP be multi-dimensional; that is, the selected organizations must have the capacity to effectively access and provide supportive services to the broad range of small business and DBE clients within their respective geographical areas and must be able to coordinate and establish effective networks with DOT grant recipients and local/regional technical assistance agencies to maximize resources and avoid duplication of effort.

Cooperative agreement awards will be up to $95,000. It is DOT's intent to fund one agreement in the following regions: Region 1, 2, 6, 8, and 10, however, there may be multiple awards, if warranted to improve DOT's diversity of contracting efforts. In addition it is OSDBU's intent to encourage diversity of representation in the LOSP by focusing on the selection of at least one Native American, Asian American and Woman organization. The geographical distribution of DOT regions is shown in map form in Attachment 1. The DOT regions for this announcement, with states and territory comprising each, are listed below:

Region 1: Connecticut, Maine, Massachusetts, New Hampshire
Region 2: New Jersey, New York, Puerto Rico
Region 6: Arkansas, Louisiana, New Mexico, Oklahoma, Texas
Region 8: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
Region 10: Alaska, Idaho, Oregon, Washington

1.4 Duration of Agreements

Cooperative agreements will be awarded for a period of 12 months) with a one year renewable option based on need and program achievement. Continuation funding will be contingent upon satisfactory performance and the availability of funds in subsequent fiscal years.

1.5 Authority

DOT is authorized under 49 U.S.C. 322 (P.L. 97–449), to develop by Cooperative Agreements, support mechanisms including liaison and assistance programs, that will enable small businesses and DBEs to take advantage of transportation-related contracts.

1.6 Eligibility Requirements

An eligible applicant organization will be: An established, non-profit, minority Chamber of Commerce or minority trade association which has the documented experience and capacity necessary to successfully operate and administer a coordinated, regional liaison outreach effort within a region of the United States.

In addition, to be eligible, a minority Chamber of Commerce or minority trade association must:

(a) Be an established 501 C(6) tax-exempt organization (provide documentation as verification);

(b) Have at least one year of documented and continuous experience prior to the date of application in providing advocacy, management and marketing assistance services and referral to technical assistance agencies to DBEs within the LOSP regional service area in which proposed services will be provided; and

(c) Have an office physically located within the LOSP regional service area.

No application will be accepted without proof of tax-exempt status.

2. Program Requirements

In conducting the activities to achieve the goals of the LOSP, the recipient shall be responsible for implementing the activities under 2.1 and 2.2 below. The OSDBU shall be responsible for conducting activities under 2.3.

2.1 Recipient Responsibilities

1. Each LOSP participant shall:

(a) Collaborate with and coordinate on programs, activities, services and technical assistance with other Federal, State and local organizations and agencies serving transportation-related small businesses and DBEs, particularly State DOTs and DOT grantees.

(b) Initiate, develop and maintain interagency referral arrangements with agencies offering specialized management and technical assistance including DOT state supportive services contractors, MBDCs, SBDCs and other appropriate programs.

(c) Establish a transportation advisory committee comprised of members who

have demonstrated expertise in the preparation of financial statements and bid/proposal development to advise on the development and implementation of LOSP activities.

(d) Conduct one (1) regional conference to address contracting opportunities within DOT modal administrations and from state and local transportation agencies within the region.

(e) Develop structured, consultative relationships with key constituent groups within the region to help build and reinforce collaboration. Such relationships will ensure that DOT non-minority and minority prime contractors as well as minority Chambers of Commerce and minority trade associations facilitate awareness and utilization of LOSP services.

(f) Implement information dissemination and education activities and strategies to maximize outreach regarding DOT procurement opportunities and the short-term lending and bonding assistance programs.

(g) Conduct an on-going evaluation of activities funded through this cooperative agreement. Evaluation will quantitatively and qualitatively describe LOSP activities, the services and the recipients of services. Each applicant must develop and implement an on-going evaluation plan.

(h) Develop structured, consultative relationships with the private sector financial community and Federal, State, regional and local agencies which provide specialized financial technical assistance services to DBEs.

(i) Establish and maintain an 800 toll free line to be made available to minority, women-owned, small and disadvantaged businesses interested in transportation-related procurements and information on the application process for the DOT Short Term Lending and Bonding Assistance Programs. Referral services shall be provided.

(j) Furnish all labor, facilities and equipment to perform the services described in this announcement.

2.2 Work Requirements

Each LOSP participant must perform work in the following functional areas:

(a) Information Dissemination and Outreach

(b) Conference and Seminar Participation

(c) Referrals to Technical Assistance Agencies

(d) Database Development

a. Information Dissemination and Outreach

Each LOSP program director shall meet with OSDBU officials to become familiar with DOT materials and literature to disseminate appropriate documents to DBEs at conferences, seminars, workshops, and to those interested in and have the capacity to perform transportation-related projects. This LOSP ''core service'' includes distribution of general information on DOT's overall DBE program, specific information on DOT's short-term lending and bonding assistance programs; and information and assistance on DOT's procurement opportunities. Materials to be disseminated shall include, but are not limited to, fact sheets, brochures, short-term lending and bonding assistance program applications, and reports and advertisements which are directed toward the DBE communities in each region.

The LOSP participant shall publish stories/articles and features in the recipient's newsletter which contain information regarding the accessibility to procurement opportunities within DOT, and the short-term lending and bonding assistance programs. The Director, OSDBU, shall approve all stories, articles, and special features prior to their publication in the recipient's monthly or quarterly newsletter.

b. Conference and Seminar Participation

The LOSP participant shall participate in regional, state and local procurement conferences on behalf of the OSDBU and disseminate DOT procurement information, short-term lending and bonding assistance program literature and other materials. The conferences/seminars shall be transportation-related and each shall be approved by the Director, OSDBU, prior to participation. The LOSP participant shall identify regional, state and local conferences where a significant number of DBEs with transportation-related capabilities are expected to be in attendance. The LOSP participant shall maintain the DOT booth at transportation-related conferences/ seminars. A list of proposed DBE conferences and seminars being considered for participation under the Cooperative Agreement shall be forwarded to OSDBU for review and approval.

The LOSP participant shall conduct one (1) regional conference and shall be responsible for all conference planning and logistics which include identifying and contacting DBEs, mailing invitational letters, handling details for exhibit booths and luncheons, preparing conference brochures as well as tentative and final conference agendas, and securing media coverage. A conference report shall be submitted to OSDBU no later than 30 days after the conference.

c. Referrals to Technical Assistance Agencies

Each LOSP participant shall provide technical assistance services by referring DBEs to agencies that offer assistance in the preparation of DOT procurement documents and applications for loans and bonds for submission on transportation-related projects. In addition, specific referrals shall be made to agencies that certify DBEs using DOT guidelines.

d. Database Development

Each LOSP participant shall develop a comprehensive data base of firms within its regional service area that have the capability to perform transportation-related contracts.

2.3 Office of Small and Disadvantaged Business Utilization (OSDBU) Responsibilities

The OSDBU shall perform the following roles as its contribution to the attainment of LOSP objectives:

1. Provide consultation and technical assistance in planning, implementing and evaluating activities under this announcement.

2. Provide orientation and training to applicants awarded funding for participation in the LOSP.

3. Systematically monitor the performance of successful applicants' activities and program compliance.

4. Assist successful applicants in collaborating and developing or strengthening linkages with State DOTs, technical assistance agencies and DOT grantees within regional geographical areas served.

5. Facilitate the exchange and transfer of successful LOSP activities and program information among regional LOSP participants.

3. Submission of Proposals

3.1 Content and Format for Proposals

Each proposal submitted to DOT must be in the format and must contain the information set forth in the application form attached as Appendix A to this announcement.

3.2 Address; Number of Copies; Deadline for Submission

Any eligible organization (as defined in Section 1.6 of this RFP) shall submit only one proposal for consideration by DOT. Applications should be double spaced, and printed in a font size not smaller than 12 points. One unbound copy of the proposal with original signatures suitable for reproduction,

plus four bound copies, should be submitted. All pages should be numbered at the top of each page. All documentation, attachments, or other information pertinent to the application must be included in a single submission.

Proposals should be submitted to: David Benton, LOSP Manager, Office of Small and Disadvantaged Business Utilization (S–40), U.S. Department of Transportation, 400 7th Street, SW., room 9414, Washington, DC 20590.

Proposals must be received by DOT/OSDBU no later than March 3, 1995 4:00 p.m., EST.

4. Selection Criteria

4.1 General Criteria

DOT will use the following criteria to rate and rank applications received in response to this announcement for the applicant's region. Applications will be evaluated for each region on a point system (maximum number of points = 100). The following five (5) maximum *weighted* categories will constitute DOT's selection criteria:

—Approach (25 points)
—Linkages/Networks (25 points)
—Organizational Capability (25 points)
—Staff Capabilities and Experience (15 points)
—Cost (10 points)

A. Approach and Linkages (50 Points)

1. Approach (25 Points)

The applicant must describe the activities proposed to be implemented under the cooperative agreement and how the work will be accomplished across the LOSP regional area. Present a well-constructed plan of action. DOT will consider the extent to which the proposed objectives are specific, measurable, time-phased, consistent with LOSP goals and the proposed activities are consistent with the applicant organization's overall mission. DOT will give priority consideration to applicants that demonstrate innovation and creativity of approach in increasing the ability of DBEs to access information on DOT contracting opportunities and financial assistance programs. DOT will also rate the quality of the applicant's plan for conducting program activities and the likelihood that the proposed methods will be successful in achieving proposed objectives.

2. Linkages (25 Points)

DOT will consider innovative aspects of the applicant's approach which build upon the applicant's strength(s) and facilitate and encourage linkages to existing resources available within the region. The applicant's structure for linking urban and rural DBEs to the LOSP should be outlined. The applicant should describe support and intended collaboration on LOSP activities from DOT grantees, prime contractors, subcontractors, State DOTs, State highway supportive services contractors, SBDCs, MBDCs and colleges and universities serving minorities including Historically Black Colleges and Universities (HBCUs), Hispanic Association of Colleges and Universities' affiliations (HACUs) and Tribal-Affiliated Colleges and Universities (TACUs). DOT will also rate the effectiveness of the applicant's strategy to provide outreach, networking and liaison activities to the regional area to be served. In rating this factor, DOT will consider the extent to which the applicant demonstrates ability to effectively access and network supportive services to the broad and diverse range of DBEs within the applicant's regional service area. Emphasis will also be placed on the extent to which the applicant identifies a clear outreach strategy related to identified needs that can be successfully carried out within the period of this agreement and a plan for forming and involving an internal transportation advisory committee in the execution of that strategy.

B. Organizational Capability (25 Points)

The applicant organization must have outreach resources and relevant experience in carrying out the purposes of the LOSP. In rating this factor, DOT will consider the extent to which the applicant's organization has recent, relevant and successful experience in advocating for and addressing the needs of minority businesses in general and transportation-related DBEs in particular. The applicant must also describe technical and administrative resources it plans to use in achieving proposed objectives (i.e., computer facilities, voluntary staff time, space and financial resources).

C. Staff Capability and Experience (15 Points)

The applicant organization should provide a list of proposed personnel for the project with salaries, educational levels and previous experience delineated. The applicant's project team must be well-qualified and knowledgeable (ensuring diversity) which shows evidence of the ability to deal effectively with the broad range of DBE clients to be served. Resumes must be submitted for all proposed key personnel, outside consultants and subcontractors. Experience of key personnel in providing services similar in scope and nature to the proposed effort must be presented in detail. The Project Director will serve as the responsible individual for the project a minimum of 50 percent of his/her time. He/she must be designated in the proposal and his/her resume must reflect appropriate knowledge of the regional area and supervisory experience.

DOT will consider the extent to which the applicant's proposed management plan (a) clearly delineates staff responsibilities and accountability for all work required and (b) presents a work plan with a clear and feasible schedule for conducting all project tasks.

D. Cost (10 Points)

The budget is the applicant's estimate of the total cost of establishing and administering its participation in the LOSP. The applicant's budget must be adequate to support the project and costs must be reasonable in relation to project objectives. Applicants are encouraged to provide in-kind costs and other innovative cost approaches.

4.2 Scoring of Applications

A review panel will score each application based upon the evaluation criteria listed above. Points will be given for each evaluation criteria category not to exceed the maximum number of points allowed for each category. Applications which are not responsive to the established criteria above will be disqualified.

"Appendix A"

Application Form for Submission of Proposals for Department of Transportation, Regional Liaison Outreach and Services Program (LOSP)

Appendix A—Application Form For Proposals for the Department of Transportation, Regional Liaison Outreach and Services Program (LOSP)

Proposals for the DOT Regional Liaison Outreach and Services Program (LOSP) should contain all of the following information and should be submitted in the following format.

Applications should be double spaced and printed in a font size not smaller than 12 points. One unbound copy of the proposal with original signatures suitable for reproduction, plus four bound copies, should be submitted. Applications, excluding attachments, will be limited to 35 pages. All pages should be numbered at the top of each page. All documentation, attachments, or other information pertinent to the application should be included in a single submission, forwarded directly to the address listed below.

Proposals should be submitted to: David Benton, LOSP Manager, Office of Small and

Disadvantaged Business Utilization (S–40), U.S. Department of Transportation, 400 7th Street, SW., room 9414, Washington, DC 20590.

Proposals must be received by DOT/OSDBU no later than March 3, 1995, 4:00 P.M. EST.

All applications must contain the following sections in the following order.

1. Table of Contents

—Identify all parts, sections and attachments of the application.

2. Application

Summary Page

—Provide a one page overview of the following:
—The applicant's proposed LOSP, its related activities including key elements of the plan of action/methodology to achieve project objectives.
—The applicant's relevant organizational experience and capabilities.

3. Understanding of the Work

—Provide a narrative which contains specific project information as follows:
—The applicant will describe its understanding of the LOSP, program goals and the role of the applicant's proposed LOSP in advancing the applicant's goals.
—The applicant will describe specific outreach needs of transportation-related DBEs in the region served and how the LOSP will address the identified needs.

4. Approach/Methodology

—Describe the applicant's methodology or plan of action for conducting the project in terms of the tasks to be performed.
—Describe the specific services or activities to be performed and how these services/activities will be implemented.
—Describe innovative and/or creative approaches to be implemented through the LOSP to increase the ability of DBEs to access information on DOT contracting opportunities and financial assistance programs.

5. Linkages

—Describe outreach activities and linkages to be implemented to ensure that rural small and minority disadvantaged businesses participate in LOSP activities.
—Describe or indicate evidence of linkages or collaborations developed or to be developed with State DOTs, DOT grantees, DOT prime contractors, other minority Chambers of Commerce as well as minority trade associations and technical assistance agencies including DOT/FHWA supportive services contractors, HBCUs, HACUs and TACUs.

6. Organizational Capabilities

—Describe recent, relevant and successful experience in advocating for and addressing the needs of small and minority businesses in general and transportation-related DBEs in particular.
—Describe relevant experience in working or collaborating with minority Chambers of Commerce and minority trade associations, DOT grantees, State DOTs, technical assistance agencies including DOT/FHWA supportive services contractors, MBDCs, SBDCs and minority institutions including HBCUs, HACUs and TACUs.
—Describe internal resources available to use in successfully performing/completing the work.

7. Staff Capabilities

—Describe the qualifications and relevant experience, in relation to project requirements, of the key personnel to be used in the project.

8. Management Plan

—Describe how personnel are to be organized in the project and how they will be used to accomplish project objectives. Outline staff responsibilities, accountability and a schedule for conducting all project tasks.

9. Budget Narrative

—Outline all proposed budget/cost information in detail.

10. Assurances

Signature Form

—Complete the attached form identified as Attachment 2.

11. Certification

Signature Form

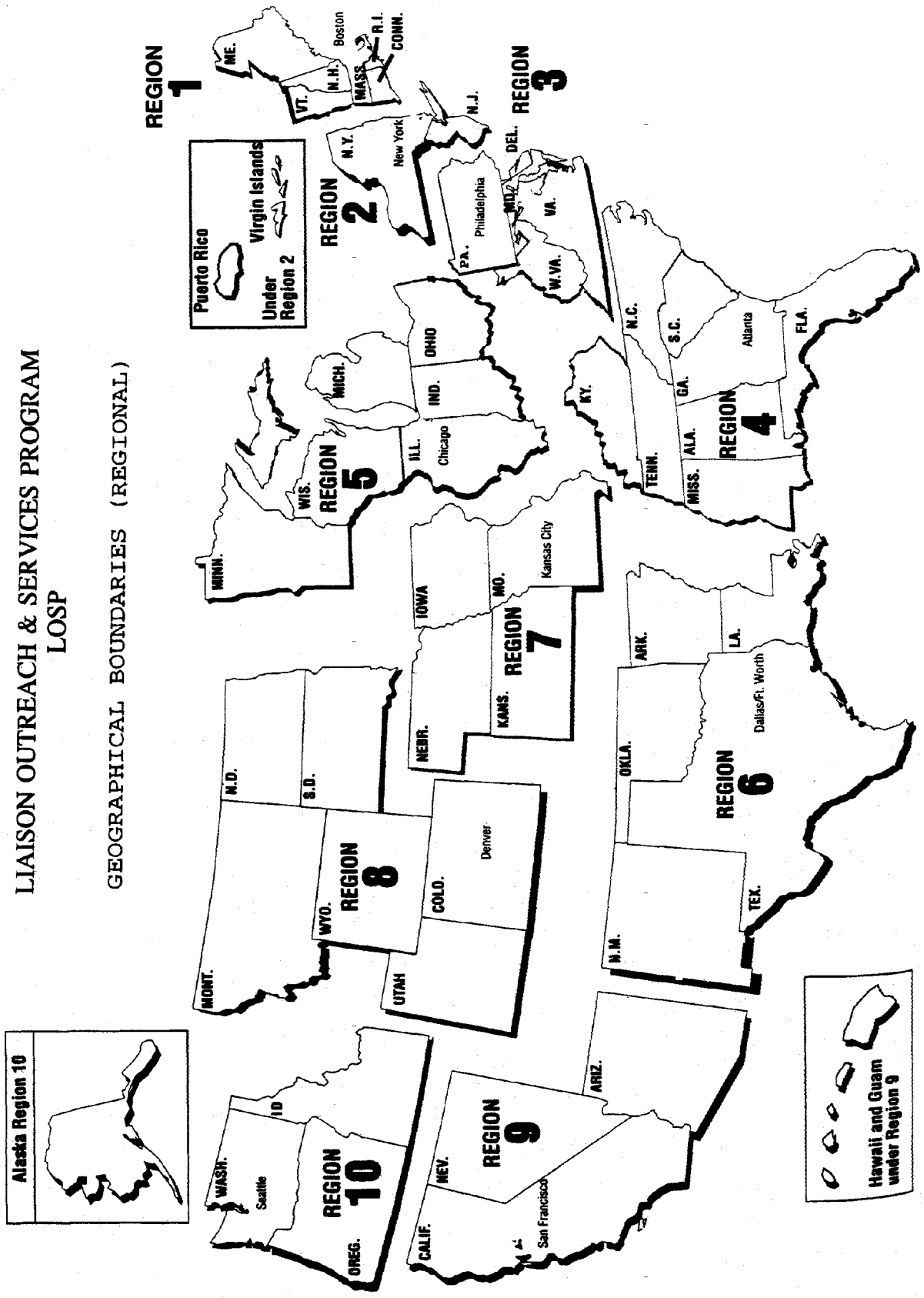
—Complete the attached form identified as Attachment 3.

12. Standard Form 424

—(Request for Federal Assistance) Complete the attached Standard Form 424 identified as Attachment 4.

Please be sure that all forms have been signed by an authorized official who can legally represent the organization.

BILLING CODE 4910–62–P


LIAISON OUTREACH & SERVICES PROGRAM
LOSP
GEOGRAPHICAL BOUNDARIES (REGIONAL)
REGION 1
ME.
VT.
N.H.
MASS.
R.I.
CONN.
Boston
REGION 2
N.Y.
New York
N.J.
Puerto Rico
Virgin Islands
Under Region 2
REGION 3
DEL.
MD.
VA.
W.VA.
PA.
Philadelphia
REGION 4
N.C.
S.C.
GA.
Atlanta
FLA.
KY.
TENN.
MISS.
ALA.
REGION 5
MINN.
WIS.
MICH.
OHIO
IND.
ILL.
Chicago
REGION 6
ARK.
LA.
OKLA.
TEX.
Dallas/Ft. Worth
N.M.
REGION 7
IOWA
MO.
Kansas City
KANS.
NEBR.
REGION 8
N.D.
S.D.
MONT.
WYO.
COLO.
Denver
UTAH
REGION 9
ARIZ.
NEV.
CALIF.
San Francisco
REGION 10
WASH.
Seattle
OREG.
ID
Alaska Region 10
Hawaii and Guam under Region 9

ATTACHMENT 2

Assurances

All recipients of Federal funding are required to assure that the recipient:

- Has the legal authority to apply for Federal assistance, and the institutional, managerial, and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management, and completion of the project described in this application.

- Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

- Will establish safeguards to prohibit employees from using their position for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

- Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

- Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 CFR 900; Subpart F).

- Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color, or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), which prohibits discrimination on the basis of disability; (d) The Age Discrimination Act of 1975, as amended (42 U.S.C. 6101-6107), which prohibits discrimination on the basis of age; (e) The Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C.290dd-3 and 290ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the National and Community Service Act of 1990, as amended; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

- Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or Federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

- Will comply with the provisions of the Hatch Act (5 U.S.C. 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

- Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. 276a and 276a-77), the Copeland Act (40 U.S.C. 276c and 18 U.S.C. 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-333), regarding labor standards for Federally assisted construction sub-agreements.

- Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires the recipients in a special flood hazard area to participate in the program and to purchase flood

insurance if the total cost of insurable construction and acquisition is $10,000 or more.

- Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved state management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. 1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).

- Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

- Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).

- Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

- Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

- Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

- Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984 or OMB Circular A-133. Audits of Institutions of Higher Learning and other Non-profit Institutions.

- Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

In addition, all recipients of Corporation assistance under this application are required to assure that the recipient:

- Will keep such records and provide such information to the Corporation with respect to the program as may be required for fiscal audits and program evaluation.

- Will not use the assistance to replace State and local funding streams that had been used to support programs of the type eligible to receive Corporation support. For any given program, this condition will be satisfied if the aggregate non-Federal expenditure for that program in the fiscal year that support is to be provided is not less than the previous fiscal year.

- Will use the assistance only for a program that does not duplicate, and is in addition to, an activity otherwise available in the locality of the program.

- Will comply with the Notice, Hearing, and Grievance Procedures found in § 176 of the Act.

- Will comply with the nondisplacement rules found in § 177(b) of the Act. Specifically, an employer shall not displace an employee or position, including partial displacement such as reduction in hours, wages, or employment benefits, as a result of the employer using an AmeriCorps participant; a service opportunity shall not be created that will infringe on the promotional opportunity of an employed individual; an AmeriCorps participants shall not perform any services or duties or engage in activities that (1) would otherwise be performed by an employee as part of the employee's assigned duties, (2) will supplant the hiring of employed workers, (3) are services or duties with respect to which an individual has recall rights pursuant to a collective bargaining; agreement or applicable personnel procedures; or (4) have been performed by or were assigned to any presently employed worker, an employee who recently resigned or was discharged, an employee who is on leave, an employee who is on strike or is being locked out, or an employee who

is subject to a reduction in force or has recall rights subject to a collective bargaining agreement or applicable personnel procedure.

Assurances - Signature

By signing this assurances page, the applicant certifies that it will agree to perform all actions and support all intentions stated in the attached Assurances.

NOTE: This form must be signed and included in the application.

Organization Name

_____

Project Name

_____

Name and Title of Authorized Representative

_____

Signature

_____

Date

_____

Certification - Lobbying Activities
As required by Section 1352, Title 31 of the US Code, the applicant certifies that:

A. No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer of Congress in connection with the awarding of any Federal contract, the making of any Federal loan, the entering into of any cooperative agreement, or modification of any Federal contract, grant, loan, or cooperative agreement;

B. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;

C. The undersigned shall require that the language of this certification be included in the award documents for all subcontracts at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Certification -- Signature

Before You Start. Before completing certification, please read Certification Instructions.

NOTE: This form must be signed and included in the application.

Signature. By signing this Certification page, the applicant certifies that it will agree to perform all actions and support all intentions stated in the Certifications set forth above. The three Certifications are:

- •Certification: Debarment, Suspension, and Other Responsibility Matters
- •Certification: Drug-Free Workplace
- •Certification: Lobbying Activities

Organization Name

Project Name

Name and Titled of Authorized Representative

Signature

Date

ATTACHMENT 4 OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

	2. DATE SUBMITTED	Applicant Identifier
1. TYPE OF SUBMISSION: *Application* ☐ Construction ☐ Non-Construction *Preapplication* ☐ Construction ☐ Non-Construction	3. DATE RECEIVED BY STATE	State Application Identifier
	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address (give city, county, state, and zip code):	Name and telephone number of the person to be contacted on matters involving this application (give area code)

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: (enter appropriate letter in box) ☐

A. State H. Independent School Dist.
B. County I. State Controlled Institution of Higher Learning
C. Municipal J. Private University
D. Township K. Indian Tribe
E. Interstate L. Individual
F. Intermunicipal M. Profit Organization
G. Special District N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other (specify):

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):

13. PROPOSED PROJECT: Start Date	Ending Date	14. CONGRESSIONAL DISTRICTS OF: a. Applicant	b. Project

15. ESTIMATED FUNDING:	
a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ .00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: — "New" means a new assistance award. — "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. — "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

ATTACHMENT 3

Certifications

Before completing certification, please read Certification Instructions on the following page.

Certification - Debarment, Suspension, and Other Responsibility Matters. This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211).

(1). The applicant certifies to the best of its knowledge and belief, that it and its principals:

(a). Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency,

(b). Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State anti-trust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction or records, making false statements, or receiving stolen property,

(c). Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1) (b) of this certification, and

(d). Have not within a three-year period preceding this application proposal had one or more public transactions (Federal, State or local) terminated for cause or default;

(2). Where the applicant is unable to certify to any of the statements in this certification, such applicant shall attach an explanation to this application.

Certification - **Drug-Free Workplace.** This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 34 CFR Part 85, Subpart F. The regulations, published in the January 31, 1989 Federal Register, require certification by grantees, prior to award, that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government-wide suspension or debarment (see 34 CFR Part 85, Section 85.615 and 85.620). The grantee certifies that it will provide a drug-free workplace by:

(1). Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(2). Establishing a drug-free awareness program to inform employees about --

(a) the dangers of drug abuse in the workplace,

(b) the grantee's policy of maintaining a drug-free workplace,

(c) any available drug counseling, rehabilitation, and employee assistance programs, and

(d) the penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(3). Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (1);

(4). Notifying the employee in the statement required by paragraph (1) that, as a condition of employment under the grant, the employee will

(a) abide by the terms of the statement, and

(b) notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

(5). Notifying the Corporation within ten days after receiving notice under subparagraph (4)(b) from an employee or otherwise receiving actual notice of such conviction;

(6). Taking one of the following actions, within 30 days of receiving notice under subparagraph (4)(b) with respect to any employee who is so convicted--

(a) Taking appropriate personnel action against such an employee, up to and including termination; or

(b) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(7). Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (1), (2), (3), (4), (5), and (6).

Certification Instructions

By signing the Certification Signature Page on the previous page, the applicant certified that it will agree to perform all actions and support all intentions stated in the Certifications.

Signing the Certification Page

1. Inability to Certify. The inability of a person to provide the certification required below will not necessarily result in denial of a grant. The applicant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the Corporation determination whether to enter into this transaction. However, failure of the applicant to furnish a certification or an explanation shall disqualify such applicant for a grant.

2. Erroneous Certification. The certification in this clause is a material representation of fact upon which reliance was placed when the Corporation determined to enter into this transaction. If it is later determined that the applicant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the Corporation may terminate this transaction for cause or default.

3. Notice of Error in Certification. The applicant shall provide immediate written notice to the Corporation to whom this proposal is submitted if at any time the applicant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. Definitions. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. An applicant shall be considered a "prospective primary participant in a covered transaction" as defined in the rules implementing Executive Order 12549. You may contact the Corporation for assistance in obtaining a copy of those regulations.

5. Certification Requirement for Subgrant Agreements. The applicant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the Corporation.

6. Certification Inclusion in Subgrant Agreements. The applicant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion-Lower Tier Covered Transactions," provided by the Corporation, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. Certification of Subgrant Principals. A grantee may rely upon a certification of a prospective participant in a lower-tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A grantee may decide the method and frequency by which it determines the eligibility of its principals. Each grantee may, but is not required to, check the Nonprocurement List.

8. Prudent Person Standard. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a grantee is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Non-Certification in Subgrant Agreements. Except for transactions authorized under paragraph 6 of these instructions, if a grantee knowingly enters into a lower-tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

[FR Doc. 95–2494 Filed 2–2–95; 8:45 am]
BILLING CODE 4910–62–C

Federal Transit Administration

Privacy Act of 1974 DOT/FTA 196, Transit Planning and Research (TTS) Mailing List

The Department of Transportation (DOT) proposes to add a new record system to its inventory of systems of records notices.

Any person or agency may submit written comments on the proposed system to the Department of Transportation, Federal Transit Administration, Attn: Henry Nejako, TTS–5, 400 Seventh Street, SW., Washington, DC 20590. Comments to be considered must be received by March 10, 1995.

If no comments are received, the proposed system will become effective on the above mentioned date. If comments are received, the comments will be considered and where adopted, the document will be republished with the change.

Issued in Washington, DC January 20, 1995.

Melissa J. Allen,

Deputy Assistant Secretary for Administration.

Narrative Statement for the Department of Transportation Federal Transit Administration

The Federal Transit Administration proposes to add the record system, DOT/FTA 196 Office of Technical Assistance and Safety (TTS) Mailing List. The purpose of the system is the administrative management of a mailing list of those individuals and businesses interested in technical information available from the Federal Transit Administration.

The authority for the maintenance of this system is 49 U.S.C. 5312(a). Authority to conduct research, development and demonstration projects implies the duty to disseminate results of those projects to interested persons. An automated list is essential to dissemination.

Individuals interested in receiving technical information from FTA disclose the subject information to a federal agency; therefore this system presents no undue threat to privacy rights of individuals.

A description of the steps taken to safeguard these records is given under the appropriate heading of the **Federal Register** system of records notice.

No changes to existing procedural or exemption rules are required for this proposed new system.

The purpose of this report is to comply with the Office of Management and Budget Circular, A–130, Appendix I, dated June 25, 1993.

DOT/FTA 196

SYSTEM NAME:

Office of Technical Assistance & Safety (TTS) Mailing List.

SYSTEM LOCATION:

Department of Transportation (DOT), Federal Transit Administration (FTA), Office of Technical Assistance & Safety, Office of Program Management Staff, TTS–5, 400 7th Street NW., room 6431, Washington, DC 20590.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals interested in technical information about transit issues.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, business address, telephone number, fax number, areas of interest, organization type, job type, date of last update.

ROUTEINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

For technical information dissemination. See Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in a master computer file by a contractor and a working file in FTA.

RETRIEVABILITY:

Access by computer terminal by any item.

SAFEGUARDS:

Available for use under the control of the Mailing List Manager.

Computer file is protected by password logon and access rights to data file.

RETENTION AND DISPOSAL:

Records are retained until notified that individual no longer desires information and then record is destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Program Management Staff, TTS–5, Federal Transit Administration (FTA), Office of Technical Assistance & Safety, Program Management Staff, TTS–5, 400 7th Street SW., room 6431, Washington, DC 20590.

NOTIFICATION PROCEDURE:

Inquiries are addressed to the Program Management Staff, TTS–5 (address same as system manager).

RECORD ACCESS PROCEDURES:

Same as above.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Conference registration lists, Post Office return forms, letter and/or verbal request to be placed on mailing list and other DOT/FTA mailing lists.

[FR Doc. 95–2497 Filed 2–2–95; 8:45 am]
BILLING CODE 4910–62P–M

Federal Highway Administration

Environmental Impact Statement: Jefferson and Shelby Counties, Alabama

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) and a Major Investment Study (MIS) will be prepared for a proposed highway project in Jefferson and Shelby Counties, Birmingham, Alabama.

FOR FURTHER INFORMATION CONTACT: Mr. Joe D. Wilkerson, Division Administrator, Federal Highway Administration, 500 Eastern Boulevard, suite 200, Montgomery, Alabama 36117–2018, telephone (334) 223–7370.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Alabama Department of Transportation, will prepare an EIS/MIS for a proposed freeway/expressway facility within the U.S. 280 corridor extending approximately 16.09 kilometers (10 miles) from E.B. Stephens Expressway in Jefferson County to just east of Alabama State Route 119 in Shelby County. Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand.

Alternatives under consideration include: (1) Taking no action, (2) conventional six-lane urban freeway with parallels service roads, (3) a four-lane raised toll facility within the right-of-way and along the sides of a six-lane arterial facility, (4) others build alternatives which may be developed through the MIS process, and (5) alternate travel demand strategies such as transit, carpooling, and vanpooling which may also be considered in

conjunction with proposed infrastructure improvements.

Letters describing the proposed action and soliciting comments will be sent to the appropriate Federal, State, and local agencies and officials. A public information meeting and a public hearing will be held. Public notice will be given of the time and place of the meeting and hearing. The Draft EIS/MIS will be made available for public and agency review and comment. No formal scoping meeting is planned at this time.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS/MIS should be directed to FHWA at the address provided above.

(Catalog of Federal Domestic Assistant Program Number 20.205, Highway, Research, Planning, and Construction. The regulations implementing Executive Order 12372 regarding inter-governmental consultation of Federal programs and activities apply to this program).

Joe D. Wilkerson,

Division Administrator, Montgomery, Alabama.

[FR Doc. 95–2671 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–22–M

Research and Special Programs Administration

Pipeline Safety User Fees

[Docket No. PS–138; Notice 1]

AGENCY: Research and Special Programs Administration, (RSPA), DOT.

ACTION: Notice of agency action and request for comments.

SUMMARY: This notice announces proposed changes in administering user fee assessments for natural gas, liquefied natural gas, and hazardous liquid pipeline facilities beginning with fiscal year 1995 (October 1, 1994) and solicits public comment on these changes.

DATES: Comments must be submitted on or before March 6, 1995: Comments may be mailed to the Dockets Branch, Room 8421, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. All comments and docket material may be reviewed in the Dockets Branch, room 8426, Between the hours of 8:30 a.m. to 5:00 p.m. Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Lisa C. Kokoszka, (202) 366–4554 regarding the subject matter of this notice, or the Dockets Unit, (202) 366–5046, regarding copies of this notice or other material that is referenced herein.

SUPPLEMENTARY INFORMATION:

I. Background:

Section 60301 of Title 49, United States Code [1] authorizes the assessment and collection of pipeline user fees to fund the pipeline safety activities conducted under Chapter 601 of that title [2]. The Research and Special Programs Administration (RSPA) assesses each operator of regulated interstate and intrastate natural gas transmission pipelines (as defined in 49 CFR part 192), and hazardous liquid pipelines carrying petroleum, petroleum products, anhydrous ammonia and carbon dioxide (as defined in 49 CFR part 195), a share of the total Federal pipeline safety program costs in proportion to the number of miles of pipeline each operator has in service. The fee schedule for LNG facilities is based on the number of facilities each operator has in service and total storage capacity of those facilities.

RSPA is authorized to collect an amount equal to or 105% of the annual Congressional appropriation for pipeline safety. The fiscal year 1995 appropriation is $37.424 million.

II. Administrative Clarifications and Proposals

RSPA is proposing several program clarifications and administrative changes described below. These proposals will insure that all operators are aware of the effects of certain terms and procedures on administering the program by the Office of Pipeline Safety (OPS). The public is specifically invited to comment on these proposals.

A. Definition of ''In Service''

The annual assessment is for those gas transmission and hazardous liquid pipelines which are ''in service''. Over the last year some operators have requested clarification of the term ''in service'' as it pertains to calculating total milage subject to assessment. As used in the assessment letter, the term ''in service'' applies to each pipeline that is: transporting a regulated commodity, or that has transported a regulated commodity and has not been abandoned during the assessment year, October 1 through September 30. This would mean that in order to be taken ''out of service'' a pipeline must be abandoned in accordance with applicable pipeline safety regulations found in 49 CFR Parts 192 and 195.

B. Procedures for Correcting Previous Mileage Reported

On occasion, operators discover that they have incorrectly reported their actual mileage or storage capacity. The operators may claim that these errors go back several years. Because the total collected is apportioned among all pipeline operators, a change in one operator's amount could conceivably affect the amount owed by all other pipeline operators. Therefore, RSPA has determined that adjustments of assessments will only be allowed for the current assessment year.

Reporting errors must be sent in writing to the Information Resources Manager, Research and Special Programs Administration, Office of Pipeline Safety, room 2335, 400 Seventh Street, SW., Washington, DC 20590. Gas operators should also submit a supplemental RSPA form 7100.2–1.

C. Assessment Procedures

Under the regulations implementing 31 U.S.C. 3717, governing debts owed to the Federal government, assessments are due 30 days after the date of the assessment. If payment cannot be made in full within the 30 day time frame, partial payments, installments, or extensions may be granted upon written request to the User Fee Manager, room 2335, 400 Seventh Street, SW., Washington, DC 20590. Interest, penalties, and administrative charges will be assessed on delinquent debts.

User fees are deposited in the Pipeline Safety Fund (the Fund) and since 1987, OPS expenditures have been made using appropriations from the Fund. Because in prior years OPS appropriations were lower than the Fund balance, RSPA was able to collect user fees late in each fiscal year (FY). However, the FY 1995 appropriation exceeds the amount currently in the Fund (approximately $17 million), and future appropriations are likely to also exceed the amount in the Fund. Therefore, in order for OPS to have assured funding to operate without a shortfall later in the fiscal year, RSPA will need to collect user fees earlier. RSPA proposes to phase in the earlier assessment over a period of four years, as follows:

[1] Formerly, section 7005 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub.L. 99–272). The change in citation is the result of the enactment, on July 5, 1994, of Pub. L. 103–272, which recodified various transportation laws.

[2] Formerly, the Natural Gas Pipeline Safety Act of 1968 and the Hazardous Liquid Pipeline Safety Act of 1979. This change in citation is the result of the enactment, on July 5, 1994, of Pub.L. 103–272, which codified various transportation laws.

Fiscal year	Date of assessment
1995	March 1995.
1996	December 1995.
1997	November 1996.
1998	October 1997.

D. Low Stress Pipelines

A final rule on hazardous liquid pipelines operating at 20 percent or less of specified minimum yield strength (low stress pipelines), was published in the **Federal Register** on July 12, 1994. This rule became effective on August 11, 1994. Low Stress Pipelines include pipelines that carry highly volatile liquids (HVL), pipelines or pipeline segments in populated areas, and pipelines or pipeline segments in navigable waterways. Therefore, operators must incorporate these low stress mileage on the verification notice which were mailed to pipeline operators on or about November 30, 1994. Onshore rural gathering pipelines, pipelines that operate at less than 20% of SMYS (non-HVL located outside populated areas and navigable waterways), and other pipelines excluded from regulation by 49 CFR 195, should not be included.

Issued in Washington, DC on January 30, 1995.

George W. Tenley, Jr.,

Associate Administrator for Pipeline Safety.

[FR Doc. 95–2672 Filed 2–2–95; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Departmental Offices; Freedom of Information Act

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of mailing addresses for Separate Freedom of Information Act (FOIA) offices for components (Bureaus) of the Department of the Treasury.

SUMMARY: The Treasury Department gives notice of separate mailing addresses for the FOIA offices for the Departmental Offices and for each of the other Treasury components. Although this information may be found elsewhere, this notice is the first publication of the list of addresses in its entirety.

EFFECTIVE DATE: Notice will be effective February 3, 1995.

ADDRESS FOR COMMENTS: Comments should be sent to Disclosure Services, Room 1054 MT, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. Comments will be made available for inspection and copying upon request at the Department of the Treasury library, Room 5010, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Alana Johnson, Assistant Director, Disclosure Services, (202) 622–0930.

SUPPLEMENTARY INFORMATION: The purpose of the Notice is to bring attention to the separate addresses for the individual FOIA offices of the Treasury Department's twelve components in accordance with Treasury regulations at 31 CFR part 1, stating that FOIA requests should be directed to the office maintaining the records. The notice identifies the individual components within the Treasury Department (ATF, IRS, etc.,) and the addresses of their own FOIA offices so that requesters may submit FOIA requests directly to the appropriate component.

The Department of the Treasury FOIA Offices

Departmental Offices

Disclosure Services—Room 1054–MT, Department of the Treasury, Washington, DC 20220

Bureau of Alcohol, Tobacco and Firearms, Freedom of Information Request, 650 Massachusetts Avenue, NW., Washington, DC 20226

Bureau of Engraving & Printing, Freedom of Information Request, 14th & C Street, SW., Washington, DC 20228

Comptroller of the Currency, Freedom of Information Request, Washington, DC 20219

United States Customs Service, Freedom of Information Request, 1099 14th Street, NW, Washington, DC 20229

Federal Law Enforcement Training Center (FLETC), Freedom of Information Request, Department of the Treasury, Building 94, Glynco, GA 31524

Financial Management Service, Freedom of Information Request, 401 14th Street, SW, Washington, DC 20227

Internal Revenue Service, Freedom of Information Request, P.O. Box 795—Ben Franklin Station, Washington, DC 20044

United States Mint, Freedom of Information Request, Judiciary Square Building, 633 3rd Street, NW, Washington, DC 20220

Bureau of the Public Debt, Freedom of Information Request, 999 E Street, NW, Washington, DC 20239

United States Secret Service, Freedom of Information Request, 1800 G Street, NW, Washington, DC 20223

Office of Thrift Supervision, Freedom of Information Request, 1700 G Street, NW, Washington, DC 20552

Dated: January 25, 1995.

Alex Rodriguez,

Deputy Assistant Secretary (Administration).

[FR Doc. 95–2717 Filed 2–2–95; 8:45 am]

BILLING CODE 4810–25–M

Departmental Offices

Privacy Act of 1974; System of Records

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of proposed amendment of a Privacy Act system of records.

SUMMARY: The Treasury Department gives notice of a proposed amendment to a system of records currently entitled ''Document Delivery Control System—Treasury/DO .194,'' which is subject to the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988.

DATES: Comments must be received no later than March 6, 1995. The amended system of records will be effective March 15, 1995, unless comments are received which result in a contrary determination.

ADDRESSES: Comments should be sent to Disclosure Services, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. Comments will be made available for inspection and copying upon request at the Department of the Treasury library, room 5010, 1500 Pennsylvania Avenue, NW., Washington DC 20220.

FOR FURTHER INFORMATION CONTACT: Dale Underwood, Privacy Act Officer, Department of the Treasury, (202) 622–0930.

SUPPLEMENTARY INFORMATION: This is to give notice of alterations to an existing system of records, currently known as ''Document Delivery Control System—Treasury/DO .194'' which is subject to the Privacy Act of 1974, as amended, 5 U.S.C. 552a. The system notice was last published in its entirety at 57 FR 13923 on April 17, 1992.

A review of the existing system notice found that the notice no longer accurately reflected the operation of the system of records due to a system upgrade which has changed the system configuration. The alterations include changing the name of the system to ''Circulation System—Treasury/DO .194'' and the addition of the following routine use to the notice:

These records and information in these records may be used to disclose information to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains.

A change in the software also allows records to be retrieved by the employee's bar code number which is associated with the individual's name or the bar code number assigned to the book or periodical.

The altered system of records report, as required by 5 U.S.C. 552a(r) of the Privacy Act, has been submitted to the Committee on Government Reform and Oversight of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget, pursuant to Appendix I to OMB Circular A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated July 15, 1994.

The system of records, Circulation System—Treasury/DO .194, is published in its entirety below.

Dated: January 25, 1995.

Alex Rodriguez,

Deputy Assistant Secretary (Administration).

Treasury/DO .194

SYSTEM NAME: CIRCULATION SYSTEM—TREASURY.

SYSTEM LOCATION:

Department of the Treasury, Library and Information Services Division, Room 5030–MT, 1500 Pennsylvania Avenue, NW, Washington, DC 20220.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees who borrow library materials or receive library materials on distribution. The system also contains records concerning interlibrary loans to local libraries which are not subject to the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records of items borrowed from the Treasury Library collection and patron records are maintained on central computer. Records are maintained by name of borrower, office locator information, and title of publication.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE(S):

Track circulation of library materials and their borrowers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information in these records may be used to disclose information to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic media.

RETRIEVABILITY:

Data can be retrieved from the system by borrower name or bar code number and publication title or its associated bar code number.

SAFEGUARDS:

Access to the system requires knowledge of password identification codes and protocols for calling up the data files. Access to the records is limited to staff of the Readers Services Branch who have a need-to-know the information for the performance of their duties.

RETENTION AND DISPOSAL:

Only current data are maintained online. Records for borrowers are deleted when employee leaves Treasury.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Library and Information Services, Department of the Treasury, Room 5030–MT, 1500 Pennsylvania Ave., NW., Washington, DC 20220.

NOTIFICATION PROCEDURE:

Inquiries should be addressed to Assistant Director, Disclosure Services, Department of the Treasury, room 1054–MT, 1500 Pennsylvania Ave., NW., Washington, DC 20220.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedures'' above.

RECORD SOURCE CATEGORIES:

Patron information records are completed by borrowers and library staff.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 95–2519 Filed 2–2–95; 8:45 am]

BILLING CODE 4810–25–M

Sunshine Act Meetings

Federal Register

Vol. 60, No. 23

Friday, February 3, 1995

This section of the FEDERAL REGISTER contains notices of meetings published under the ''Government in the Sunshine Act'' (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10:00 a.m., Thursday, February 23, 1995.

PLACE: 2033 K St., NW., Washington, DC, Lower Lobby Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED: Application of the Chicago Board of Trade as a Contract Market in futures and options of Illinois Soybean Yield Insurance, Iowa Corn Yield Insurance, Kansas Winter Wheat Yield Insurance, and North Dakota Spring Wheat Yield Insurance.

CONTRACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 95–2837 Filed 2–1–95; 8:45 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 a.m., Tuesday, February 14, 1995.

PLACE: 2033 K St., NW., Washington, DC, 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 95–2838 Filed 2–1–95; 2:27 pm]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10:00 a.m., Tuesday, February 28, 1995.

PLACE: 2033 K St., N.W., Washington, D.C., 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 95–2839 Filed 2–1–95; 2:27 pm]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10: 30 a.m., Thursday, February 23, 1995.

PLACE: 2033 K St., N.W., Washington, D.C., 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 95–2840 Filed 2–1–95; 2:27 pm]

BILLING CODE 6351–01–M

U.S. CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10:00 a.m., Wednesday, February 8, 1995.

LOCATION: Room 420, East West Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Open to the Public.

MATTER TO BE CONSIDERED:

Toy Labeling/Reporting Requirements

The staff will brief the Commission on final labeling and reporting requirements that would implement the Child Safety Protection Act of 1994.

For a recorded message containing the latest agenda information, call (301) 504–0709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sadye E. Dunn, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20207; (301) 504–0800.

Dated: February 1, 1995.

Sadye E. Dunn,

Secretary.

[FR Doc. 95–3856 Filed 2–1–95; 2:29 pm]

BILLING CODE 6355–01–M

FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting, Tuesday, February 7, 1995

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Tuesday, February 7, 1995, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, N.W., Washington, D.C.

Item No., Bureau, and Subject

1—Office of Engineering and Technology—Title: Amendment of Parts 2 and 15 of the Commission's Rules to Deregulate the Equipment Authorization Requirements for Digital Devices. Summary: The Commission will consider action concerning: (1) the type of equipment authorization required for personal computers and peripheral devices; (2) the authorization of modular components used to construct personal computers; and (3) the accreditation requirements for laboratories testing computers.

2—Office of Engineering and Technology and Wireless Telecommunications—Title: Allocation of Spectrum Below 5 GHz Transferred from Federal Government Use (ET Docket No. 94–32). Summary: The Commission will consider action concerning use of 50 megahertz of spectrum being transferred from Federal Government to private sector use.

3—Common Carrier—Title: *Computer III* Further Remand Proceedings: Bell Operating Company Provision of Enhanced Services. Summary: The Commission will consider action in response to the remand, in part, of the BOC Safeguards Order.

4—Common Carrier—Title: Price Cap Performance Review for Local Exchange Carriers; Treatment of Video Dialtone Services under Price Cap Regulation (CC Docket No. 94–1). Summary: The Commission will consider application of the price cap rules to video dialtone services.

5—Common Carrier—Title: Applications of NEW ENGLAND TELEPHONE AND TELEGRAPH COMPANY for Authority Pursuant to Section 214 of the Communications Act of 1934, as Amended, and Section 63.01 of the Commission's Rules, to Construct, Operate and Maintain Facilities to Provide Video Dialtone Service to Communities in Rhode Island and Massachusetts (File Nos. W–P–C–6982 and W–P–C–6983).—Summary: The Commission will consider action on applications to provide commercial video dialtone services.

6—Cable Services—Title: Implementation of Sections of the Cable Television Consumer Protection and Competition Act of 1992: Rate Regulation (MM Docket No. 92–266 and MM Docket No. 93–215).—Summary: The Commission will consider providing local franchising authorities and small systems with additional methods of complying with cable rate regulations.

7—Cable Services—Title: Implementation of Sections of the Cable Television Consumer Protection and Competition Act 1992: Rate Regulation (MM Docket No. 92–266).—Summary: The Commission will reconsider its actions, which prohibit small operators and low-price systems that have been provided with transition relief from adjusting their transition rates to reflect increases in inflation.

8—Mass Media—Title: Amendment of Part 74 of the Commission's Rules With Regard to the Instructional Television Fixed Service (MM Docket No. 93–24).—

Summary: The Commission will consider action concerning methods to enhance the efficiency of the processing of applications in the Instructional Television Fixed Service.

9—General Counsel—Title: Amendment of 47 CFR Section 1.1200 *et seq.* Concerning Ex Parte Presentations in Commission Proceedings.—Summary: The Commission will consider whether to propose revisions in its ex parte rules.

10—International—Title: Market Entry and Regulation of Foreign-affiliated Entities.—Summary: The Commission will consider action concerning market entry and regulation of foreign-affiliated entities in U.S. markets.

Additional information concerning this meeting may be obtained from Audrey Spivack or Maureen Peratino, Office of Public Affairs, telephone number (202) 418–0500.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–2794 Filed 2–1–95; 11:18 am]

BILLING CODE 6712–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 11:32 a.m. on Tuesday, January 31, 1995, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Andrew C. Hove, Jr., seconded by Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), concurred in by Director Eugene A. Ludwig (Comptroller of the Currency), and Chairman Ricki Tigert Helfer, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, N.W., Washington, D.C.

Dated: January 31, 1995.

Federal Deposit Insurance Corporation.

Patti C. Fox,

Acting Deputy Executive Secretary.

[FR Doc. 95–2802 Filed 2–1–95; 11:19 am]

BILLING CODE 6714–0–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, February 8, 1995.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: February 1, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–2792 Filed 2–1–95; 11:16 am]

BILLING CODE 6210–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Previously Held Emergency Meeting

TIME AND DATE: 4:40 p.m. Tuesday, January 31, 1995.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314–3428.

STATUS: Closed.

MATTERS CONSIDERED:

1. Administrative Action under Sections 206 and 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).

2. Delegation of Authority. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).

The Board voted unanimously that Agency business required that a meeting be held with less than the usual seven days advance notice, that it be closed to the public, and that earlier announcement of this was not possible.

The Board voted unanimously to close the meeting under the exemptions stated above. General Counsel Robert Fenner certified that the meeting could be closed under those exemptions.

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (703) 518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 95–2841 Filed 2–1–95; 2:28 pm]

BILLING CODE 7535–01–M

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of February 6, 1995.

An open meeting will be held on Wednesday, February 8, 1995, at 10:00 a.m., in Room 1C30. A closed meeting will be held on Friday, February 10, 1995, at 2:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Wallman, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the open meeting scheduled for Wednesday, February 8, 1995, at 10:00 a.m., will be:

The Commission will consider the adoption of proposed rules 18f–3 and 6c–10 under the Investment Company Act of 1940, and related rule and form amendments. Rule 18f–3 would allow mutual funds to issue multiple classes of shares, and form amendments would prescribe prospectus disclosure requirements for multiple class and master-feeder funds. Rule 6c–10 would allow mutual funds to impose back-end loads, including contingent deferred sales loads; the form amendment would clarify that prospectus disclosure requirements for deferred sales loads apply to all types of back-end loads.

The Commission also will consider proposing for public comment amendments to rule 6c–10 to allow mutual funds to impose sales loads paid in one or more installments. Related form amendments would prescribe prospectus disclosure requirements for installment loads. For further information, please contact Karrie McMillan at (202) 942–0695 (rule 18f–3) or Nadya B. Roytblat at (202) 942–0693 (rule 6c–10).

The Commission will consider whether to approve proposed rule changes by the American Stock Exchange, Inc., Chicago

Board Options Exchange, Incorporated, Chicago Stock Exchange, Incorporated, Municipal Securities Rulemaking Board, National Association of Securities Dealers, Inc., New York Stock Exchange, Inc., Pacific Stock Exchange Incorporated, and Philadelphia Stock Exchange, Inc. adopting a continuing education requirement for registered persons. For further information, please contact Francois Mazur at (202) 942–0184.

The subject matter of the closed meeting scheduled for Friday, February 10, 1995, at 2:00 p.m., will be:

Institution of injunctive actions.
Settlement of injunctive actions.
Settlement of administrative proceedings of an enforcement nature.
Institution of administrative proceedings of an enforcement nature.
Opinion.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary (202) 942–7070.

Dated: February 1, 1995.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–2810 Filed 2–1–95; 11:38 am]

BILLING CODE 8010–01–M

UNITED STATES ENRICHMENT CORPORATION BOARD OF DIRECTORS

TIME AND DATE: 8:00 a.m. Tuesday, February 7, 1995.

PLACE: USEC Corporate Headquarters, 6903 Rockledge Drive, Bethesda, Maryland 20817.

STATUS: The meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

- Review of commercial and financial issues of the Corporation
- Review of personnel rules and practices
- Procedural matters

CONTACT PERSON FOR MORE INFORMATION: Barbara Arnold, 301–564–3354.

Dated: January 31, 1995.

William H. Timbers, Jr.,

President and Chief Executive Officer.

[FR Doc. 95–2793 Filed 2–1–95; 11:17 am]

BILLING CODE 8720–01–M

Friday
February 3, 1995

Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 308, et al.

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381

[Docket No. 93–016P]

RIN 0583–AB69

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing requirements applicable to all FSIS-inspected meat and poultry establishments that are designed to reduce the occurrence and numbers of pathogenic microorganisms in meat and poultry products and to reduce the incidence of foodborne illness associated with the consumption of those products. The proposals would (1) clarify the responsibility of establishment management to ensure compliance with sanitation requirements; (2) require at least one antimicrobial treatment during the slaughter process prior to chilling of the carcass; (3) establish enforceable requirements for prompt chilling of carcasses and parts; (4) establish interim targets for pathogen reduction and mandate daily microbial testing in slaughter establishments to determine whether targets are being met or remedial measures are necessary; and (5) require that all meat and poultry establishments develop, adopt, and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Points). FSIS is also announcing its intent to initiate rulemaking jointly with the Food and Drug Administration (FDA) to establish Federal standards for the safe handling of food during transportation, distribution, and storage of the products prior to delivery to retail stores, as well as further efforts to encourage adoption and enforcement by States of consistent, science-based standards to ensure food safety at the retail level. These proposals and initiatives are part of a comprehensive strategy to improve the safety of meat and poultry products when they are delivered to the consumer.

DATES: Comments must be received on or before June 5, 1995.

ADDRESSES: Submit written comments in triplicate to Diane Moore, Docket Clerk, Room 3171 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments, as permitted under the Poultry Products Inspection Act, should be directed to the appropriate person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: (1) GENERAL: Dr. Judith A. Segal, Director, Policy, Evaluation, and Planning Staff, (202) 720–7773; (2) SANITATION: Dr. Isabel Arrington, Staff Officer, Inspection Management Program, Inspection Operations, (202) 720–7905; (3) ANTIMICROBIAL TREATMENTS: Dr. William O. James, II, Director, Slaughter Inspection Standards and Procedures Division, Science and Technology, (202) 720–3219; (4) TEMPERATURE CONTROLS: Carl S. Custer, Staff Officer, Processed Products Inspection Division, Science and Technology, (202) 501–7321; (5) MICROBIAL TESTING: Dr. Richard A. Carnevale, Assistant Deputy Administrator, Scientific Support, Science and Technology, (202) 205–0675; (6) HACCP: Dr. Dorothy Stringfellow, Director, HACCP Office, Science and Technology, (202) 690–2087; (7) TRANSPORTATION AND RETAIL: Patrick J. Clerkin, Director, Evaluation and Enforcement Division, Compliance Program, Regulatory Programs, (202) 254–2537, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

OBTAINING COPIES OF THIS DOCUMENT: Paper or diskette copies of this document may be ordered from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Orders must reference NTIS accession number PB95–166021 for a paper copy and PB95–502217 for the diskette version. For telephone orders or further information on placing an order, call NTIS at (703) 487–4650 for regular service or (800) 533–NTIS for rush service. To access this document electronically for ordering and downloading via FedWorld, dial (703) 321–8020 with a modem or Telnet fedworld.gov. For technical assistance to access FedWorld, call (703) 487–4608.

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I. Background

Purpose of This Document

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that meat and poultry products are safe, wholesome, and accurately labeled. Current FSIS regulatory requirements and inspection procedures contribute much to the achievement of these goals, but there is a critical gap in the FSIS program. The current program does not directly target pathogenic microorganisms, which frequently contaminate otherwise wholesome carcasses. It also does not make meat and poultry establishments legally responsible for taking systematic, preventive measures to reduce or eliminate the presence of pathogenic microorganisms in meat and poultry products. This gap in the FSIS program has important public health implications because a significant portion of the cases of foodborne illness in the United States is associated with the consumption of meat and poultry products that are contaminated with pathogenic microorganisms.

To protect public health and reduce the risk of foodborne illness, FSIS proposes to fill the gap in its current system by requiring new measures that will target and reduce the presence of pathogenic microorganisms in meat and poultry products. FSIS is also beginning a fundamental shift in the paradigm governing its inspection program. FSIS

will begin to build the principle of prevention into its inspection program by requiring all meat and poultry establishments to adopt the Hazard Analysis and Critical Control Point (HACCP) approach to producing safe meat and poultry products. FSIS will also take steps to encourage preventive measures on the farm, require preventive controls during transportation, and support State-based HACCP controls at retail.

The purpose of this document is to initiate the rulemaking required to bring about these changes in the FSIS program. This document will also explain these changes in the context of a broad and long-term strategy to improve the safety of meat and poultry products. The safety of any food product can be affected—positively or negatively—at virtually every step in the process of producing the agricultural commodity on the farm, converting the agricultural commodity into a food product through slaughter and other processing, distributing the product to the consumer, and preparing the product for consumption. While this document focuses on changes that are needed within FSIS-inspected establishments, these changes are part of a broader food safety strategy. This strategy addresses each step in the process and takes a long-term approach to building a comprehensive food safety system that works effectively to protect consumers by preventing food safety problems.

To place the regulatory program in context, this document will first describe the origins and history of the FSIS program, the problem of foodborne illness in the United States, and FSIS's food safety objectives and proposed strategy for achieving them.

Origins and History of the FSIS Program

The following historical account briefly describes the purposes and operation of the inspection program from its late-nineteenth century inception through the current efforts to improve the program.

1890–1945

Federal meat inspection legislation dates from 1890, when countries in Europe raised questions about the safety of American beef. Congress gave the U.S. Department of Agriculture (USDA) responsibility for ensuring that exports would meet European requirements and, in 1891, for conducting ante- and postmortem inspection of livestock slaughtered for meat intended for distribution in the United States.

In 1906, the graphic picture of insanitary conditions in meat-packing establishments described in Upton Sinclair's novel *The Jungle* outraged the U.S. public. Congress responded by passing the Federal Meat Inspection Act (FMIA), one of the first Federal consumer protection measures. It established sanitary standards for slaughter and processing establishments, and mandated antemortem inspection of animals (cattle, hogs, sheep, and goats) and postmortem inspection of every carcass.

It also required the continuous presence of Government inspectors in all establishments that manufactured meat products for commerce. Because the program depended heavily on veterinary skills, it was implemented by USDA's Bureau of Animal Industry which, during that first year, oversaw the inspection of nearly 50 million animals.

The companion Food and Drug Act of 1906 was implemented by a different section of USDA, the Bureau of Chemistry. It covered the safety of all food products except meat and poultry, but it did not require continuous inspection. The Food and Drug Administration (FDA), which now implements the law, was formed in USDA in 1930 and transferred to the Public Health Service in 1940. Meat inspection, which primarily focused on carcass inspection by veterinarians, remained in USDA.

The meat inspection program that developed early in this century used organoleptic methods, based on sight, touch, and smell. The major public health concerns of the time were the potential for transmission of diseases from sick animals to humans and the lack of sanitary conditions for animal slaughter and production of processed products. The purpose of carcass inspection was to keep meat from diseased animals out of the food supply. Federal inspectors under the supervision of veterinarians checked every live animal and every carcass for signs of disease. They also watched for insanitary practices and the use of dangerous preservatives.

In addition to requiring carcass-by-carcass inspection in slaughter establishments, the 1906 meat inspection law provided for continuous USDA inspection of processing operations. Processing, which for the most part consisted of cutting and boning whole carcasses and the production of sausages, ham, and bacon, was usually done in or near the slaughterhouse. Processing was viewed as an extension of slaughter and was conducted by the same FSIS personnel. From the inception of the Program, however, the Agency recognized that, in processing inspection, the inspector focused on the operation of the overall production line, not on each production unit (in contrast to slaughter inspection, where inspectors focused on each carcass).

The FMIA covered all meat and meat products in interstate commerce. It did not cover poultry. At that time, chickens and turkeys were produced mainly on small farms for personal consumption or sale in the immediate area. They were inspected only by the purchaser.

1946–1975

Developments after World War II had a major impact on the meat and poultry industry. New establishments opened, beginning a surge of growth that continued through the 1950's and 1960's. The market for dressed, ready-to-cook poultry expanded rapidly, and both the meat and the poultry industries began turning out many new kinds of processed products. An increasing proportion of the total meat and poultry supply was being processed into hams, sausages, soups, frankfurters, frozen dinners, pizza, and so forth. Between 1946 and 1976, the volume of such products almost quadrupled.

New technology, new ingredients, and specialization added complexity to the once-simple processing industry. Small establishments, many producing solely for intrastate commerce, began producing new products outside the slaughterhouse environment. Processing inspection could no longer be managed as an extension of slaughter inspection.

The growth of the processing sector presented the inspection program with major challenges. First, the skills needed by the Agency called increasingly on the disciplines of food technology and microbiology, along with those of veterinary medicine. The Agency began to recruit and develop more people with the specialized skills necessary to design processing inspection systems.

Second, more inspectors were needed to meet the industry's growing production and geographic expansion. A system of ''patrol'' inspection assignments, with one inspector visiting several processing establishments daily, was devised to fulfill the statutory requirement for continuous inspection in those establishments.

Third, new technologies made it difficult for consumers to check levels of fat, water, and other ingredients used as fillers, increasing the risk of economic adulteration. As a result, USDA inspectors were increasingly called on to protect consumers in this technically complex area. Controlling the use of certain vegetable proteins as

ingredients in meat food products, for example, became important, because vegetable proteins can mask the addition of water to a product. The development of equipment to salvage formerly discarded high-protein tissue from bones and fatty tissue made time-temperature requirements necessary to guard against the growth of spoilage organisms. Standards had to be set for the use of these ingredients and the labeling of products containing them.

Meanwhile, better animal husbandry practices had improved animal health and reduced the public health risk from diseased carcasses. The Agency's extensive, statutorily mandated carcass-by-carcass inspection continued, however, with the important objective of eliminating from commerce the unpalatable signs of disease (such as tumors and lesions), meat from animals with diseases that could pose a human health risk (such as salmonellosis or cysticercosis), fecal contamination of meat and poultry carcasses, and visible damage (such as bruises). Establishment sanitation also remained an important object of inspection in both slaughter and processing facilities.

The Poultry Products Inspection Act (PPIA) of 1957 made inspection mandatory for all poultry products intended for distribution in interstate commerce. It was modeled after the Federal Meat Inspection Act.

The potential for unseen health hazards in the food supply also attracted increasing regulatory attention. In 1962, Rachel Carson's *Silent Spring* raised public awareness of the possible harmful effects of pesticides and other chemical contaminants in food. In 1967, the Agency established the National Residue Program, the Federal Government's principal regulatory mechanism for determining and controlling the presence and level of those chemicals in meat and poultry that may present a public health concern.

Because of the increasing volume and complexity of food production and the potential for various forms of adulteration that consumers could not, by themselves, determine, Congress enacted new legislation during this period to assure the safety and wholesomeness of all foods, including meat and poultry products. The 1958 Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act (FFDCA) provided for FDA approval of new food additives and their conditions and levels of use.

The Wholesome Meat Act of 1967 and the Wholesome Poultry Products Act of 1968 amended the basic laws governing mandatory meat and poultry inspection to assure uniformity in the regulation of products shipped in interstate, intrastate, and foreign commerce. These Acts provide the statutory basis for the current meat and poultry inspection system. Both Acts gave USDA new regulatory authority over allied industries, including renderers, food brokers, animal food manufacturers, freezer storage concerns, transporters, retailers, and other entities. Both Acts incorporated adulteration and misbranding prohibitions tied to important provisions of the FFDCA relating to food and color additives, animal drugs, and pesticide chemicals. Both Acts provided stronger enforcement tools to USDA, including withdrawal or refusal of inspection services, detention, injunctions, and investigations. Both Acts extended Federal standards to intrastate operations, provided for State-Federal cooperative inspection programs, and required that State inspection systems be ''at least equal to'' the Federal system.

Also, under these Acts, meat and poultry products from foreign countries that are sold in the United States must have been inspected under systems that are equivalent to that of USDA.

1970s–Present: Increasing Demand for Inspection

By the 1970s, the need to focus on ''invisible'' hazards to public health had raised the ratio of analytical to organoleptic activities, and the ratio of out-of-plant to in-plant activities. The bulk of the Agency's resources continued to be allocated, however, to in-plant activities addressing the issues of animal disease and establishment sanitation. During the 1970s, national budget constraints reduced the funds available for inspection throughout the United States. As individual States exercised their right to request that the Agency take over their inspection programs, FSIS had either to eliminate some inspection activities or change the way they were performed, to provide the additional coverage.

The driving force behind FSIS's program changes from the 1970s on was the need to keep up with industry's expansion and its productivity gains, including the incorporation of automation in the slaughter process that increased the rate at which carcasses could move through the slaughter facility (typically referred to as ''line speed''). Automation has had a particularly great impact on poultry operations, where inspectors have had to face faster and faster line speeds, which today can be as high as 91 birds per minute.

The industry changed in many ways during this period. The poultry industry became, to a large extent, vertically integrated, with large companies controlling each step of the process from production of birds to slaughter, processing, distribution, and marketing of chicken and turkey products under brand names. The beef and pork industries grew, but generally did not become vertically integrated. Beef cattle and swine continued to be produced by a large number of independent farming businesses. Consolidation occurred in slaughter and processing operations, and production increased. Increased production meant more meat and poultry products awaited inspection by FSIS inspectors.

The Agency strained to keep pace with an industry radically different in scale and scope from what it had been in 1906. In September 1976, the Agency hired the management consulting firm of Booz, Allen and Hamilton, Inc., to perform an in-depth study to find less costly ways to inspect meat and poultry that would not reduce the level of consumer protection. The study recommended, among other things, that FSIS:

- Use quality control mechanisms to shift responsibilities from inspectors to the establishment, giving inspectors a verification responsibility.
- Establish microbiological criteria for finished products.
- Explore substitution of air chilling for water chilling of poultry carcasses.
- Require chlorination of chiller water for poultry.
- Expand food safety education for consumers and food handlers.

The study elicited a generally negative response from consumer groups and some members of FSIS's workforce, who interpreted the recommended role changes as an abdication of Agency responsibility. Anticipating higher costs and concomitant price hikes, industry also objected to the recommendations. FSIS decided to pursue only some of the recommendations.

One that it did pursue in processing establishments, the voluntary Total Quality Control (TQC) program, was implemented in 1980. The General Accounting Office (GAO) had recommended a TQC-type program in December 1977, to afford the Agency flexibility to tailor inspection frequency to individual establishments' needs. This program applied a different kind of inspection to establishments that FSIS approved for a self-monitored production control program designed to assure that processed products would meet regulatory requirements. In those

establishments, the inspector, instead of personally generating production process information, used establishment production records on the production process, supplemented by in-plant observations, to verify that product was in compliance. In many establishments, TQC reduced the time needed for inspection, but the statutory provision for ''continuous'' inspection meant that, even under TQC, an inspector had to visit the establishment at least daily.

In 1978, the Agency issued its own report, ''A Strengthened Meat and Poultry Inspection Program.'' Among other things, the report observed that the poultry postmortem system had been designed before both the vertical integration of the poultry industry and the increasing attention to production control, which had helped producers overcome major animal and poultry health problems. With the introduction of high-speed production lines, the traditional inspection system had become ''severely stressed,'' with inspectors ''forced to work at speeds well over those at which peak effectiveness is expected.'' Scientific evidence indicated that with the improvement in animal health, little of the carcass examination performed by inspectors was necessary to protect public health. However, carcass-by-carcass inspection continued to address the wholesomeness and quality aspects of meat and poultry that consumers demanded.

Between 1980 and 1986, the Agency introduced what became known as streamlined inspection systems (SIS) in high-speed poultry slaughter operations. These systems shifted routine tasks that controlled for quality, rather than safety, from inspectors to establishment employees. Since an increasing amount of the poultry (and meat) supply was being produced under brand names, the Agency believed that establishments would be motivated to protect the reputation of their products by performing systematic quality control for visible, unpalatable defects. Under streamlined inspection, establishment employees, working under FSIS supervision, would perform detection and trimming of carcass defects that affect the ''quality,'' but not the ''safety'' of the product—functions previously performed by FSIS inspectors. The attempt to streamline carcass inspection by shifting non-public health tasks to the industry was criticized by consumer groups and inspectors, who interpreted the modernization initiative as a pretext for deregulation.

In 1986, Congress granted the Agency the authority to vary the frequency and intensity of inspection in processing establishments on the basis of the risk presented by the particular establishment and process. Again, FSIS's proposal to implement this authority was interpreted by consumer groups as an effort to reduce inspection. They opposed it, as did some Agency employees. Industry members supported the concept but were skeptical about how it would be implemented. For lack of support, the Agency withdrew its proposal, and the legislative authority for it expired in 1992.

Each of the foregoing modernization initiatives aroused the same concerns: Increased line speeds compromised job performance; new procedures had not been adequately or objectively tested; and, generally, streamlined slaughter inspection policies would not protect consumers. While SIS for poultry survived, the controversy blocked FSIS's attempt to extend SIS to cattle. A special review in 1990 by the National Academy of Sciences (NAS) pointed out deficiencies in the current system's handling of microbiological hazards but concluded that a SIS for cattle would be at least as effective as traditional inspection. However, consumers and the Agency's inspection workforce equated SIS for cattle with deregulation—license for industry to increase line speeds at the expense of public health. Congress ordered the Agency to stop the pilot tests then in progress in five cattle operations.

Today, FSIS inspectors perform hundreds of tasks during slaughter and processing operations. Slaughter inspection occurs in two phases: ante- and postmortem. During antemortem inspection, the inspectors observe all red meat animals at rest and in motion, segregating any abnormal animals they detect before the animals enter the slaughter facility. Based on further examination by a Veterinary Medical Officer (VMO), abnormal animals are either condemned or allowed to enter the slaughter process under special handling.

Because the large number of chickens and turkeys FSIS inspects (more than 6 billion slaughtered annually) makes antemortem bird-by-bird inspection impracticable, inspectors or VMO's conduct the antemortem inspection of poultry on a flock or lot basis. The poultry are observed while in coops or grouped for slaughter, before or after they are removed from trucks. Abnormal birds are condemned.

Antemortem inspection can detect some diseases (for example, rabies, listeriosis, and heavy metal toxicosis) through distinct clinical signs that cannot be detected by gross postmortem inspection. Additionally, some types of microbial diseases that can seriously contaminate the slaughter environment, such as abscesses and anthrax, can be detected by antemortem inspection. In those cases, the affected animals are prevented from entering the slaughterhouse.

During the postmortem phase of Federal inspection, the viscera and carcasses of all animals and birds slaughtered are examined by an FSIS inspector on the processing line. (See Figures 1 and 2 for illustrative schematics of beef and broiler chicken slaughter.) Many of the bacteria implicated in cases of foodborne illness live in the intestinal tracts of meat animals and poultry, present no evidence of overt pathologies in the animal, and can be shed in the feces. For this reason, line inspectors require physical removal of visible fecal and ingesta contamination of flesh.

For red meat, inspectors examine the heads, viscera, and carcass at one or more postmortem inspection stations. For poultry the viscera, carcasses, and, for older poultry, heads are examined at a single postmortem inspection station. To detect abnormalities at these stations, the red meat inspector performs a sequence of observations, palpations, and incisions of tissues; the poultry inspector, a sequence of observations and palpations. For both red meat and poultry, visible contaminants (such as feces), damage, and other abnormalities are detected and eliminated to ensure only meat and poultry that appear fit for human consumption ''pass'' inspection. Only VMO's and VMO-supervised inspectors make the final determination.

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Figure 1. Beef Slaughter

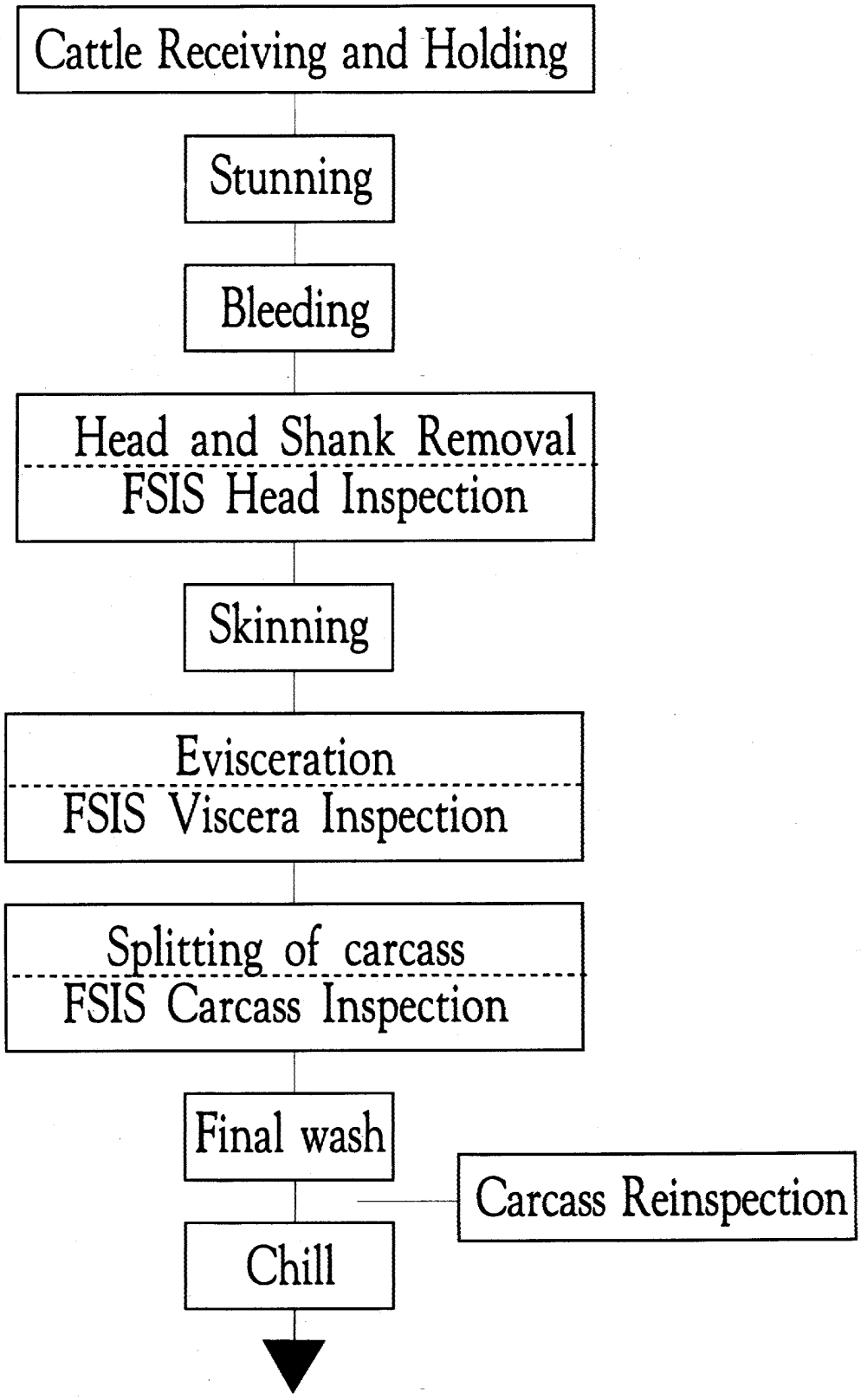
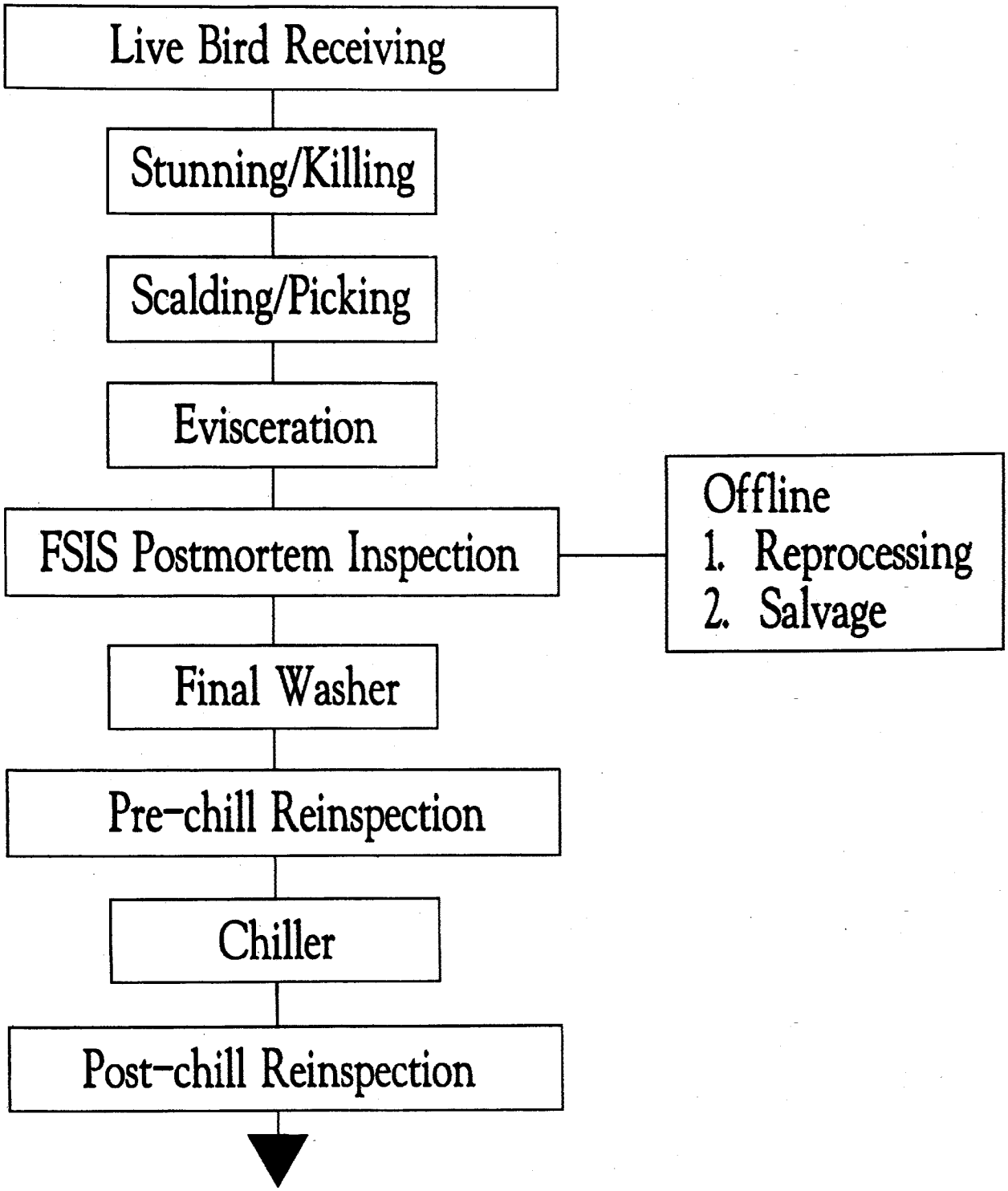


Figure 2. Broiler Chicken Slaughter



BILLING CODE 3410–DM–C

The prevention of ingesta and fecal contamination of beef and poultry carcasses in slaughter establishments is a focal point of the current inspection system, because contamination of the flesh with feces and ingesta is a potential cause of contamination of meat and poultry products with harmful bacterial pathogens, such as *Salmonella, Campylobacter* and *E. coli* 0157:H7. Contamination can occur as a result of feces entering the slaughter facility on the external surface of the animal and contaminating the carcass during the skinning or defeathering process or as a result of ingesta or feces being spilled from the intestinal tract during evisceration or other steps in the process. Meat and poultry carcasses found to bear fecal contamination must be condemned or, if possible, reworked to remove the contamination in an accepted manner. Removing visible fecal contamination is important, but it does not assure the absence of harmful bacteria that cannot be detected visually.

The law requires inspected meat and poultry products to bear an official inspection legend (21 U.S.C. 601(n)(12), 453(h)(12)). Specifically, the words ''inspected and passed'' must appear on meat products found not to be adulterated (21 U.S.C. 606, 607; 9 CFR 312.2, 312.3); ''inspected for wholesomeness by U.S. Department of Agriculture'' must appear on poultry products (9 CFR 381.96). The term ''wholesome'' has traditionally been applied to meat or poultry found upon visual inspection to be free of disease, not decomposed, and to be otherwise fit for human consumption. While ''wholesome'' as used in this context is not intended to be synonymous with ''safe,'' consumers could reasonably infer a connection between ''wholesomeness'' and food safety. Similarly the words ''inspected and passed'' on meat products could be understood by consumers as a statement about safety, despite the fact that organoleptic inspection does not address invisible hazards, such as pathogenic microorganisms.

This problem concerning the meaning of the inspection legend arises in part from the fact that the requirement to place an inspection legend on every product that passes inspection was adopted before the safety concerns posed by pathogenic microorganisms, drug residues, and other invisible hazards came to the fore. Visual inspection does not directly address these safety issues on a carcass-by-carcass or product-by-product basis. Thus, some contend that the inspection legends serve only to mislead contemporary consumers and should be discontinued. FSIS invites public comment on this issue.

Of the 129,831,110 meat-animal carcasses inspected during Fiscal Year 1993, 384,543 (or .3 percent) were condemned for disease, contamination, or adulteration during ante- or postmortem inspection. Of the 7,085,491,852 poultry carcasses inspected that year, 63,926,693 (or .9 percent) were condemned. Today, more than 7,300 FSIS inspectors enforce the inspection laws in approximately 6,200 meat and poultry establishments. Inspection activities start prior to slaughter and continue throughout processing, handling, and packaging.

FSIS ensures compliance with inspection laws and regulations outside inspected establishments through control and condemnation of misbranded or adulterated products. Specifically, during FY 1993, FSIS detained suspect products 796 times (involving 13,081,409 pounds of product) and monitored product recalls 36 times (involving 5,726,378 pounds of product). During the same period, 145,526 meat and poultry product labels were reviewed; 10,154 were not approved. Other measures FSIS uses to enforce the regulations include withholding inspection pending correction of serious problems, controlling product distribution, working with companies to recall violative products, and seeking court-ordered product seizures when necessary.

The Performance-Based Inspection System (PBIS) is a modernization initiative implemented in processing establishments during 1989. PBIS is a structured, automated information system that helps the Agency document findings resulting from inspector tasks; record deficiencies found and actions taken; and discuss deficient findings and corrective actions with establishment management. PBIS is intended to make processing inspection more uniform nationwide and provides FSIS with its first easily accessible database on establishment performance. It enables the Agency to capture, store, and sort the vast quantities of information generated by the 13 million inspection tasks performed in processing establishments each year. These data allow the Agency to examine the long-term operation of a particular establishment or the performance of a particular control point nationwide. Decisions on inspection intensity are based on these data, although the frequency is never less than one visit per day.

FSIS expects to implement PBIS in slaughter operations during FY 1996.

Foodborne Illness in the United States

The safety of the meat and poultry supply has been widely discussed during the past few years. Although food safety can be affected by multiple factors, including animal drug and pesticide residues and unintentional environmental contaminants, the following discussion focuses on pathogenic microorganisms that are associated with foodborne illness, including the illness and preventable deaths associated with meat and poultry consumption. Pathogenic microorganisms are widely recognized by scientists to be the most significant causes of foodborne illness.

Foodborne illness can strike individuals of all ages, sexes, nationalities, and socioeconomic levels. The most common types of foodborne illness associated with pathogenic microorganisms typically appear as acute gastroenteritis with sudden onset of vomiting or diarrhea, or both, with accompanying abdominal pain. However, the exact combination of symptoms may vary widely, depending on the type of microorganism and the immune status of the person infected. For example, certain types of bacteria often cause bloody diarrhea, including *E. coli* 0157:H7 and, in a smaller percentage of cases, *Campylobacter jejuni. E. coli* 0157:H7 produces a strong toxin (''shiga-like'' toxin) which can lead to blood clotting abnormalities and kidney failure (hemolytic uremic syndrome) and can cause death, especially in young children and the elderly. Even if recovery from the acute illness is complete, 15–30 percent of persons with hemolytic uremic syndrome will have evidence of chronic kidney disease. While *Salmonella* ordinarily causes transitory and non-life-threatening acute gastroenteritis, *Salmonella* can get into the bloodstream of some infected patients, particularly patients who are very young, very old, or immunosuppressed (such as persons with AIDS); these bloodstream infections can have serious complications, including death. Infections caused by *Salmonella* may also trigger autoimmune phenomena, such as reactive arthritis, which may result in long-term disability.

While there is general consensus that foodborne illness is a major cause of morbidity and mortality in this country, estimates of the incidence of foodborne illness vary widely. The Centers for Disease Control and Prevention (CDC) maintains a national foodborne disease surveillance system, but the data in this

system are recognized not to provide an accurate estimate of foodborne disease incidence. With the exception of a few pathogens, the data deal only with outbreaks (two or more cases of illness linked to a common source); are based on voluntary reporting by State health departments; and are dependent almost entirely on passive surveillance (that is, cases and outbreaks voluntarily reported to local health authorities).

A somewhat better picture of disease incidence can be obtained through national laboratory-based reporting systems. The model for this is the CDC system for reporting of salmonellosis. Again, however, data are in most instances passively collected, and are dependent on physicians submitting cultures; if a patient does not see a doctor, or the doctor does not collect a stool culture, the case does not enter the reporting system. Further, of the major foodborne pathogens, laboratory-based surveillance is available only for *Salmonella*. Recognizing these deficiencies, a number of groups have attempted to estimate actual rates of disease occurrence, drawing both from CDC databases (with their inherent limitations, discussed above) and extrapolating from population-based studies in specific geographic areas. ''Best estimates'' of the incidence of specific diseases, and the percentage of these diseases thought to be foodborne, are provided in Table 1, below (together with the source of these estimates). These estimates are in basic agreement with compilations put together by expert committees of the National Academy of Sciences and, most recently, by the Council for Agricultural Science and Technology.

Taken together, these data suggest that foodborne pathogens account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated annually with meat and poultry products contaminated with pathogenic microorganisms. Even these estimates may be low; at least one investigator has suggested that total cases of foodborne illness may reach 33 million cases a year, with up to 9,000 deaths.

TABLE 1.—SOURCES OF DATA FOR SELECTED FOODBORNE PATHOGENS, 1993

Pathogen	Total cases (#)	Total deaths (#)	Source(s) for case and death estimates	Percent foodborne (%)	Source
Bacteria:					
Campylobacter jejuni or coli	2,500,000	200–730	Tauxe	55–70	Tauxe et al.
Clostridium perfringens	10,000	100	Bennett et al	100	Bennett et al.
Escherichia coli O157:H7	10,000–20,000	200–500	AGA Conference	80	AGA Conf./CDC comm.
Listeria monocytogenes	1,795–1,860	445–510	Roberts and Pinner	85–95	Schuchat.
Salmonella	800,000–4,000,000	800–4,000	Helmick et al./Bennett et al	87–96	Bennett et al./Tauxe & Blake.
Staphylococcus aureus	8,900,000	7,120	Bennett et al	17	Bennett et al.
Parasite:					
Toxoplasma gondii	4,111	82	Roberts et al	50	Roberts et al.

Sources:

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TABLE 2.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993

Pathogen	Foodborne illness		Foodborne* costs (bil $)	Percent from meat/poultry (%)	Meat/poultry related		Total costs* meat/poultry (bil $)
	Cases (#)	Deaths (#)			Cases (#)	Deaths (#)	
Bacteria:							
Campylobacter jejuni or coli	1,375,000–1,750,000	110–511	0.6–1.0	75	1,031,250–1,312,500	83–383	0.5–0.8
Clostridium perfringens**	10,000	100	0.1	50	5,000	50	0.1
Escherichia coli 0157:H7	8,000–16,000	160–400	0.2–0.6	75	6,000–12,000	120–300	0.2–0.5
Listeria monocytogenes	1,526–1,767	378–485	0.2–0.3	50	763–884	189–243	0.1–0.2
Salmonella	696,000–3,840,000	696–3,840	0.6–3.5	50–75	348,000–2,880,000	348–2,610	0.3–2.6
Staphylococcus aureus**	*1,513,000*	1,210	1.2	50	*756,500*	605	0.6
Subtotal	3,603,526–7,130,767	2,654–6,546	2.9–6.7	N/A	2,147,513–4,966,884	1,395–4,191	1.8–4.8

TABLE 2.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993—Continued

Pathogen	Foodborne illness		Foodborne* costs (bil $)	Percent from meat/poultry (%)	Meat/poultry related		Total costs* meat/poultry (bil $)
	Cases (#)	Deaths (#)			Cases (#)	Deaths (#)	
Parasite:							
Toxoplasma gondii	3,056	41	2.7	100	2,056	41	2.7
Total	3,606,582–7,133,823	2,695–6,587	5.6–9.4	N/A	2,149,569–4,968,940	1,436–4,232	4.5–7.5

The costs of the foodborne illnesses (see Table 2, above) are borne by those who become ill and their families, coworkers, and employers, as well as the food industries, and taxpayers. Costs to stricken individuals include medical bills, time lost from work, pain and inconvenience. Food industry costs include possible product recalls, establishment closings and cleanup, and higher premiums for product liability insurance. Perhaps most costly in the long term is loss of product reputation and reduced demand when an outbreak is traced back and publicized. These and other ''defensive'' industry costs of foodborne disease run in the millions of dollars annually and are, for the most part, entirely avoidable. Taxpayer costs include medical treatment for those who cannot afford it and higher health insurance premiums.

Other taxpayer costs include public health-sector expenses to operate a disease surveillance system and to investigate and eliminate disease outbreaks. Approximately $300 million is spent on microbial foodborne disease annually by the Federal public health-sector. Federal costs average about $200,000 per foodborne illness outbreak.

The Department's Economic Research Service and CDC estimate the cost of all foodborne illness in 1993 to have been between $5.6 and $9.4 billion. Meat and poultry products were associated with approximately $4.5–$7.5 billion; the remaining $1.1 to $1.9 billion was associated with non-meat and poultry sources. Table 2 summarizes data on a pathogen-by-pathogen basis.

Foods contaminated with pathogenic microorganisms can lead to infection and illness in two major ways. The first is by direct consumption of the contaminated food under conditions that allow the survival of the pathogen or its toxin, such as when a meat or poultry product is consumed raw or undercooked, or products precooked during processing are recontaminated and consumed directly. The second is through cross-contamination in the kitchen or other food-handling areas, for example, when raw chicken or beef with a *Salmonella*-contaminated exterior contaminates a person's hands, a cutting board, countertop, or kitchen utensil, which then comes into contact with cooked product or foods consumed raw, such as salad. For some pathogens, such as *Salmonella,* it is likely that more cases of illness result from cross-contamination than from direct consumption of undercooked product.

Microbiological surveys of meat and poultry products have been conducted by FSIS over several decades. In cooked, ready-to-eat products, the frequency of pathogenic microorganisms has been relatively low. In regulatory testing programs of domestically produced, cooked, ready-to-eat meat and poultry products, for example, *Salmonella* has generally been found to be present in only about 0.1 percent of the samples tested and *Listeria monocytogenes* in about 1.5–3 percent of samples tested.

The frequency of pathogenic microorganisms in raw, ready-to-cook products has been greater. For example, FSIS has conducted surveys on the prevalence of *Salmonella* in various raw products, including broiler chickens, beginning as early as 1967. In these surveys, *Salmonellae* were isolated from 28.6 percent of 597 samples in 1967; from 36.9 percent of 601 samples in 1979; from 35.2 percent of 1693 samples in the 1982–1984 study; and from approximately 25 percent of the samples in the 1990–1992 study. FSIS studies on fresh pork sausage involved retail-size samples. *Salmonellae* were isolated from 28.6 percent of 566 samples in 1969, and from 12.4 percent of 603 samples in 1979. A benchmark study on raw beef was initiated in January 1987 and completed in March 1990. The prevalence of *Salmonella* in 25 gram portions was found to be 1.6 percent, the prevalence of *Listeria monocytogenes* was 7.1 percent and the prevalence of *E. coli* 0157:H7 was 0.1 percent.

In 1992, FSIS began a series of Nationwide Microbiological Baseline Data Collection Programs designed to provide a microbiological profile of various classes of inspected product. The first, on steer and heifer carcasses, was reported in January 1994. *Clostridium perfringens* was recovered from 2.6 percent of 2,079 carcasses; *Staphylococcus aureus* from 4.2 percent of 2,089 carcasses, *Campylobacter jejuni/coli* from 4.0 percent of 2,064 carcasses; *E. coli* 0157:H7 from 0.2 percent of 2,081 carcasses; and *Salmonella* from 1.0 percent of 2,089 carcasses.

The ongoing outbreaks of salmonellosis, attributed to consumption of contaminated meat, poultry and other food products, and the recent outbreaks of illness caused by *E. coli* 0157:H7 in undercooked ground beef, illustrate how serious the public health threat can be, even when the incidence of contamination of carcasses is relatively low.

For example, on January 13, 1993, a physician in Washington State reported to the Washington State Department of Health a cluster of children with Hemolytic Uremic Syndrome, a serious condition that is the major cause of acute kidney failure in children. Also reported was an increase in emergency room visits for bloody diarrhea. This outbreak was reported to CDC.

Cultures taken from symptomatic patients indicated that *E. coli* 0157:H7 was the causative organism. During January 16–17 an epidemiological case-control study conducted by Washington State and CDC strongly suggested the consumption of hamburgers at a chain of fast food restaurants as the source of the infection. The investigation revealed that the hamburger patties were cooked by the restaurants to a temperature below the Washington State standard of 155°F, and in some instances below the 140°F then recommended by FDA.

By February 4, 350 people in Washington State had contracted illnesses of the kind associated with *E.*

coli 157:H7 and, of these cases, 230 were culture-confirmed. In addition, 12 people had become ill in Idaho and 30 in Nevada. It was also learned that illness had occurred among 34 persons in San Diego, California, in December and January. The outbreaks in each of these States all had in common the consumption of hamburger at the same chain of fast food restaurants. The greater proportion of these cases were primary infections, that is, the persons affected became ill directly from eating contaminated hamburgers. The other cases were secondary infections—the affected persons contracted their illnesses through contact with a person who was infected with the pathogen.

Eventually, four people died and more than 500 other persons became ill during the course of the epidemic.

An important aspect of the Department's review of this experience was the finding that the winter 1992–93 outbreak was not caused by a failure in the operation of the inspection system as currently designed. Rather, it stemmed in part from an inspection system that does not directly require the reduction, minimization, or elimination, if possible, of pathogenic microorganisms in raw product leaving inspected establishments. The specific pathogen in this example was highly virulent, meaning that a very low dose was sufficient to cause illness. During the beef-grinding process, harmful bacteria can easily be spread throughout a large volume of product. When such product becomes widely distributed and is cooked inadequately to kill any pathogens that might be present, preventable deaths may result.

The Relationship Between Foodborne Illness and Consumer Knowledge and Behavior

The National Academy of Sciences' *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS–C)* (1990) reiterated the theme of numerous other studies, ''* * * the public expects the government to ensure zero risk of meat-borne disease through inspection. The [NAS] committee heard little evidence that the public is aware that some bacterial contamination of raw meat is inevitable and no mention of the crucial role of food handling, preparation, and serving methods in limiting foodborne diseases.'' The disturbing but real fact that consumers fail to make a connection between their food handling behavior and safe food recurs throughout the literature on the subject.

Behavioral research shows that food habits are the most difficult of all forms of human behavior to change. This finding is supported by research of consumer knowledge and practices, which indicates that a large portion of the U.S. population lacks basic food safety information and skills and engages in food handling and preparation practices that epidemiological studies have linked with a significant number of foodborne illness outbreaks. Moreover, little correlation exists between consumers' food safety knowledge and their food handling and preparation practices. Even people who characterize themselves as ''knowledgeable'' do not necessarily follow good food safety procedures.

These findings about consumer behavior related to safe food handling and preparation support the need for a comprehensive pathogen reduction effort. Food safety can best be assured only if each participant in the food system—from the producer all the way through to the consumer—understands, accepts, and acts on his or her responsibility for food safety. While FSIS will pursue and support all possible means of consumer education and outreach, the Agency realizes that consumer education alone will not control pathogen-related foodborne illness. This is truer today than ever before, as more people in our society are assuming responsibility for food handling and preparation in the home and elsewhere, without experience in food preparation and knowledge of safe food handling and storage methods. These people include:

- Food service workers, many of whom are high-turnover, part-time, or teenaged workers who receive inadequate training;
- Men and women in the workplace, who have minimal time for food preparation and often little experience or interest in food preparation;
- Children, who are increasingly expected to shop for and prepare their own meals;
- Immigrants, who might not be able to read food handling instructions, or whose cultural practices include eating raw or rare meat and poultry products.

Vulnerable sectors of the population, more severely affected by foodborne illness, are also increasing in size:

- Immunocompromised persons (i.e., persons with diabetes, cancer, chronic intestinal diseases, organ transplants, and AIDS);
- Persons 65 years and older—a growing proportion of the population—who, due to the normal decline in immune response, are at increased risk.

In 1993, to increase awareness about pathogens, FSIS promulgated a regulation requiring safe handling labels on most raw meat and poultry products. The Agency's Meat and Poultry Hotline provides consumers with immediate responses to questions about meat and poultry handling and safety. These steps and other education activities are important but they are not a substitute for building into the meat and poultry production and regulatory system measures to reduce to the maximum extent possible the presence of pathogenic microorganisms in meat and poultry products purchased by U.S. consumers.

External Studies and Recommendations for Change

During the past decade, the National Academy of Sciences (NAS), the General Accounting Office (GAO), the National Advisory Committee on Microbiological Criteria for Food (NACMCF), and consumer groups have evaluated and called for change in the current inspection system.

In 1983, FSIS asked NAS to evaluate the scientific basis of its inspection system and recommend a modernization agenda. The resulting report, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program*, was issued in 1985. This was the first comprehensive evaluation of the scientific basis for the Federal meat and poultry inspection system. The report provided a blueprint for change, recommending that FSIS focus on pathogenic organisms and require that all official establishments operate under a Hazard Analysis and Critical Control Point (HACCP) system to control pathogens and other safety hazards. This report ''encourages FSIS to move as vigorously as possible in the application of the HACCP concept to each and every step in establishment operations, in all types of enterprises involved in the production, processing, and storage of meat and poultry products.''

Two later NAS studies reinforced these recommendations, urging the Agency to focus on public health goals:

- *Poultry Inspection: The Basis for a Risk Assessment Approach* (1987) concluded that a risk-assessment approach is needed to evaluate health hazards associated with poultry. Critical control points at which known pathogenic microorganisms may be introduced into the poultry production system should be identified and monitored, preferably as part of a HACCP program.
- The most recent NAS report, *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS–C)* (1990) stated that traditional meat inspection, relying on

organoleptic examinations, is not fully effective in protecting the public from foodborne health hazards. FSIS was urged to move to a risk-based inspection system targeted at significant public health risks, especially those associated with pathogenic microorganisms.

The GAO has also been advocating improvements in the present inspection system in reports and Congressional testimony. In numerous reports (see list below), GAO endorses HACCP as a scientific, risk-based system to better protect the public from foodborne illness. This sentiment is most clearly expressed in the 1994 *Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry,* which states:

> A HACCP system is generally considered the best approach currently available to ensure safe foods because it focuses on preventing contamination rather than detecting contamination once it has occurred.* * * To better protect the public from foodborne illnesses, we believe FSIS must now move to a scientific, risk-based inspection system. Such a system would allow FSIS to target its resources towards the higher risk meat and poultry products and establishments by increasing inspection of such products and establishments, developing methods or tools that would help inspectors detect microbial contamination, increasing product testing, and helping establishments develop and operate microbial testing programs.

This report further recommends that Congress ''revise the meat and poultry acts to provide FSIS with the flexibility and discretion to target its inspection resources to the most serious food safety risks.''

These basic recommendations are echoed in the five GAO reports describing the current inspection system and recommending changes to improve its effectiveness, listed below:

''Meat Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited'' (1994);

''Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety'' (1993);

''Food Safety: Building a Scientific Risk-Based Meat and Poultry Inspection System'' (1993);

''Food Safety: Inspection of Domestic and Imported Meat Should be Risk-Based'' (1993);

''Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply'' (1992).

A third major proponent of HACCP is the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established in 1988 by the Secretary of Agriculture to advise and provide recommendations to the Secretaries of Agriculture and of Health and Human Services on developing microbiological criteria to assess food safety and wholesomeness. Since 1989, NACMCF has prepared a series of reports on the development and implementation of HACCP. As one of its first tasks, the Committee developed ''HACCP Principles for Food Production'' in November 1989. In this report the Committee endorsed the HACCP system as a rational approach to ensure food safety and delineated seven HACCP principles to standardize HACCP in the Committee's own work, as well as in industry, regulatory applications, and training. In 1992, the Committee issued an updated guide, ''Hazard Analysis and Critical Control Point System.''

To describe the HACCP system more concretely, in 1993 NACMCF published *The Role of Regulatory Agencies and Industry in HACCP.* In that report, NACMCF articulated the roles of regulatory agencies and industry in implementing HACCP, and recommended what the responsibilities of FDA, USDA, other agencies and industry should be during various phases of HACCP implementation.

In June 1993, NACMCF developed a model, ''Generic HACCP for Raw Beef,'' which provides a HACCP plan for beef slaughter and processing (see Appendix). It focuses on the slaughter and processing portions of the total ''farm to consumption'' scope of a complete HACCP program.

Similar recommendations for program change have come from consumer, industry, State, and local government representatives, as well as other constituent groups. Consumer representatives at recent public hearings and the HACCP Round Table held in March 1994 supported implementation of HACCP throughout the meat and poultry industry.

Industry groups, in clarifying their support for HACCP to control pathogens, contend that HACCP-based food production, distribution, and preparation by industry can do more to protect public health than any Federal inspection program. They recommended that HACCP be used to anticipate microbiological hazards in food systems and to identify risks in new and traditional products. State departments of health and agriculture also endorsed the HACCP approach.

FSIS Agenda for Change

The meat and poultry inspection program currently addresses many matters of great importance to the safety and quality of the food supply, including supervision of industry compliance with sanitation standards, exclusion of diseased animals from the food supply, examination of carcasses for other visible defects that can affect safety and quality, inspecting for economic adulteration, and monitoring for chemical residues. These activities respond to some of the public's most basic expectations regarding the safety and quality of the food supply and reflect the standards and requirements established by Congress in the laws FSIS administers. FSIS is strongly committed to effectively implementing these statutory requirements.

As the experience of recent years and the many external studies and reports indicate, however, there is a need for fundamental change in the FSIS program. The most critical reason for change is the need to ensure that the FSIS inspection program is fully meeting its paramount obligation to protect public health. To meet this obligation, there is a pressing need to better address the public health problem of foodborne illness associated with the consumption of meat and poultry products.

As documented in the preceding sections, many cases of foodborne illness are caused annually by pathogenic microorganisms that enter the food supply during the slaughter and processing of meat and poultry products. With respect to raw meat and poultry products, the current system of inspection addresses this problem only indirectly, by enforcing sanitation requirements and inspecting for visible fecal and ingesta contamination and other visible defects that can be pathways for contamination of carcasses by pathogenic microorganisms.

The current system must be enhanced to deal more directly with pathogenic microorganisms. In particular, the system needs to be changed to make better use of the science and tools of microbiology to reduce, and where possible eliminate, pathogenic microorganisms. Such change is needed to protect public health.

Change is also needed to clarify the respective responsibilities of the meat and poultry industries and the FSIS inspection program when it comes to the safety of the food supply. Companies producing meat and poultry products are responsible for ensuring that their products are safe and do not violate any of the statutory provisions defining adulteration and misbranding. FSIS is responsible for inspecting products and facilities to verify that these requirements have been met and for taking appropriate remedial and enforcement actions when the requirements have not been met.

This line between industry and FSIS responsibility has become blurred. This may be due in part to the continuous presence of FSIS inspectors in meat and poultry establishments and the statutorily mandated USDA inspection legend, which together may have encouraged some establishments to rely on FSIS to ensure the safety of the establishment's products rather than take full responsibility themselves for the safety of their products. Because the FSIS inspector is obligated to prevent adulterated product from leaving the establishment, some establishments may operate on the assumption that what is not specifically prohibited or detected by the FSIS inspector may continue. This is not acceptable.

Likewise, the FSIS inspection program has too often taken on the burden of expending significant inspectional resources to bring establishments into compliance—such as in cases of repeat violators of sanitation standards—rather than finding efficient means to hold establishments accountable for complying with applicable standards. As a result, the inspection resources needed to ensure that all establishments have appropriate production controls are frequently spent on intensified inspection of poor performers. For these reasons, the lines of responsibility for food safety must be clarified.

Finally, change is needed to move toward a more preventive approach to ensuring the safety of food. The current system relies too heavily on FSIS inspectors to detect and correct problems after they have occurred, whether in establishments or after the product has left the establishment. This is not the most efficient use of FSIS resources, and, especially in the case of pathogenic microorganisms, it is not effective in protecting public health. Many meat and poultry establishments, as well as other segments of the food industry, have found that safety can best be ensured by systems designed to prevent food safety problems. To protect public health and make the best use of its resources, FSIS needs to build the principle of prevention into its inspection system.

The changes FSIS plans in its inspection program—targeting pathogenic microorganisms, setting priorities on the basis of public health risk, clarifying roles and responsibilities, and building in the principle of prevention—constitute an institutional paradigm shift that can significantly enhance the effectiveness of the FSIS program and reduce the risk of foodborne illness.

To achieve such change, FSIS must articulate its food safety goal in broad terms and adopt a food safety strategy that will work to achieve both a real reduction of pathogens in the near term and, in the long term, the fundamental changes in the inspection program that are needed to better protect public health.

FSIS Food Safety Goal

It is tempting to think of food safety as an absolute. In an ideal world, there would be no cases of foodborne illness. The world we live in is, however, far from ideal. The production of the food that feeds 250 million Americans every day is an enormously complex task. It is undertaken in a natural environment where hazards, including pathogenic microorganisms, are common. It requires a level of technological intervention—in the form of machinery, chemicals, and processing—that itself can introduce hazards. And it is an enterprise that depends, in the end, on a vast array of human interventions and activities, which means that human error is a constant factor that can contribute to food safety hazards.

FSIS believes the public can understand that safety is not an absolute, and the laws FSIS administers do not speak in absolute terms. FSIS also believes, however, that public expectations are justifiably high when it comes to measures the food production system should take to reduce risk and ensure the safety of food. Furthermore, the laws FSIS administers set high standards—for example, meat and poultry products are deemed ''adulterated'' and thus unlawful if they are for any reason ''unhealthful''—and they empower FSIS to take actions needed to meet those standards and meet the public's high expectations concerning the safety of the food supply.

FSIS believes its food safety goal should be to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur.

There is no single technological or procedural solution to the problem of foodborne illness, and the Agency's food safety goal will not be achieved overnight. Indeed, inherent in the nature of the Agency's goal is the concept that food safety requires continuous efforts to improve how hazards are identified and prevented. It is based on the public health principle that, on a continuing basis, society should seek out and take preventive measures to reduce the risk of illness. It reflects the Agency's belief that steps that can be taken today to reduce the risk of foodborne illness should be taken today, but that steps judged adequate today may not be judged adequate tomorrow.

In the case of the major enteric pathogens that contaminate meat and poultry products during the slaughter process, FSIS believes that the risk of foodborne illness associated with these pathogens is largely avoidable and can be minimized by proper implementation of HACCP. This does not necessarily mean absolute elimination of such pathogens, but it does mean preventing and reducing contamination with these pathogenic microorganisms to a degree that very substantially reduces and minimizes the risk of foodborne illness.

Achieving this food safety goal requires long-term commitment and action by Government and industry. It also requires general agreement on a regulatory strategy that can achieve the goal.

FSIS Food Safety Regulatory Strategy

FSIS believes that to achieve its food safety goal, and bring about the change described above, a new regulatory strategy is needed. The major elements of the Agency's proposed strategy are outlined in this section, with a brief explanation of how the regulatory changes FSIS is proposing in this document will advance the strategy.

1. *FSIS must clearly define the minimum requirements all establishments must meet to produce safe meat and poultry products and make establishments readily accountable for meeting them.* Good sanitation and basic good manufacturing practices (GMP's) are generally regarded as essential prerequisites for the production of safe food. The current FSIS program includes sanitation regulations that set out certain standards of cleanliness establishments are required to meet; and the Agency has provided guidance, in the form of a Sanitation Handbook, on how sanitation requirements can be met. FSIS also has promulgated regulations that impose various specific requirements, especially regarding processing operations, that might be characterized as GMPs.

In the sanitation area, however, FSIS has not spelled out clearly the responsibility every establishment has to install procedures that ensure sanitation requirements are met every

day, both before operations commence and during operation. In the GMP area, certain important food safety-related practices that have emerged in recent years have become recognized by the majority of the industry as appropriate GMPs, but they have not been made part of the basic regulatory requirement all establishments must meet.

FSIS believes it is important, especially for the near term, to codify certain minimum practices all establishments must observe to produce safe meat and poultry products and to improve the Agency's ability to hold establishments accountable for following those practices. Thus, FSIS is proposing: (1) to require that all establishments develop and adopt standard operating procedures for their sanitation programs, (2) to require that all slaughter establishments incorporate at least one effective antimicrobial treatment to reduce the levels of microorganisms on carcasses before they enter the chilling step, and (3) to codify specific time and temperature requirements for cooling of carcasses post-slaughter.

The majority of meat and poultry establishments already observe some or all of the practices FSIS is proposing to require. They are basic to producing a safe product, and FSIS believes all establishments should observe them. By codifying these practices in the Agency's regulations, FSIS will have an effective means to hold all establishments accountable for meeting them. Codifying these basic requirements is by no means a complete or long-term solution to the food safety problem but rather is part of the Agency's effort to ensure, as more fundamental improvements are being developed, that readily available improvements are incorporated into the system in the near term. FSIS invites comment on whether elements of current GMP's should be mandated by the Agency.

2. *FSIS must stimulate improvement in food safety practices by setting public health-oriented targets, guidelines, or standards all establishments must meet.* This is the centerpiece of the FSIS food safety strategy and the most important departure from the Agency's current regulatory approach. In its past regulation of the slaughter process and of raw, ready-to-cook meat and poultry products, FSIS has not clearly defined what safety means or set public health targets, guidelines, or standards for reducing the incidence of contamination of these products with human pathogens (pathogens that cause illness in humans). Consequently, there has been no basis for evaluating from an objective, public health standpoint whether the measures establishments have taken to prevent harmful contamination are adequate or should be deemed acceptable. FSIS has instead focused on managing its current system of visual inspection and encouraging industry efforts to reduce pathogens, but without an effective tool for requiring or evaluating those efforts.

FSIS believes that setting public health targets, guidelines, or standards is the most powerful and effective tool available for bringing about changes in FSIS-inspected establishments, especially slaughter establishments, that will reduce levels of pathogenic microorganisms and improve the safety of meat and poultry products. The concept is simply that, by establishing targets, guidelines, or standards establishments are required to meet, FSIS can stimulate the innovation and change needed to reduce risk from all sources of foodborne hazards—whether biological, chemical, or physical—and, at the same time, have a tool for holding all establishments accountable for achieving an acceptable level of food safety performance.

FSIS realizes that this new approach raises some new and difficult scientific and policy issues and thus may be controversial in some quarters. The most important issues concern the basis upon which the targets, guidelines, or standards (hereafter referred to generally as ''microbial limits'') will be set and the consequences for an establishment that does not meet them.

There are many possible approaches for setting and using microbial limits. One approach is to set specific quantitative limits for each significant pathogenic microorganism on the basis of a scientific risk assessment, and to use this limit as the basis for excluding from commerce any raw product that exceeds the limit. This is the approach typically taken in the regulation of food additives, chemical contaminants, and physical defects, and provides the most direct and perhaps most effective means of ensuring that standards necessary to protect public health are being met. One difficulty with this approach to pathogenic microorganisms is that the scientific data and understanding concerning the link between specific levels of many pathogens and the risk of foodborne illness that would be needed to set such limits based solely on considerations of public health are not currently available. A second, perhaps more significant difficulty is the fact that the levels of additives and other chemicals generally remain stable, whereas levels of microorganisms can change over time, due to growth and destruction. As explained in a later section of this document, FSIS intends to work with the scientific and public health communities to develop the scientific basis for setting quantitative limits for specific pathogens.

Another approach to pathogen reduction is to set targets for reduction based on what is judged achievable with available science and technology, and to require individual establishments to meet such targets on a consistent basis, by adoption of appropriate process controls. Even with this approach, there are difficult issues concerning the basis upon which such targets should be set. FSIS believes, however, that enough is known today and can be learned during the course of this rulemaking to make this approach viable and very useful in the near term.

Later in this document, FSIS is proposing to set interim targets for pathogen reduction, using as the starting point the current baseline incidence of *Salmonella* contamination of finished carcasses in all raw meat and poultry slaughter operations and in raw ground meat or poultry products, and requiring reductions in *Salmonella* in relation to the current baseline. FSIS believes that significant reductions in the incidence of contamination with this human pathogen are achievable in the relatively near term, and that the process improvements some establishments will have to make to reach the goal will also reduce the levels of other pathogens.

Key to the FSIS strategy for using public health-based microbial limits to reduce pathogens is the recognition that what is scientifically supportable and appropriate will evolve over time. FSIS believes the interim step it is proposing in this new area to target and reduce the incidence of *Salmonella* is feasible and can be effective in the near term, but it is just a first step. As knowledge and methodologies improve, additional pathogens could be targeted, targets could be lowered, and the use of the targets could expand eventually to include their use in some cases as legal standards for products.

FSIS will be working closely in the coming years with the scientific and public health communities, the industry, and public interest groups to consider how microbial limits can best be used to reduce the risk of foodborne illness. Later in this document, FSIS discusses some of the difficult scientific issues that need to be resolved to make the fullest use of microbial limits.

3. *FSIS must make meat and poultry establishments responsible for microbial testing of their products to ensure proper process control and verify achievement of microbial limits.* To

reduce pathogens and protect public health, FSIS believes that microbial testing must become an integral part of the operation of every meat and poultry establishment and that the primary responsibility for testing should rest with the establishment, not FSIS. Over the long term, microbial testing will play a key role in verifying the successful implementation of an establishment's HACCP plan. FSIS also believes that establishments should be responsible for testing their products to verify achievement of any microbial limits that FSIS establishes for regulatory purposes. Later in this document, FSIS is proposing to require daily microbial testing to determine whether, over time, the proposed interim targets for pathogen reduction are being met in all establishments that have slaughter operations or produce raw ground meat or poultry products.

4. *FSIS must foster scientific and technological innovation within the meat and poultry industries to reduce pathogens and the risk of foodborne illness and must remove any unnecessary regulatory obstacles to innovation.* In the past, innovation in the meat and poultry industries has been directed primarily to developing new products and increasing productivity. This innovation has been beneficial because it has responded to consumer demand and need for a diverse, convenient, and economical food supply. One of the principle advantages of holding establishments accountable for meeting public health-driven microbial limits is to provide an incentive for establishments to innovate as they reduce the risk of foodborne illness.

FSIS believes that scientific and technological innovation in the meat and poultry industry will play a key role in meeting the Agency's food safety goal. FSIS will, therefore, be reviewing its current procedures for evaluating and approving new pathogen reduction technologies for use in meat and poultry establishments, and is committed to modifying or eliminating any procedures or requirements that stand as unnecessary obstacles to the prompt implementation by industry of innovations that can reduce the risk of foodborne illness. FSIS invites public comment on how FSIS can improve its program to facilitate beneficial innovation.

5. *FSIS must build the principle of prevention into the operations of meat and poultry establishments and into the FSIS inspection program.* As discussed earlier in this document, food safety can be ensured most effectively and economically by installing systems that prevent problems from occurring rather than relying on end product testing or government inspection to detect and correct problems after they occur. There is wide agreement on this among government and industry officials, consumers and the scientific community. FSIS is proposing to build the principle of prevention into the inspection system by requiring that all meat and poultry establishments adopt and operate under HACCP systems.

6. *FSIS must approach its food safety mission broadly, and address potential hazards that arise throughout the food production and delivery system, including before animals enter FSIS-inspected establishments and after meat and poultry products leave those establishments.* There is wide agreement that ensuring food safety requires taking steps throughout the chain of production, processing, distribution, and sale to prevent hazards and reduce the risk of foodborne illness. Although not the subject of this document, FSIS will work with producers and others to develop and implement ''preharvest'' food safety measures—measures that can be taken on the farm to reduce the risk of harmful contamination of meat and poultry products.

FSIS is also announcing in this document initiatives it plans to undertake in cooperation with the Food and Drug Administration to develop Federal standards that will help ensure the safe handling of meat and poultry products during transportation from FSIS-inspected establishments to the retail level. FSIS and FDA will also work together to encourage adoption and enforcement by State governments of consistent, science-based standards at the retail level.

FSIS believes that its food safety goal can be achieved and legitimate public expectations met only by building a chain of responsibility for food safety, extending all the way from the farm to the consumer.

In the next part of this document, FSIS proposes a set of regulatory changes that it believes will advance the Agency's food safety regulatory strategy.

II. Discussion of Regulatory Proposals

Overview

Because the safety of any meat or poultry product can be positively or adversely affected at virtually every step in the manufacturing process, FSIS is proposing the series of regulatory changes discussed in this section. Collectively, these changes would reduce the incidence of pathogenic microorganisms on meat and poultry products, not only by reducing their numbers at critical points during processing, but also by denying those pathogens that are present the opportunity to grow.

As independent measures, standard operating procedures for sanitation, antimicrobial treatments, and time and temperature requirements for chilling and cooling finished carcasses and parts could have only limited impact on food safety. Together, they can make a significant contribution to reducing pathogenic microorganisms and other contaminants throughout the manufacturing process. These measures are a precursor to HACCP, which ensures process control through carefully selected critical control points. The above-listed measures, discussed at length in II A, have in fact been implemented in many establishments, including many now operating under HACCP systems. By effecting immediate pathogen reduction in meat and poultry products during the period of transition to HACCP, these interdependent measures would address urgent public health needs. Additionally, implementing these measures would introduce into non-HACCP establishments the concept and actuality of process control, which is the essence of HACCP. Each proposed measure can be reasonably expected to constitute a critical control point under most HACCP plans so, while the proposed regulatory provisions may no longer need to be mandated upon implementation of HACCP, establishments would likely retain them as critical elements of process control.

The second component of this three-part regulatory package, the microbiological testing program (discussed under II B), would also be implemented during the transition to HACCP. It, too, is integral to the regulatory strategy, because microbial testing will establish a tangible, achievable, measurable target: a reduction in the incidence of *Salmonella* in raw product. As with the near-term interventions discussed above, the microbial testing program would effect pathogen reduction almost immediately upon implementation. As is the case with the near-term interventions, microbial testing can be expected to constitute an element of process control under HACCP.

The third component of this three-part regulatory package is HACCP (discussed under III C). As indicated earlier, the interim measures which, as proposed, would be implemented during the transition to HACCP would likely continue under HACCP as elements of process control, selected on

the basis of each establishment's hazard analysis.

The proposed sanitation SOP's, antimicrobial treatment, cooling, and microbial testing requirements are compatible with and establish important parts of the foundation for establishments' subsequent adoption of HACCP procedures. It is expected that HACCP controls will give establishments the flexibility to meet the objectives reflected in FSIS's existing requirements for meat and poultry products. Once HACCP systems are integrated fully into all establishments, many existing regulations may be redundant. Anticipating the implementation of HACCP proposed in this document, FSIS has initiated a review of existing regulations, with the intention of removing those no longer needed, as well as of ensuring that regulations that remain are sufficiently flexible to be HACCP-compatible. FSIS invites comment on which regulations should be eliminated or modified. Even now, it may be possible to identify means to achieving prescribed regulatory ends that are as effective as the means set forth in current regulations—that are, in other words, ''equivalent'' to provisions set forth in regulations. FSIS invites comment on specific regulations for which such performance standards might be appropriate, either immediately or upon implementation of HACCP.

A. Transition to HACCP

The following is a discussion of regulations being proposed which, together, are intended to reduce significantly the level and frequency of consumers' exposure to foodborne illness associated with pathogenic microorganisms and other biological, chemical, and physical hazards in meat and poultry products.

The transitional regulations proposed in this document would be made effective 90 days after publication of the final rule (near-term initiatives). The proposed HACCP requirements would be implemented in phases during the three years following the publication of the final rule. As noted above, the near-term initiatives are designed to reduce the level and frequency of consumers' exposure to pathogenic microorganisms now, pending the more comprehensive controls that will be in place in each establishment under the proposed HACCP regulations.

The proposed regulations, roughly in order of their sequence in slaughter and processing operations, are as follows:

- A requirement that all federally inspected establishments develop and adhere to written standard operating procedures (SOP's) specifically relating to direct contamination or adulteration of product;
- A requirement that slaughter establishments use an antimicrobial treatment on all carcasses;
- A requirement to meet specific time requirements for chilling and cooling of all finished carcasses and parts;
- A requirement that certain raw product be tested for *Salmonella,* a representative pathogen, and that establishments achieve targeted reductions in the incidence of *Salmonella,* in relation to the current national baseline incidence, in 2 years (discussed under II B, below);
- A requirement that all establishments adopt HACCP systems (discussed under II C, below).

FSIS intends to proceed to final rulemaking on the specific changes proposed in this document as soon as possible. After comments are reviewed and analyzed, if it is determined that some portions of this proposal can be made into final rules sooner than others after the close of the comment period, they will be separated from the other portions so as to not delay regulatory action on this important public health matter.

These proposals reflect ideas and suggestions generated from many people and organizations. Recent events have prompted a beneficial, ongoing dialogue between FSIS and consumer organizations, trade associations, and other Government agencies, among others, as well as among FSIS employees and their bargaining representatives, on what regulatory changes the Agency should undertake. FSIS values and relies greatly on the input from all these sources, and intends to continue this dialogue throughout this rulemaking and in its future regulatory activities.

1. Sanitation Standard Operating Procedures (SOP's)

Need for SOP's

Proper sanitation is an important and integral part of every food process and a fundamental requirement under the law. Insanitary facilities and equipment, and poor food handling and personal hygiene practices among employees create an environment in which pathogens can flourish. The law is quite clear: product produced or held under insanitary conditions is deemed adulterated, without any further showing required by the Government. FSIS inspectors are expressly charged with ensuring that product inspected and passed was in fact produced under sanitary conditions.

FSIS recognizes that current sanitation practices and performances vary widely among the diverse array of plants FSIS regulates. Well-run meat and poultry establishments have tight quality control and sanitation programs, including written sanitation SOP's, premised in large part on the direct and substantial link between the existence of insanitary conditions during production of meat and poultry products and the likelihood that bacteria—including pathogenic bacteria—will contaminate the finished product. Some establishments, however, do not have adequate programs and do not consistently maintain good sanitation. FSIS is nearing completion of its project to conduct unannounced reviews of 1,000 federally inspected meat and poultry establishments. The findings, based on 551 reviews so far, show that 60 percent (820) of 1,340 serious deficiencies were found in sanitation. Poor sanitation is the most frequently observed problem in meat and poultry establishments.

FSIS is proposing to require that all inspected establishments develop written sanitation SOP's to prevent direct contamination or adulteration of product before and during operations. Establishments would be required to maintain daily records to document adherence to the SOP's. The proposed sanitation SOP's would be compatible with the proposed HACCP requirement. Like HACCP, the sanitation SOP's reflect a commitment by establishment management to consistently control operations in the interests of public health. The SOP's demonstrate that establishment owners know their operations and how to keep the facilities and equipment clean. FSIS encourages both innovation and self-reliance in the achievement of good sanitation in all inspected establishments.

Self-reliance is important because identification of sanitation requirements has been viewed by some establishment owners and personnel as the inspector's responsibility. Such establishments often fail to take the initiative to find and remedy insanitary conditions, relying instead on the inspector to find deficiencies.

Mandatory sanitation SOP's are intended to clarify that sanitation is industry's responsibility, not the inspector's. The sanitation SOP's reflect the establishment's commitment to accomplish those activities consistently, independent of the inspector.

Written SOP's would make it easier for FSIS inspectors to perform their proper role of verifying that establishment management is conducting its operations in a sanitary

environment and manner. Failure to adhere to the ''core elements'' of an SOP (the proposed regulatory requirements) would be presumptive evidence of insanitation and enforcement action, where necessary, would be taken. As is now the case, inspectors will not permit an establishment to operate under insanitary conditions. Falsification of records designed to document daily sanitation activities would, in addition to indicating insanitation, be treated as a criminal act subject to prosecution.

As a more efficient tool for ensuring that establishments are carrying out their sanitation responsibilities, sanitation SOP's can provide the basis for improved utilization of FSIS inspectional resources. Sanitation SOP's thus support the transition to HACCP because, under HACCP, FSIS inspectors will be called upon to perform a number of additional safety-related inspectional tasks to verify that HACCP plans are working properly. If less time can be spent ensuring that basic sanitation requirements are being met, more time will be available for these new tasks.

Some plants already have SOP's, take their sanitation responsibilities seriously, and require a relatively modest investment of inspector time to ensure sanitation requirements are met. Other plants do not consistently perform well in the sanitation area and frequently require a substantial investment of inspector time to ensure basic sanitation compliance before daily operations begin.

In plants where procedural requirements are consistently followed and inspectional observations verify that good sanitation is being consistently achieved, FSIS expects that sanitation SOP's will provide the basis for adjusting the manner and frequency of FSIS preoperational sanitation inspection.

FSIS invites comment on the role sanitation SOP's should play in allocating responsibility between establishment employees and FSIS inspectors for preoperational sanitation, including the role FSIS employees should play in authorizing daily startup of operations.

Content of SOP's

Sanitation SOP's would, at a minimum, detail procedures the establishment will conduct to prevent direct contamination or adulteration of product before and during operations. Such procedures would constitute the required, core elements of an SOP. The SOP's would also identify establishment personnel responsible for evaluating the conduct and effectiveness of the sanitation SOP's, and for making corrections when needed. FSIS encourages establishments to incorporate additional sanitation procedures that provide increased assurance that insanitary conditions will be prevented.

Each establishment would maintain a daily record of the actions prescribed in the SOP, and make such records available to Program employees for inspection audit and verification. Records would, at a minimum, record deviations from the core elements of the SOP (the proposed regulatory requirements), along with corrective actions taken in conjunction with the monitoring of daily sanitation activities. Production could not start until the core elements of the sanitation SOP's that are applicable to preoperational sanitation have been completed.

The daily monitoring of the sanitation program by the establishment representative could include microbiological tests, routine organoleptic inspection of areas and equipment, and direct observation of sanitation procedures while being performed by designated employees.

FSIS will provide guidance materials, including examples, on development of sanitation SOP's prior to the implementation of this requirement.

The following are specific practices relating to sanitation that might be included in an SOP:

- Preoperational microbiological testing: Tests for verifying the efficacy of cleaning, sanitizing, and disinfecting procedures. Many establishments also currently perform preoperational microbiological testing for quality control purposes. The technology for preoperational sanitation microbiological testing is readily available and easy to use.
- Disinfection of equipment prior to startup: Some data exist to indicate that equipment should be sanitized immediately prior to the startup of operations.
- Use of an automated hand washer with approved sanitizing solution effective for up to six hours. This has been proven to be an important sanitary practice.
- Handwashing between each carcass in skinning and evisceration operation.
- Cleaning cattle prior to slaughter: Washing and drying, clipping, dehairing, and any other acceptable method to remove dirt, fecal matter and other potential sources of contamination from the exterior of animals before the edible portions of the carcasses are exposed. The hides of animals are a known source of carcass contamination. Feedlot cattle in general and most bovines during the winter and ''mud season'' carry heavy loads of mud, fecal material and bacterial contamination on the hide. Sanitary removal of the hide under these conditions is very difficult. One method to control this source of contamination is washing animals prior to slaughter. Another possibility is clipping the hair over the areas where opening cuts will be made and sanitizing the hide prior to cutting. Yet another procedure being tested is the complete removal of hair from the hide using a chemical hair remover (depilatory).

The Agency has been asked to consider making mandatory certain GMP's for sanitary slaughter by, among others, the American Meat Institute. The Agency is requesting comments on whether GMP's or other sanitation practices should be made mandatory elements of the sanitation SOP.

The adoption of HACCP systems by establishments would not replace the need for establishments to maintain sanitation SOP's. The proposed HACCP regulations require sanitation SOP's as a prerequisite to a HACCP plan. Sanitation activities that directly affect the control of a processing hazard would be determined according to the criteria discussed in the HACCP portion of this document, and would, where appropriate, be identified as critical control points in individual HACCP plans. Sanitation activities not identified as critical control points under HACCP should remain in the sanitation SOP's. Any SOP requirement incorporated into a HACCP plan could be removed from the SOP's for sanitation.

2. Antimicrobial Treatments

This proposed rulemaking would require, for the first time, that slaughtering establishments apply antimicrobial treatments or interventions to livestock and poultry carcasses. Under the proposal, any one or more of the treatments would have to be applied prior to the chilling or cooling operation. Mandating antimicrobial treatments is a new approach for FSIS. It reflects the judgment that, at least until significant progress is made in reducing or eliminating the presence of pathogenic microorganisms in livestock and poultry at the preharvest stage and in sanitary dressing techniques and practices, some amount of contamination of beef and poultry carcasses with pathogenic microorganisms is likely to occur—even in establishments that attempt to follow the best current practices. To reduce the food safety hazard posed by such pathogens, establishments should be

required to take affirmative measures to reduce or eliminate contamination.

One concern regarding the use of antimicrobial treatments is that such treatments will be relied on as a substitute for careful sanitary dressing techniques which provide the best opportunity to prevent contamination from occurring in the establishment. Other concerns are that some treatments are ineffective at least for certain organisms, and certain treatments, such as carcass washes or soaks, might make matters worse by spreading contamination and can cause economic adulteration.

FSIS agrees that antimicrobial treatments must not be allowed to substitute for careful sanitary dressing procedures, and that any interventions must be effective and not result in economic adulteration. FSIS also agrees that no one treatment will be effective for all pathogens of possible public health concern. FSIS believes that the best way to prevent harmful contamination of meat and poultry products is by adopting multiple approaches throughout production, slaughter, and processing that will contribute to preventing or reducing the likelihood and degree of microbial contamination, especially by pathogens.

FSIS believes that mandating at least one antimicrobial treatment prior to the chilling process is an integral part—but only one part—of the strategy for reducing pathogens on meat and poultry proposed in this document. Product not properly treated with at least one antimicrobial treatment would be retained; the Inspector in Charge would determine its disposition. FSIS invites public comment on this approach, as well as on the issues raised in the discussion below concerning what treatments are effective and appropriate.

Past and Current Agency Policy

Despite establishment's best efforts to reduce or eliminate contamination during slaughter and dressing procedures, livestock and poultry carcasses still may harbor pathogenic microorganisms. The sources of these organisms, most of which are associated with the living livestock and poultry, are not fully understood, and fully effective preharvest preventive measures, while under study, are not currently available. Thus, introduction of pathogenic microorganisms into establishments along with the animals cannot be absolutely prevented at this time. The use of the best slaughter and sanitary dressing procedures and technologies can reduce the likelihood that product will be contaminated by these invisible pathogens, but they cannot guarantee the absence of pathogenic bacteria on raw meat or poultry product.

FSIS recognizes that the technologies now available for reducing bacterial contamination on raw carcasses are limited. Indeed, the inspection regulations currently have no listings for antimicrobial agents as such. However, FSIS has over the years permitted a number of such treatments to be used in inspected establishments on a case-by-case basis, and is proposing to include some of these in the regulations through this rulemaking. Some currently available treatment methods are described below.

New antimicrobial procedures, including variations on those listed below, will be approved for use by FSIS to meet the proposed requirement for an antimicrobial treatment, provided data are submitted demonstrating they are safe and effective for that purpose. Current interventions generally provide at least a one order of magnitude (i.e., a 90-percent) reduction in the numbers of bacteria of concern on treated carcasses.

Antimicrobial treatments are interventions that decrease microorganisms present on the surfaces of meat and poultry carcasses. Antimicrobial treatments are not designed to compensate for sloppy sanitary dressing procedures on the slaughter floor, and under this proposal, will not be permitted to be used for that purpose.

Thus, the proposed use of antimicrobial treatments does not imply a change in current FSIS policy regarding removal of physical contaminants from meat and poultry carcasses. Fecal, ingesta, or milk contamination on cattle carcasses must be removed by trimming. Wash/trim studies are underway to determine the best way to remove these visible contaminants. Public comment and discussion, including peer review, of the data from these studies will be solicited and reviewed as part of the Agency's evaluation and decisionmaking process on this issue.

FSIS policy concerning visible contaminants on poultry continues to require carcasses to be free of fecal contamination before entering the chillers. The process control program set forth in the current regulations provides Finished Product Standards (FPS) for poultry where feces are one of the ''nonconformances'' that are summed with other nonconformances to determine compliance with the standard (9 CFR 381.76). This is only a measure of the presence of this nonconformance, not a tolerance. Finished poultry carcasses are subject to the same requirements as are finished livestock carcasses, with no visible fecal matter permitted. Because of confusion on this point, FSIS is proposing to remove feces from the FPS for poultry to make clear the current policy that there is no tolerance for feces.

The Agency's proposal to codify the zero tolerance policy for fecal contamination was one of a number of recently proposed changes to its poultry inspection regulations, designed primarily to address concerns about pathogens (July 13, 1994, 59 FR 35639). The proposal drew more than 400 comments. Although many critical comments were received, a great majority of the comments on point supported the use of antimicrobial treatments and removal of feces from the Finished Product Standards. Because these two elements of the July 13 proposal are incorporated in this proposal, comments are again being solicited. This does not, however, preclude completion of the July rulemaking on these two issues and the issuance of final rules based on that proposal.

One part of the July proposal that was criticized in the comments is the requirement that the antimicrobial treatment be limited to application prior to the chilling or cooling system. Some commenters indicated that certain antimicrobial treatments for use in the chilling or cooling systems are more effective than treatments applied before this point. Additionally, some held that certain post-chill treatments, such as irradiation, may provide a more effective treatment option. FSIS's intent was, and is, that poultry entering chill tanks be as clean as possible. However, FSIS invites comments on whether mandated antimicrobial treatments should be restricted to pre-chill application, as proposed above.

Irradiation is another issue related to this proposal on antimicrobial treatments. Irradiation is statutorily defined as a ''food additive'' under the Federal Food, Drug, and Cosmetic Act (FFDCA) and thus its safety is evaluated by FDA, which must approve its use as a food additive in a regulation specifying safe and lawful conditions of use. FDA has approved irradiation for use in controlling foodborne pathogens on uncooked poultry (21 CFR 179.26), and FSIS has promulgated regulations under the PPIA specifying inspection requirements for establishments using that process (9 CFR 181.149). FDA currently is considering a petition to permit use of irradiation to control pathogens on uncooked meat. Irradiation is not being considered an

antimicrobial treatment for purposes of this proposal because irradiation facilities are to date extrinsic, stand-alone operations that cannot easily be integrated into a slaughter operation—the focus of the present effort. Furthermore, although irradiation has been shown to be a highly effective pathogen control mechanism, it is a capital-intensive process largely unavailable to most inspected slaughter establishments. Notwithstanding these considerations, firms would be able to use irradiation on raw poultry under existing regulations, in addition to the antimicrobial treatments now being proposed.

Approved Antimicrobial Treatments

A number of methods for reducing the number of bacteria that may be on carcasses have been suggested, e.g., exposing the carcass to hot water, chemical sanitizers, such as chlorine or trisodium phosphate (TSP), and short chain food grade acids, such as lactic, acetic, and citric acids.

Antimicrobial treatments currently permitted by FSIS are techniques involving the rinsing of carcasses with a wash or spray, normally using either hot water or a solution of water and a substance approved by FSIS for that use on the basis that it has been found to be effective and its use is consistent with applicable FDA regulations governing food additives. Some mechanical process modifications currently in use have been shown to enhance the results of rinsing procedures. Countercurrent scald tanks with a postscale spray have been shown to be effective in reducing bacterial levels on poultry carcasses.

Equipment and utensils used in preparing or handling meat and poultry products in inspected establishments are subject to inspection to ensure that their use will not result in adulteration or misbranding of the finished product. To promote efficiency and uniformity in this element of FSIS's inspection duties, FSIS reviews newly developed equipment and utensils intended for use in inspected establishments and publishes a listing of equipment and utensils found to be acceptable for that use (9 CFR 380.5, 381.53). Establishments and other manufacturers of mechanical devices designed for antimicrobial treatments, such as scalding tanks and spray cabinets and devices, must obtain approval of their equipment from the Facilities, Equipment and Sanitation Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington DC 20250. A copy of the current list of approved equipment and utensils also is available from that office.

The use of an antimicrobial treatment on raw meat and poultry carcasses would reduce the levels of bacteria on the product, but it would not eliminate the need for continued careful handling of those products before and after the antimicrobial treatment. The following are available antimicrobial treatments that FSIS tentatively concludes could satisfy its proposed requirements for a mandatory antimicrobial treatment. FSIS invites comment on each of these.

(a) *Hot water.* Hot potable water or steam may be used to reduce microbiological counts on meat and poultry. Washing carcasses with hot water has been shown to be effective in reducing the level of bacteria on carcass surfaces.

The decontamination of carcasses using hot water has a number of advantages. These include: (1) reliable reduction of contaminants, (2) removal of loose extraneous material, (3) no impairment of meat properties, (4) no chemical reaction with equipment, such as the corrosive effects associated with acetic acid, (5) no disposal problems, and (6) readily available and easily accomplished.

Disadvantages with hot water sprays include: (1) the need for greater pumping pressures, (2) less recoverable heat energy from the outlet water steam, (3) the likelihood of nozzle blockage if water is recirculated, and (4) the production of mist which condenses on surfaces in the vicinity of the cabinet if baffles are not used.

Scientific studies over the course of the past twenty years have investigated whether the use of hot water (74°–95°C, 165°–201°F) instead of the commonly used lower water temperatures (30°–35°C, 85°–95°F) can reduce the general microflora of aerobic mesophiles present on the carcass, including members of the family Enterobacteriaceae. This taxonomic group includes some of the most important foodborne pathogens. Hot water rinses have been shown to be effective against a number of foodborne pathogens including *Escherichia coli* O157:H7, *Salmonella, Yersinia enterocolitica,* and *Listeria monocytogenes.* Quantitative studies assessing the impact of hot water treatment on the survival of *E. coli* O157:H7 have suggested that it can reduce the levels present on the carcasses by 84–99.9 percent, as well as the number of contaminated carcasses. Other studies with *E. coli* biotype 1 (*E. coli* O157:H7 is one of hundreds of *E. coli* serovars) have indicated that hot water can reduce levels by 99–99.9 percent.

The effects of hot water washing are dependent on two separate mechanisms. The first is simply the physical washing action of the rinsing. This can account for a significant portion of the overall effect, particularly if the bacteria are only loosely attached to the carcass surface. In addition, the thermal effects of the elevated temperatures produce some degree of heat inactivation. As with any thermal processing, the extent of the inactivation will be directly proportional to both the duration and temperature of the heating material (i.e., water temperature). A hot water rinse can achieve up to a 99.9 percent (3 log) decrease in the levels of various pathogenic and non-pathogenic bacteria. It potentially can achieve up to a 99.9 percent reduction in *E. coli* O157:H7.

Hot water sprays are most effective when applied in a manner that raises the water film on the surface of the carcass (surface temperature of the carcass) to 82°C (180°F) for 10 seconds. Exposure of beef carcasses to 80°C (176°F) water results in a greying of the meat surfaces; however, the color returns to its normal appearance after chilling. When the carcass surface is exposed to 82°C (180°F) for more than 20 seconds, tissue discoloration becomes permanent.

Researchers have tested the effectiveness of hot water using sprays or dips and using decontamination cabinets, with hot water only and with chemical sanitizers.

One study found that treating beef carcasses with a steam and hot water spray at 176°F–205°F (80°C–96°C) for 2 minutes, sprayed from one foot (25 cm.), lowered bacterial numbers. A volume of 18.9 liters of water was sprayed for each carcass. Some discoloration of the carcass surface occurred initially, but normal color returned after cooling for 24 hours.

Another study found a hot water treatment of beef and mutton samples inoculated with *E. coli* more effective in reducing bacterial numbers than a naked flame, steam chamber, steam ejection, or washing with water at 37°C (99°F). When hot water temperatures were below 60°C (140°F), no significant color change was noted. Above 85°C (185°F), the color change was marked and permanent. Permanent color changes of the surface tissues caused by using water at 95°C (203°F) for three minutes did not extend more than about 0.5 mm below the surface. Temperatures of 70°C (158°F) and above gave at least a two log (99 percent) reduction of inoculated *E. coli* on samples.

The hot water spray cabinet used on lamb carcasses had water leaving the nozzles at 95°C, but the temperature of the water reaching the carcass could not be raised above 74°C (165°F). They were able to obtain a 99 percent decrease in inoculated *E. coli* at all sites when sheep carcasses were immersed in 80°C (176°F) water for 10 seconds. Immersion for 30 seconds gave little extra kill of inoculated bacteria. In-plant immersion tests on carcasses that had not been inoculated showed a 98 percent reduction in bacterial numbers.

Researchers have found that pouring hot water at 169°F (77°C) on beef (tissue slices) and mutton (carcass) samples for 10 seconds destroyed more than 99 percent of *E. coli* and *Salmonella* inoculated ($10^{6.5}$/cm²) onto the samples. Tissues surfaces were not permanently discolored. When beef slices (2.5 cm thick) swabbed with bacterial culture were exposed to hot water (60°, 65°, 70°, 80°, 90°C) for intervals of 10, 30, 60, and 120 seconds, it was found that the time of exposure was not a factor, but a progressive decrease in *E. coli* counts from $>10^1$ at 60°C to $>10^4$ at 90°C was noted. Coliform and aerobic mesophilic bacteria counts on six naturally contaminated sheep carcasses were reduced from 100 cells/cm² to below detectable limits and 8,500 to 310 cells/cm² respectively.

A 1979 study applied cold water (16°C, 60°F)(<14 kg/cm²), hot water 76°C–80°C [168°C–176°F])(14 kg/cm²), and steam (95°C) to previously frozen beef plate strips. Treatment with cold water alone reduced the counts by about one log. Steam alone only reduced the count by 0.06 log. Initial reduction in counts by hot water alone was 2.0 log. Samples held at 3.3°C were cultured for several days after treatment. After an initial lag phase of less than a day for samples treated with cold water or steam, the rates of bacterial growth were greater on the treated samples than on untreated controls. By the fifth day the aerobic plate counts for steam and cold water treated samples exceeded the aerobic plate count on the control samples. Presumably this was due to the greater surface moisture from the treatment. The rate of bacterial growth on samples treated with hot water was similar to that on controls, but the initial 2-log difference was maintained through 12 days of storage resulting in nearly 5 additional days for counts to reach 10^8/cm².

A 1981 study reported that lamb carcasses sprayed with hot water at temperatures >169°F (77°C) caused significant decreases (1.0 $\log_{10}$/cm²) in APC. As temperature was increased the reduction in bacterial numbers observed by spray washing was increased.

Another researcher used a deluge method instead of conventional pressure spraying. Advantages cited include: construction simplicity, cheaper running cost, and greater reduction in bacteria. However, unlike spray decontamination, coverage of the abdominal and thoracic cavities was only about 65 percent. He found a significant (<0.05) linear relation between the log reduction in inoculated *E. coli* and average water film temperature which varied with exposure time immediately after treatment. Longer exposure (20 sec vs 10 sec) produced significantly greater reduction at higher temperatures (44.5°, 66.0°, 74.2°, 83.5°C). There was no significant growth of *E. coli* between 24 and 48 hours, which is consistent with the findings of several other researchers. After chilling for 48 hours, sides exposed to 83.5°C had a slight and apparently permanent bleaching of the fat and meat tissue in the area of the upper thoracic cavity.

In a 1993 study, carcasses were sprayed with 2 liters of hot (95°C) water for 40 seconds with the intent of raising the meat surface temperature to 82°C for 10 seconds before final wash and after final wash. The apparatus was designed to raise the temperature within 30 seconds and maintain it at 82°C for 10 seconds. Culture samples taken from hot water-treated carcasses before final wash had a mean $\log_{10}$/cm² of 1.1 while controls had $\log_{10}$/cm² of 2.4. Culture samples taken from hot water-treated carcasses after the final wash had a mean $\log_{10}$/cm² of 1.5 while controls had $\log_{10}$/cm² of 2.3. It was unclear why a greater reduction in bacterial numbers occurred when carcasses were sprayed with hot water before the final carcass rinse. A 15–20 minute elapsed time between hot water and final wash may have allowed more bacterial attachment to take place. The volume of the spray and the size of droplets were found to have a profound effect on the temperature of the water contacting the carcass surface.

In view of this research, FSIS is proposing that hot water treatments used to meet the intent of this regulation be applied such that the temperature of the water at the surface of the carcass is ≥ 165°F (≥ 74°C) for ≥ 10 seconds. If applied by a spray, this is likely to require that the water be heated to a somewhat higher temperature. The hot water would have to contact all carcass surfaces. Other combinations of time and temperature of hot water also may be effective. FSIS would like comments on this point.

FSIS considers the final beef carcass wash to be an appropriate point at which to apply hot water as an antimicrobial treatment. The final carcass wash occurs at the end of the slaughter and dressing process, after trimming and FSIS postmortem inspection is completed. The final carcass wash is usually the last step in the dressing process before the carcass enters the cooler for chilling. The final carcass wash removes blood, bone dust, hair, dirt, and other accidental contamination. On November 1, 1994, FSIS announced that hot water rinses will be allowed at the final beef carcass wash without prior approval. An establishment wishing to apply hot water to beef carcasses at the final wash no longer must obtain prior approval by FSIS. However, FSIS notes that a hot water wash used pre-evisceration might also meet the intent of this regulation and therefore has the potential advantage of removing/destroying bacteria before they have had time to become tightly attached to carcass tissues. FSIS invites comments on whether the use of hot water wash to satisfy the proposed requirement of an antimicrobial treatment should be limited to the final carcass wash or should be permitted at other stages of the slaughter and dressing process.

A list of studies on various methods of applying hot water to meat and poultry carcasses is on file in the FSIS Docket Clerk's office, and is available from the Director, Slaughter Inspection Standards and Procedures Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250. FSIS welcomes additional data on the effectiveness of hot water as an antimicrobial treatment, especially regarding the effectiveness of varying temperatures and times of exposure.

(b) *Lactic, acetic, and citric acid solution sprays.*

Lactic, acetic and citric acids are weak acids that have long been consumed by humans in a variety of foods. They occur naturally (e.g., citric acid in limes), have been added in the processing of a broad variety of foods (e.g. acetic acid in mayonnaise), and develop in the fermentation of foods (e.g., lactic acid in cheese).

FDA lists acetic acid as Generally Recognized As Safe (GRAS) as a direct food substance in 21 CFR 184.1005 if used at levels not exceeding current good manufacturing practice (CGMP). The acetic acid listing specifies that the CGMP results in a maximum level in meat of 0.6 percent as served. While the use of acetic acid on fresh meat was not reviewed by the Select Committee on GRAS Substances in reaching its

conclusion on the safety of food use of acetic acid, FDA believes that use of acetic acid as proposed in this rule will result in residual levels on product ''as served'' below the most restricted use levels specified in § 184.1005 for acetic acid (FDA November 29, 1982), 0.15 percent for ''all other food categories.''

Lactic acid is approved as GRAS at 21 CFR 184.1061 with no limitations other than good manufacturing practice. In addition, lactic acid is listed for use as an antimicrobial agent in foods, also at a level not to exceed good manufacturing practice.

Citric acid is listed for multiple purpose use in 21 CFR 182.1033, when used in accordance with good manufacturing practices.

In addition, sections 318.7(c)(4) and 381.147(f)(4) of the regulations (9 CFR 318.7(c)(4) and 381.147(f)(4)) currently allow the use of acetic, lactic, and citric acids as acceptable ingredients in various meat and poultry products when used as acidifiers or as esterifiers in margarine. Citric acid may also be used as an anticoagulant, a flavoring agent, and a synergist at various levels in various meat and poultry food products. Citric acid is acceptable as a curing accelerator to speed up color fixing or preserve color during storage of cured pork and beef cuts and cured comminuted meat food products.

In 1990, FSIS determined that lactic, acetic and citric acids can be safely and effectively used as antimicrobial treatments on meat and poultry carcasses and by-products during slaughter and dressing procedures. That determination was based on an extensive review of the scientific literature on methods of reduction of bacteria on meat surfaces.

During the past twenty years the use of organic acid rinses to reduce spoilage and pathogenic microorganisms on foods has been studied extensively. Numerous researchers have demonstrated that organic acid rinses can produce a significant reduction in bacterial levels on the surfaces of meat and poultry. Although most of these studies have been conducted under laboratory conditions, there have been some studies that have specifically assessed the efficacy of these antimicrobial systems under production conditions. Also, some of the laboratory research has been conducted under simulated in-plant conditions.

The results achieved in the various research trials have not been unequivocal, in part because the effectiveness of the compounds is dependent on their interactions with a number of other factors. Some of the factors that have been identified include (1) pre- versus post-rigor tissue, (2) pre-washing prior to treatment, (3) tissue type, (4) method for acid delivery, (5) droplet size, (6) flow rate/pressure, (7) temperature, (8) pH, (9) contact time, (10) bacterial species, (11) type of acid, (12) buffering capacity, and (13) moisture content. Differences in study design, especially factors such as methods used to collect tissue samples and analyze for bacterial species or the preadaptation of bacterial cells to an acid environment, affect results. Interpretation of research results can also be confounded by difficulty in obtaining valid microbiological data because of large carcass to carcass variations, as well as differences in microflora associated with different slaughter facilities, carcasses, and sample sites on individual carcasses.

The literature suggests it is important to lower the pH of the meat surface if bacteria are to be controlled effectively by using an organic acid. Most organic acids are effective only at low pH values of pH 5.5. Apparently the anion exerts some effect on bacteria at pH values of pH 5.5. The pH affects the extent of dissociation. Undissociated weak acids are more effective than the dissociated form and dissociate to produce acidification of the cell interior.

Overall, the available scientific data indicate that washing of carcasses with organic rinses or sprays can achieve a 90–99.9 percent reduction in levels of spoilage bacteria (e.g., *Pseudomonas fluorescens*) though in some cases the reductions were not statistically significant and in others no improvement was noted. In addition, acid sprays and dips have also been shown to decrease the levels of specific pathogens, as well as the incidence of carcasses that are positive for specific pathogens. This includes activity against *Salmonella* spp., *Staphylococcus aureus, Campylobacter jejeuni, Yersina enterocolitica,* and *Listeria monocytogenes.* However, these techniques do not and cannot be expected to completely inactivate or eliminate pathogens.

One of the bacterial species that appears to be among the more resistant to the effects of organic acids is *E. coli* O157:H7. A number of investigators have found that O157:H7 has a relatively high acid tolerance. Again, the extent of inactivation achieved with *E. coli* O157:H7 has varied among the various studies. For example, one researcher found that *E. coli* O157:H7 reductions were similar to those observed for *Salmonella* spp. and *Listeria monocytogenes,* with up to a 99.9 percent reduction in the levels of all three bacteria from inoculated tissues and concluded that an acetic acid carcass sanitizer could be used as an effective method to control these bacterial pathogens. Conversely, another reported that up to 1.5 percent acid treatments did not appreciably reduce *E. coli* O157:H7, whether at 20° or 55°C and ''was of little value in disinfecting beef of *E. coli* O157.'' It has been reported that there are differences among *E. coli* O157:H7 isolates in relation to their acid tolerances. These investigators also found that inactivation was dependent on acid concentration (5 percent gave greatest reductions), and tissue type (reductions greater on adipose tissue than lean). Some investigators have suggested that lactic acid is more effective than acetic or citric acid against *E. coli.* It has been suggested that the primary determinants of effectiveness were the pH achieved at the surface of the carcass and the corresponding period of exposure.

Organic acids apparently are more effective when applied as soon after slaughter as feasible, and when they are at elevated temperatures (53°–55°C). The bacteria found on a carcass soon after slaughter are believed to be present in a water-film on the surface and, therefore, are relatively easy to remove, contrasted with bacteria that have become attached to the carcass surface itself by the time chilling is complete and are therefore more difficult to remove.

Overall, organic acid rinses appear to be a generally effective antimicrobial intervention that have several distinct advantages. Specifically, the advantages include: (1) the technique can achieve up to a 99.9 percent (3 log) decrease in the levels of specific pathogenic and non-pathogenic bacteria; (2) the effectiveness of the application can be readily monitored; (3) the technology can be implemented through a relatively straightforward modification of existing equipment; and (4) this is a process for which there are no apparent ''tradeoffs'' in relation to other risks or negative attributes (e.g., the presence of residues or the need to eliminate environmentally sensitive byproducts). The primary disadvantage is that the effectiveness of acetic acid rinses against *E. coli* O157:H7 is not as great as against other pathogens, and at least some studies indicate that these rinses may not achieve the results desired.

In 1992, FSIS issued a directive (FSIS Directive 6340.1, 11/24/92) that provided guidance to FSIS employees on conditions of use, and how to evaluate and respond to livestock establishments' requests for approval of pre-evisceration carcass spray systems using an acid spray to reduce the

microbial population and retard further microbial growth on livestock carcasses. For beef carcasses, FSIS also recently authorized establishments to use acetic, citric, or lactic acids on inspected and passed carcasses before chilling in conjunction with the final wash without prior FSIS approval on an establishment-by-establishment basis.

FSIS is proposing that, to satisfy the proposed requirement for at least one antimicrobial treatment, acetic, lactic, or citric acid could be applied to carcass surfaces prior to entering the cooler. FSIS is preparing to propose in a separate rulemaking that these organic acids be listed, as approved antimicrobial agents, in 9 CFR 318.7 and 381.147 for livestock and poultry uses, respectively, in a solution of 1.5–2.5 percent concentration and in such a fashion that all carcass surfaces would be contacted.

FSIS invites comments on whether the use of these acids to satisfy the program requirements for an antimicrobial treatment should be limited to post-inspection application in conjunction with the final carcass wash or should be permitted at earlier stages of the slaughter and dressing process, such as after skinning but before evisceration and completion of postmortem inspection by FSIS inspectors, or during chilling. FSIS also invites comment on whether organic acid sprays should be considered an acceptable antimicrobial treatment in beef slaughter establishments in light of the reported acid-resistance of *E. coli* O157:H7, which is a pathogen of particular public health concern in beef.

A list of studies on the application of organic acids on meat carcasses is on file with the FSIS Docket Clerk and may be obtained from the Director, Slaughter Inspection Standards and Procedures Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250.

(c) *Trisodium phosphate (TSP).* The application of TSP to raw poultry carcasses by spraying or dipping with a solution of water and food grade TSP was recently approved by FSIS. Trisodium phosphate (TSP) is listed in the FDA regulations as GRAS for multiple purpose use, in accordance with good manufacturing practices. FDA has affirmed that application of TSP to raw poultry carcasses is consistent with the GRAS listing for TSP. Additionally, TSP (sodium phosphate, tribasic) is listed in the Food Chemicals Codex III (1981).

FSIS has granted interim approval for use of TSP at pre-chill and post-chill locations, and has begun rulemaking procedures to include this compound in 9 CFR 381.147(f)(4), Table 1, under the new class of substances to be called ''antimicrobial agents'' (59 FR 551). TSP reduces bacterial levels, including pathogenic bacteria, on raw poultry carcasses when applied by spraying or dipping the raw poultry carcasses for up to 15 seconds post-chill or for up to 30 seconds pre-chill with an 8–12 percent solution of TSP in water. TSP may be applied to raw chilled poultry as a solution maintained at 45°F–55°F, and to raw poultry as a solution maintained at 65°F–85°F.

Industry, university, and Agriculture Research Service studies demonstrate TSP induced reductions in carcass *Salmonella* levels ranging from 90 to >99.9 percent (1.2 to 8.3 $\log_{10}$). The higher *Salmonella* reductions were associated with pre-chill TSP applications. Mean carcass *Salmonella* prevalence was reduced from up to 23 percent to approximately 1 percent. Industry studies demonstrate median reductions in carcass *Enterobacteriaceae* and *E. coli* levels of approximately 99.5 percent (2.5 $\log_{10}$). In a study conducted by an independent laboratory, *Campylobacter* average prevalence was reduced from 100 percent to 30 percent with mean numerical reductions of >99.9 percent (4 $\log_{10}$) following TSP application to raw, unchilled poultry carcasses. TSP application to raw poultry, under the above stated time, concentration, and temperature conditions of use, therefore, causes statistically significant reductions in these most common gram negative pathogens associated with raw poultry.

As part of the poultry chilling process, poultry carcasses may gain moisture up to the levels permitted in 9 CFR 381.66(d). Poultry establishments using TSP are not exempted from the moisture absorption and retention limits contained in 9 CFR 381.66(d). To preclude the potential for economic adulteration of poultry carcasses as a result of TSP treatments, federally inspected establishments applying TSP to raw poultry carcasses will include the TSP application in their washing, chilling, and draining method as outlined in 9 CFR 381.66(d)(8).

Commercial use of TSP has only recently begun in some poultry establishments. It is not yet widely used. A commercial study investigating the efficacy of TSP in reducing bacterial levels on beef carcasses is in progress.

Federally inspected establishments using TSP as an antimicrobial agent on raw poultry have consistently met local and State effluent phosphate discharge requirements by making minor modifications to their effluent flocculation methods.

FSIS is proposing to permit TSP to be applied to poultry carcass surfaces at any point prior to entering the chiller as one means to meet the proposed requirement for an antimicrobial treatment. FSIS intends to propose in another rulemaking a regulation to list TSP in part 381.147(f)(4), Table 1, as an approved antimicrobial agent. TSP would be applied in a solution of 8–12 percent concentration in such a fashion that all carcass surfaces would be contacted.

A list of studies done on the application of TSP to poultry carcasses is on file in the FSIS Docket Clerk's office, and is available from the Director, Slaughter Inspection Standards Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250.

(d) *Chlorinated water.* The washing of carcasses with chlorinated water to reduce the amount of spoilage and pathogenic microorganisms on carcasses is a longtime practice in the poultry industry. As early as 1951, researchers noted the effectiveness of in-plant chlorination in lowering bacteria counts on product, increasing shelf life, reducing odors in the establishment, and reducing slime on equipment.

Chlorine is now used in most poultry establishments, primarily in chill water, to minimize bacterial cross-contamination and as an effective sanitizing agent on facilities and equipment, usually at FSIS-sanctioned levels of 20 to 50 parts per million (ppm) available chlorine.

A FSIS study published in 1992 showed significant microbial reductions on raw chicken carcasses and giblets immersed in chlorinated chill water. In this study, the addition of 25 ppm of chlorine in the chill water resulted in a significant decrease in aerobic plate counts, *Enterobacteriaceae*, and *E. coli*. Some reduction also occurred without chlorine in chill water indicating that chilling carcasses in this manner actually reduces the bacterial load on carcasses. The effect on *Salmonella* was a reduction in the amount of cross-contamination. Without chlorine, the percent of carcasses exiting the chiller with *Salmonella* versus the percent going in increased significantly. With the addition of chlorine, the differential was not significant. The conclusion was that chlorine aids in the control of cross-contamination in the chillers.

Chlorinated water has long been recommended for reducing bacteria in poultry processing establishments. In one study 34 ppm chlorine reduced salmonellae in broiler chill water to non-detectable levels, and resulted in significant reductions (10–13 percent) in

the incidence of *Salmonella* on the carcasses.

A 1968 study demonstrated that by incorporating chlorine (20 ppm) into sheep carcass wash water, bacterial numbers were reduced significantly, but usually less than one log. Another study showed increased reductions in bacterial numbers were obtained as the chlorine level in water used to wash lamb carcasses was increased up to 357 ppm. Another researcher observed similar reductions when lamb carcasses were washed with 150 and 250 ppm chlorine. A study in 1977 found that up to $\log_{10}0.7/cm^2$ reduction could be obtained by using water containing 200–250 ppm chlorine to spray beef tissue.

An initial mean reduction of 0.31 log on beef tissue has been achieved by treating it with a 200–250 ppm chlorine wash. FSIS considers the application of chlorine at levels up to 30 ppm on poultry, including giblets and salvaged parts, and in poultry chiller water, to be prior sanctioned under the food additive provisions of the Federal Food, Drug, and Cosmetic Act. The comparable use of chlorine in sprays applied to livestock carcasses is also a practice that has long been permitted by FSIS.

The vast majority of poultry establishments and a growing number of meat establishments apply chlorine solutions during slaughter and processing. To meet the intent of the regulation, FSIS would allow the application of 20–50 ppm chlorine in the final wash for livestock and poultry carcasses.

Some environmental risks have been associated with the use of chlorine, most significantly from the formation of byproducts of chlorine reactions with organic compounds in water. The trihalomethane (THM) byproducts are the current focus of regulation of drinking water chlorination by the Environmental Protection Agency under the Safe Drinking Water Act. It has been reported that there is an association between long-term exposure to chlorinated drinking water and a 9–15 percent higher incidence of human bladder and rectal cancer. The researchers were of the opinion, however, that the public health risks from microbial contamination in unchlorinated water ''greatly exceed'' the risks of possible increased incidence of bladder and rectal cancers.

Because one of the THMs, chloroform, is an animal carcinogen, FSIS contracted with a private firm to perform a quantitative cancer risk assessment on chloroform residues recovered from the fat and skin of whole broiler chickens purchased at retail. Based on this assessment, estimates of additional lifetime cancer risk in the population from consumption of chloroform residues in chicken ranged from two in one billion (2×10^{-9}) to five in 100 million (5×10^{-8}) for fat, and from two in one billion (2×10^{-9}) to four in 100 million (4×10^{-8}) in skin based on estimates of chicken consumption. These are well below the level of one in one million (1×10^{-6}) additional lifetime cancer risk generally considered negligible by EPA and FDA in their regulation of pesticides and other chemicals, such as animal drug residues.

FSIS believes that these extremely small risks are clearly outweighed by the public health benefits of chlorine in reducing microbial contaminants on product. FSIS permits the use of nitrites in cured products on a similar basis; the antimicrobial safety benefits provided consumers by its use greatly outweigh the very small risk posed by possible carcinogenic byproducts.

At the request of FSIS, ARS is studying the possible risks from any mutagens that might be formed with the use of chlorinated poultry chiller water. Early phases of this study indicate only that very low levels of mutagenic compounds are associated with chlorinated poultry chiller water and that they increase as the chlorine levels used increase.

FSIS will continue to monitor closely all data on the safety of chlorine when used on carcasses as an antimicrobial agent, and will continue to reevaluate the risks and benefits associated with approved use.

FSIS invites comments on the risks and benefits of chlorine used to reduce and control microbial levels on meat and poultry products.

Product for Export

Application of antimicrobial treatments under this proposed regulation might interfere with the export of the products. This may be especially true for products from carcasses treated with certain chemicals. For example, Canada limits the use of chlorine on poultry products to a maximum of 20 ppm, and chlorine is not permitted at all in some of the countries of the European Union.

Therefore, so as not to interfere with the export of meat and poultry products, and enable companies to meet the expectations of their customers, FSIS is proposing to exempt from antimicrobial treatment product designated for export only. This exemption would apply only to product being prepared for export to a country which will not accept product exposed to the antimicrobial treatment installed in the establishment under this proposed regulation. Exempted export product must be properly identified, segregated, and labeled. FSIS invites comments on this proposed exemption.

3. Temperature Controls

Temperature is one of the primary factors affecting bacterial multiplication; the lower the temperature, the more slowly the multiplication occurs. Carcass surfaces become contaminated with bacteria during the slaughter and dressing procedures, while carcass interiors remain uncontaminated. Rapid cooling of carcasses prevents the multiplication of pathogenic bacteria on the carcass surface, and thus reduces consumer exposure and risk.

FSIS has concluded that most raw meat and poultry products must be rapidly chilled to 50°F and then maintained at 40°F or below to minimize the risk to public health from pathogens on those products. The technology needed to achieve the proposed chilling standards is readily available and for the most part already installed in establishments. The change being proposed is that appropriate time-temperature controls for handling raw product, already generally adhered to by many establishments, will become mandatory for all establishments.

Accordingly, a new section 318.25 would be added to the meat inspection regulations requiring that establishments cool livestock carcasses and raw meat products so the products reach a temperature of 50°F or below within specified time periods and maintain cooled carcasses and raw meat products at 40°F or below throughout handling, holding, and shipping to other official establishments, with certain exemptions. One exception is for raw product going directly into processing that includes a pathogen-lethal heating step, and thereby results in a ''ready-to-eat'' product. Raw product would be partially exempt from the time-temperature requirements applying to fresh carcasses because when product enters a ready-to-eat process, other time-temperature controls applicable to the raw ingredients would apply. Additionally, the processing treatment required for ready-to-eat products stabilizes the product by killing both pathogens and spoilage bacteria. Another exception to the proposed cooling requirements is for ''hot-boned'' product, that is, muscle tissue removed from the carcass before chilling, which would have to be cooled within 5 hours (meat) or 1.5 hours (poultry) to a surface temperature of 10°C (50°F). Any edible parts removed from the carcass and not to be heat processed directly, e.g., livers, hearts, and heads with cheek meat, must

enter a chiller within 1 hour and chill at the same rate as carcasses.

This proposal also would amend section 381.66 of the poultry regulations so they are substantially consistent with the proposed meat inspection regulations regarding temperature and chilling requirements. Section 381.66 currently requires that all poultry slaughtered and eviscerated in an official establishment be chilled immediately after processing so that the internal temperature is reduced to 40 °F or below within a time period appropriate to the size of the carcass. It further requires that eviscerated poultry to be shipped from the establishment in packaged form be maintained at 40 °F or below, with certain exceptions. Section 381.66 would be amended to include new time/temperatures requirements, to mandate corrective actions when time/temperature controls fail, and to eliminate other provisions inconsistent with those being proposed for meat. FSIS believes the proposed time-temperature cooling requirements for meat are equivalent to those in effect and being proposed for poultry in terms of their public health benefits and are readily attainable under current commercial conditions.

Time-Temperature Requirements

FSIS is proposing that establishments cool the surface of meat carcasses to 50 °F or below within 5 hours and to 40 °F or below within 24 hours from the time that carcasses exit the slaughter floor. This cooling rate is based on the best estimate of what is needed to minimize multiplication of pathogenic organisms and what is achievable in a well-controlled meat establishment. Controlling the surface temperature also ensures that the interior is cooling at a reasonable rate.

Carcasses and raw meat products would be required to be maintained at an internal temperature of 40 °F or below during handling, holding, and shipping. FSIS considered a higher temperature limit because at temperatures below 50 °F, spoilage bacteria generally multiply faster than pathogens. Thus, meat below 50 °F generally will spoil before excessive pathogenic bacterial multiplication can occur. For example, spoilage bacteria, such as *Pseudomonas* spp., *Pediococcus* spp., and *Lactobacillus* spp., not only increase faster than pathogenic bacteria, below 50 °F, but some also form inhibitory compounds. However, FSIS rejected a higher temperature limit and is proposing 40 °F because: (1) The lower temperature provides an additional margin of safety against the multiplication of pathogenic bacteria, (2) 40 °F has long been the maximum temperature recommended, as set forth in Agriculture Handbook No. 412; (3) the U.S. industry generally uses much lower temperatures (e.g., 30 °F (−1.1 °C) to retard spoilage as well); and (4) 40 °F would be the same as the temperature currently required for chilling poultry products (9 CFR 381.66).

Except for hot-boning operations, where muscle tissue is removed from the carcass before cooling, FSIS is not proposing a set time to attain an internal temperature of 40 °F. This is because, when the surface temperature of a product reaches 40 °F within the proposed 24 hours and is maintained at that temperature, the laws of thermodynamics ensure that the interior will cool to a safe temperature within a reasonable time frame. Since carcass weight and composition affect the interior cooling rate, a set time to an internal temperature would be too strict for heavy carcasses and too lenient for light carcasses.

There are additional reasons to use surface temperatures. First, any bacterial pathogens on a fresh carcass are concentrated on its surface. The deep tissue of carcasses, with few exceptions, is sterile. Thus, the control point should be where the potential hazard exists. Second, the surface is the most prudent place to measure temperatures. Probing the deep muscle tissue of carcasses before they are fully cooled could cause a public health problem by injecting any bacterial pathogens on the surface into the sterile warm interior.

Hot-boned product, however, would be controlled by internal temperature. Cutting into the carcass increases the probability of deep tissue contamination due to tears in the muscle facia, flexing, punctures, and additional handling. Therefore, the internal temperature is the critical control point. And, since the integrity of the carcass has been violated, the internal temperature is the appropriate monitoring point.

The proposed cooling rates, holding temperature, and corrective actions specified in the proposed rule are based primarily on the thermodynamics of cooling meat and the effect of temperature on bacterial multiplication. Further information on how these were calculated is available in ''The Scientific Basis for Proposed Time-Temperature Requirements,'' a paper on file in the FSIS Docket Clerk's office and available upon request from Director, Processed Products Inspection Division, FSIS, U.S. Department of Agriculture, Washington, D.C. 20250.

This proposed rule would also require that carcasses and raw meat products reach a temperature of 40 °F or below prior to leaving the establishment. Requiring a temperature of 40 °F or below prior to entering commerce provides added assurance that during transportation the product will be maintained at 40 °F and bacterial multiplication will be restricted. Carcasses or raw meat products are permitted, however, to enter a ready-to-eat process at the establishment, before being cooled to an internal temperature of 40 °F.

Slaughtering establishments would be required to begin cooling raw meat products other than carcasses within 1 hour of removal of the tissues from the carcass. Establishments generally remove raw meat products, such as livers, hearts, heads, and cheek meat, before the carcass exits the slaughter floor. These products have a history of poor microbiological quality because the products are packed in boxes before cooling or are moved to the cooler only after a delay. The requirement that cooling of these products begin within 1 hour of removal from the carcass would reduce the opportunity for pathogenic bacterial multiplication and improve the microbiological quality of these products. The cooling rate proposed for these products is the same as that for the carcass surface—50 °F within 5 hours and 40 °F within 24 hours.

The method used to measure the surface temperature of a carcass or a raw meat product would be at the discretion of the establishment. Pressing the side of a temperature probe against the meat surface is the easiest and most inexpensive method. Because air has low heat capacity relative to meat, this method should give a good estimation of the meat surface temperature. Shielding the probe from room air should increase the measurement accuracy. For shielding, one suggestion is to place two carcasses together and measure the contacting surfaces. Shielding the probe from room air with a food contact material having low heat conductance and capacitance, such as a dry sponge in a plastic bag, after proper sanitizing, would also be effective.

The time-temperature profiles being proposed might be modified for certain raw products if other factors such as dryness or acidity are factored in. Therefore, it is possible that an establishment's designated processing authority could develop alternative time and temperature procedures for cooling, shipping, receiving, and, or holding carcasses and raw meat products that would produce microbial profiles equivalent to or better than those produced under the proposed requirements. The Agency is therefore

proposing to allow use of time and temperature limits equivalent to those specified in the proposed requirements. Any such alternate procedures would, however, be difficult to monitor for regulatory purposes. FSIS welcomes comment on this point.

Written Plan for Meeting Time and Temperature Requirements

Establishments would be required to develop, implement, and place on file a written plan for meeting the time and temperature requirements either prescribed in this proposed rule or in alternative procedures developed by a processing authority. The plan would include the establishment's designated control points, i.e., the points within an establishment's operation where temperatures would be measured; monitoring procedures; records to be kept; standards for the control points, including the cooling rate, holding temperature, and shipping temperature; corrective actions to be followed if deviations occur, including a system for separating and identifying noncomplying product; and, when applicable, the name of the processing authority. The plan would be required to be maintained at the establishment for as long as the plan is being used by the establishment. The plan and monitoring records must be made available to Program employees upon request.

Establishments would be required to monitor and record the maximum temperature of a representative number of carcasses and raw meat products periodically during the establishments' operation, as set forth in their written plan for doing so. The frequency of monitoring temperatures in a day's operation by establishments would vary, depending on the size and type of an establishment's operations. Establishments would include in this written plan the control points and the frequency of measuring the temperatures in a day's operation. Establishments would be required to use temperature measuring devices readable and accurate to 2 °F (0.9 °C). The monitoring records would be maintained for up to 6 months after the temperature measurement, or until such time that may otherwise be specified by the Administrator. Program employees would verify the frequency of temperature measurement to ensure that the establishment's written plan is being followed. Inspection personnel would also measure temperatures at various control points and compare these temperatures with those measured and recorded by the establishment.

Effect on Commercial Meat Manufacturing

Because raw poultry is already subject to chilling regulations, it is expected that this proposed regulation primarily will affect meat establishments.

Present commercial meat manufacturing and distribution practices are diverse. Some establishments slaughter animals, prepare raw meats, and process and ship ready-to-eat products. Others may only slaughter and dress animals, debone meat, or prepare raw meats as ingredients for ready-to-eat products. This proposed rule would cover all official establishments that slaughter, receive, store, transport or otherwise handle carcasses and raw meat products.

The following is a brief discussion of present commercial meat manufacturing and distribution operations and how this proposal would affect those operations.

(a) *Slaughter establishments.* Slaughter establishments receive live animals and produce raw meat. The establishment's task is to remove the animal's hide and viscera in a manner that results in meat with as few bacteria as possible. This task is called ''sanitary dressing.'' After dressing, establishments cool carcasses to retard the multiplication of any pathogenic or spoilage bacteria.

The primary means of cooling is to move the carcass into a cold room where the temperature and air movement reduce carcass temperature. Some establishments use various procedures to enhance carcass cooling. The carcass spray chill method increases the cooling rate through direct heat absorption and enhanced evaporative cooling. The sprayed water directly absorbs some carcass heat on contact then absorbs even more when it evaporates. Spray chilling is also advantageous to the manufacturer in that it reduces the amount of weight lost from the carcass by evaporation. The disadvantage is that the increased surface moisture facilitates multiplication of bacteria.

A related practice is hot-boning, which involves the removal of the meat before the carcass is fully cooled. The advantage of hot-boning is that the meat is reduced to smaller, more easily cooled pieces, and the meat is available for processing sooner than if it were removed only after the carcass is fully cooled. However, hot-boning poses a hazard if exposed warm meat surfaces remain at warm temperatures long enough to allow bacterial multiplication.

This proposal would permit any of these cooling procedures as long as the proposed cooling temperatures and time periods are met.

(b) *Shipping and receiving.* Slaughter establishments may ship meat food products in several forms, such as carcasses, cuts, manufacturing meat, or ground meat. In the past 20 years, the geographic concentration of raw meat processing has made boxed meat the primary form in which raw meat is shipped. Boxed meat is often shipped in 60-pound containers of boneless manufacturing meat, cuts, primal cuts, or subprimal cuts.

However, establishments still ship carcasses and larger containers of manufacturing meat weighing 500 pounds or more.

Processing establishments manufacture raw meat products, ready-to-eat meat products, or both. Processing establishments that are not also slaughter establishments must receive raw meat products from other establishments. This proposed rule would affect such processing establishments by requiring them to ensure that raw product received is at the required internal temperature of 40 °F or below, and to maintain the raw meat product ingredient at that temperature in conformance with the proposed requirements.

This proposed rule would require that establishments cool the carcasses and raw meat products to an internal temperature of 40 °F or below prior to shipping such products to help ensure that, if the products are shipped to other official establishments, the products arrive at the receiving establishments at an internal temperature of 40 °F or below.

The shipping establishment would be required to record the date and time of shipment on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying a shipment. This is necessary to enable the receiving establishment to determine the number of hours the products have been in shipment.

Compliance with the requirement ends when the raw meat product enters a ready-to-eat process at the establishment or is no longer in the possession or under the control of the establishment. Product in the possession of or under the control of the establishment remains the responsibility of the establishment. Establishments must undertake all reasonable precautions to ensure that such product is maintained as required under the proposed rule, even when it is in a transport vehicle or otherwise not physically at the establishment.

Although this proposal directly affects only FSIS-inspected establishments, FSIS encourages adherence to the proposed time/temperature requirements by all who handle or store raw meat and poultry products. At the end of this preamble, the Agency discusses plans to consider increasing oversight of the commercial handling of meat and poultry at locations outside inspected establishments, including during transportation, distribution and storage to the retail level. FSIS will be considering measures to ensure proper handling and cooking of raw and poultry products throughout the food safety continuum.

B. Microbial Testing; Interim Pathogen Reduction Targets

As discussed earlier, the centerpiece of the FSIS food safety strategy is to articulate what constitutes an acceptable level of food safety performance by a meat or poultry establishment and hold the establishment accountable for achieving that level of performance. In the case of pathogenic microorganisms on raw product, this means establishing targets, guidelines, or standards and requiring establishments to conduct regular microbial testing to verify current processes and practices are achieving those targets, guidelines, or standards, or whether further measures are required.

FSIS is proposing interim targets for pathogen reduction and microbial testing in slaughter establishments. This is an initial step toward measurable reductions in the incidence of contamination of meat and poultry products with pathogenic microorganisms. It also is a first step toward the eventual incorporation of microbial testing as an integral part of process control and verification in facilities operating under the HACCP approach proposed later in this document.

Before describing the proposal for interim targets and microbial testing, a brief description of the Agency's current use of microbial testing is provided.

1. Current Testing Program

FSIS's current regulatory use of microbial testing is generally directed at detecting product that is contaminated with bacteria of particular public health concern.

FSIS has made and will continue to make, on a case-by-case basis, determinations that a meat or poultry product presents an unacceptable public health risk, and is adulterated, due to the presence of specific pathogenic microorganisms in or on the product. Affected product may be processed or raw. The discretionary authority to take immediate action in such cases to protect public health is an essential part of the Agency's food safety mandate.

Processed products that purport to be fully cooked and/or ready-to-eat have been and will continue to be deemed adulterated if found to contain pathogenic bacteria or toxic metabolites. These are products that consumers are likely to eat without further cooking. Consumers should be able to rely on processor's claims, implicit or explicit, that the product is fully cooked and/or ready-to-eat. Such product should in fact be ready to eat; further cooking should not be required to protect the consumer from pathogens.

FSIS currently operates programs to test various products for specified pathogens. Before establishing microbial testing programs, and if there is evidence of a potential public health risk from a pathogen being in or on a particular processed, ready-to-eat product, FSIS performs a risk evaluation that focuses primarily on the pathogenicity of the organism and the seriousness of the resulting disease.

If it is determined that there is a public health threat due to the risk of serious illness from consumption of a contaminated product, the Agency undertakes three related actions. First, product tested and found positive for the prohibited organism or toxin is retained and any implicated product in commerce is recalled voluntarily by the producing establishment. Second, the Agency undertakes a testing program to detect other products similarly contaminated and acquires data to decide if further actions are required. FSIS works with the manufacturer and distributors to return all implicated products to the inspected establishment. Appropriate public notices are given. Recalled product is destroyed or, if appropriate, reprocessed to destroy the contaminant, under FSIS oversight. Third, FSIS works with the establishment to determine the cause(s) of the contamination and to ensure that appropriate processing or other changes are made by the establishment to prevent a recurrence.

FSIS has made numerous determinations in the past that particular pathogens will, if found on a particular processed, fully cooked and/or ready-to-eat product, cause that product to be considered adulterated under the law, and has instituted testing programs accordingly. The following ready-to-eat products are tested for the presence of the microorganisms or their toxins, which, if found, will cause the product to be deemed adulterated, as indicated:

—Cooked beef: *Listeria monocytogenes, Salmonella*
—Sliced ham: *Listeria monocytogenes, Salmonella*
—Cooked meat patties: *E. coli* O157:H7
—Dry and semi-dry fermented sausages: Staphylococcal enterotoxin
—Jerky: *Listeria monocytogenes, Salmonella*
—Large diameter cooked sausages (e.g., bologna, salami): *Listeria monocytogenes, Salmonella*
—Small diameter cooked sausages (e.g., hot dogs, kielbasa, bratwurst): *Listeria monocytogenes, Salmonella*
—Meat and poultry salads and spreads: *Listeria monocytogenes, Salmonella*
—Cooked poultry products: *Listeria monocytogenes, Salmonella*

Most recently, FSIS determined that raw ground beef found to contain *Escherichia coli* O157:H7 is considered adulterated. This determination was made based on several factors. First, only small numbers of the O157:H7 strain of *E. coli* are required to cause serious illness or death, especially among children and the elderly. Second, traditional and accepted cooking practices for raw ground beef (e.g., a medium rare or slightly pink hamburger) do not kill *E. coli* O157:H7. Third, the illness caused by the bacteria can be transmitted to others (especially among highly susceptible small children). FSIS is conducting limited sampling and testing of raw ground beef in establishments and in the marketplace for the presence of *E. coli* O157:H7.

The key characteristic of current FSIS microbial testing programs is that sampling and testing is conducted by FSIS to detect violations and dangerous product contamination and to stimulate preventive measures by industry. Current programs do not involve microbial testing by establishments as part of an effort to verify process control and evaluate the adequacy of an establishment's efforts to control and reduce pathogens. FSIS believes its current testing programs serve a useful purpose but are not adequate by themselves to protect consumers. Microbial testing by companies to verify process control and demonstrate progress toward pathogen reduction is an integral part of FSIS's food safety strategy.

2. Proposed Targets and Testing

One approach to regulating pathogenic microorganisms in meat and poultry slaughter operations would be to determine, based on risk assessments, the levels of specific pathogens on raw meat and poultry products that do not pose a significant risk of illness and

prohibit distribution of products exceeding such levels. The acceptable level of pathogens would be effectively zero (<1 per 25 grams) in at least some cases. The establishment of such standards is the approach generally taken for the regulation of chemical additives in food. It provides a very direct means of controlling and avoiding substances in food that present a public health concern.

FSIS has not taken this approach in the past with respect to pathogenic microorganisms on raw meat and poultry. FSIS has been constrained by the lack of a scientific basis for determining the levels at which specific pathogens do or do not present a safety hazard, particularly in regard to the potential for pathogens to increase or decrease during distribution, marketing and consumption. FSIS also has relied in part on the fact that proper cooking kills pathogens present on raw product. The closest FSIS has come to this approach is its recent decision to treat raw ground beef contaminated with any amount of *E. coli* O157:H7 as adulterated within the meaning of the FMIA, but this was based on the fact that traditional and accepted cooking methods for raw ground beef (such as in a ''medium rare'' hamburger) do not kill this dangerous pathogen.

FSIS believes that determining the levels of specific pathogens that pose a public health risk and using those levels for regulatory purposes is a desirable goal because it provides a very direct means of defining an acceptable level of food safety performance by a meat or poultry establishment and for holding the establishment accountable for achieving it. As a general matter, however, this approach currently is not available to FSIS to deal with the broad array of pathogens in raw meat and poultry. There are large gaps in the scientific knowledge required to determine levels of specific pathogens that do and do not pose a hazard. For example, with certain infectious pathogens where the primary mode of transmission involves cross-contamination, it is currently not possible to correlate pathogen levels with risk of disease (e.g., *Campylobacter jejuni* in raw poultry).

FSIS intends to continue to work with the scientific and public health communities and the meat and poultry industry toward determining what levels of specific pathogens on specific products pose public health concerns requiring regulatory action and to reduce pathogens below those levels to the maximum extent possible. However, the scientific and public health policy issues involved are complex and their resolution will require a concerted, long-term effort. Some of the issues and FSIS's plans for public meetings to begin addressing them are described below in Part III.

For the present, FSIS has decided to pursue an alternative strategy for pathogen reduction that is based on the same principle of articulating an acceptable level of food safety performance and holding establishments accountable for meeting it, but that also takes account of what is achievable today. Specifically, FSIS is proposing interim targets for reducing the incidence of contamination of meat and poultry carcasses and ground meat and poultry products with *Salmonella*, coupled with requirements for all affected establishments to conduct microbial testing to determine whether their targets are being achieved. FSIS believes that significant progress can be made in pathogen reduction by taking advantage of current technologies and industry capabilities, even as the Agency's HACCP program develops and the scientific basis for setting more definitive targets, guidelines or standards evolves.

The proposed *Salmonella* testing program is an important element of FSIS's food safety strategy because it will:

(1) reduce the prevalence of pathogens of public health concern;

(2) induce process changes by some establishments that are needed to achieve both the target for *Salmonella* and a reduction in the frequency and level of contamination of raw meat and poultry with other pathogens;

(3) establish the principle that the FSIS's inspection program and establishment process control programs must begin directly targeting and reducing pathogenic microorganisms of public health concern;

(4) begin building the foundation for HACCP, which will rely on microbial targets, guidelines, and standards to help define the process controls that will be needed to achieve the desired level of food safety performance; and

(5) begin building a database on the prevalence of *Salmonella* contamination, which will be used for national trend analysis and as an essential tool for setting future pathogen reduction goals.

The Agency's interim target and microbial testing proposal includes the following major elements:

(1) selection of *Salmonella* as the target pathogen;

(2) identification of a national baseline occurrence of *Salmonella* contamination for each major species and for ground meat and poultry;

(3) adoption of, as an interim target for pathogen reduction, the requirement that within two years, or some other period specified by FSIS through this rulemaking, each establishment achieve an incidence of contamination below the current mean national baseline;

(4) a requirement that each establishment conduct daily testing for *Salmonella* to determine whether the establishment's process controls are, over a specified period of time, achieving the interim target; and

(5) prompt development and implementation of remedial plans by establishments not meeting the target within a specified period.

The Agency invites public comment on its proposal to establish interim targets for pathogen reduction and require microbial testing. The proposal's major elements are outlined below following a brief discussion of the public health rationale for targeting reduction in incidence of a specific pathogen as a step toward reducing the risk of foodborne illness associated with meat and poultry products.

3. Public Health Benefit of Interim Pathogen Reduction

As noted in earlier portions of this document, *Salmonella, Campylobacter, E. coli* O157:H7, *Listeria monocytogenes, Staphylococcus aureus,* and *Clostridium perfringens* constitute the major bacterial pathogens associated with foodborne illness. *Healthy People 2000* outlines goals for reducing the incidence of each of these pathogens. *Salmonella, Campylobacter, E. coli* O157:H7, and *Clostridium perfringens* appear to be introduced into meat and poultry primarily at the time of slaughter. Public health concerns arise from this initial contamination, in combination with other variables including subsequent handling by industry and the consumer, opportunities for cross-contamination, cooking practices, and the like. These variables have been described in detail in the 1987 National Academy of Sciences report, *Poultry Inspection: The Basis for a Risk Assessment Approach.*

While FSIS cannot quantify the reduction in disease incidence which will occur with specific interim reductions in bacterial contamination of raw product, simply reducing the percentage of product containing a pathogen should result in a reduction in disease incidence, although mishandling may still occur.

Each pathogen has a somewhat different epidemiology, and responds to different interventions in different ways; for example, some interventions may be very effective for *Salmonella,* but have

a minimal effect on *E. coli* O157:H7. For these reasons, it will be important for the long term that testing be pathogen-specific: i.e., establishments should look for what is known to be important in a particular product line, and target interventions and monitoring to that particular pathogenic microorganism. As a part of implementing HACCP, processors will need to determine what pathogens are a major risk for their product, and design interventions and monitoring accordingly.

Even under HACCP, it will not be practical or necessary to test all products for all pathogens. Nonetheless, there are certain pathogens, such as *Salmonella,* which are present on virtually all raw food products. *Salmonella* is the leading cause of bacterial foodborne illness in this country, and causes the greatest economic burden. As such, it is likely that virtually any HACCP based testing program for pathogens on raw product would identify *Salmonella* during the hazard analysis as an organism of primary concern. Based on these considerations, FSIS is proposing reduction in the incidence of product contamination with *Salmonella* as an interim target for pathogen reduction.

FSIS recognizes that reductions in incidence of *Salmonella* contamination does not guarantee equal reduction in other pathogens. Nonetheless, insofar as interventions designed to decrease the incidence of contamination with *Salmonella* reduce overall levels of fecal and ingesta contamination, which is the largest single avenue for contamination of meat and poultry by pathogenic microorganisms, those interventions should have a beneficial effect on other human pathogens of animal intestinal origin. The Agency recognizes that there are other foodborne human pathogens of public health concern that can be isolated from raw meat and poultry product. The Agency would welcome comments on the targeting of other pathogens in addition to or in lieu of *Salmonella.*

The following sections discuss the major elements of the proposed interim targets for pathogen reduction and requirements for microbial testing.

4. Use of Salmonella as a Target Pathogen

FSIS proposes to require that each establishment that conducts slaughter operations or produces raw, ground meat or poultry products sample and test representative product daily for the presence of *Salmonella.*

Due to logistical problems involved with attempting to test for all possible pathogens, the Agency is proposing the use of *Salmonella* at this stage as a target organism. *Salmonella* was selected for this purpose because: (1) intervention strategies aimed at reducing *Salmonella* can be expected to have comparable effects against most other human enteric foodborne pathogens, (2) current methodologies are available to recover *Salmonella* from a variety of products, (3) FSIS baseline data suggest that *Salmonella* colonizes a variety of animals and birds often enough for changes to be detected and monitored, and (4) *Salmonella* is the most common cause of foodborne illness.

5. The Identification of National Baseline Levels as Reference Points for Pathogen Reduction

FSIS proposes that all establishments that conduct slaughter operations or produce raw ground meat or poultry products produce such products such that the frequency of occurrence of *Salmonella* is at or below the current national baseline average. These proposed baseline levels tentatively identified by FSIS are provided in the chart below, showing the frequency of occurrence in terms of the percent of tests expected to be positive for *Salmonella:*

Commodity	Frequency of occurrence of Salmonella (% +)
Steers/Heifers	1
Broilers	25
Raw Ground Beef	4
Fresh Pork Sausages	12
Cows/Bulls	1
Hogs	18
Turkeys	15
Ground Poultry	.....

To the extent possible, FSIS has used data from its Nationwide Microbiological Baseline Data Collection Program as the basis for the proposed baselines assigned to these raw commodities. This program provides data on the prevalence of major pathogens and indicator microorganisms associated with meat and poultry. The data generated from these programs provide a comprehensive microbiological profile of the raw commodities studied. The baseline studies on steers and heifers and ground beef are completed. Studies on cows and bulls, market hogs, and ground turkey and broilers are in progress, while studies are planned for ground chicken and turkeys.

The pathogen reduction baselines for those commodities where FSIS baseline studies have not been completed are estimates based on the best data currently available to the Agency. FSIS recognizes that the data available for some species are limited. The Agency believes, however, that this rulemaking will generate additional data that will help refine the baselines tentatively identified here.

The following is a summary of how the baselines were determined for each of the raw products of concern.

The baseline established for *Salmonella* frequency of occurrence on steer and heifer carcasses is based on the FSIS Nationwide Microbiological Baseline Data Collection study conducted from 1992 to 1993. In this program, 2,089 samples were analyzed for *Salmonella,* as well as other microorganisms, and 1 percent of the samples were found to contain *Salmonella.*

Raw ground beef from federally-inspected establishments was tested by FSIS. Out of 563 samples taken in this baseline study, 4 percent were positive for *Salmonella.*

FSIS has also conducted several, more limited studies which help provide an estimate of the frequency of occurrence of *Salmonella* in regulated commodities, such as broilers, where baseline studies are underway or planned. The data for *Salmonella* on broilers is from a FSIS nationwide study conducted from 1990 to 1992. This survey found *Salmonella* in 25 percent of the 1,874 birds sampled.

A 1979 FSIS study of retail-size, fresh pork sausages showed *Salmonella* in 12 percent of the 603 samples tested. The 12 percent frequency of occurrence for *Salmonella* as a baseline in fresh sausages was derived from this study.

The 1 percent frequency of occurrence of *Salmonella* on cow and bull carcasses is an estimate based on the completed baseline study on steers and heifers. The baseline study for cows and bulls is in progress.

As noted above, FSIS has not completed nationwide surveys for hogs, turkeys, or ground poultry, but such studies are in progress or scheduled for 1995. There have been no studies conducted for *Salmonella* in ground poultry, so revelant data was not available to establish a baseline. Few studies have been conducted for *Salmonella* on hog carcasses. An industry group's recent review of the literature reported several studies of *Salmonella* on pork carcasses conducted between 1961 and 1973. The studies reported wide ranges in the incidence of *Salmonella,* from 49 percent to 56 percent, due in large part to the variety of sampling procedures used. FSIS believes that in the absence of more

recent and comprehensive U.S. data on hogs, the best available data is that provided by a Canadian National Survey, which FSIS believes to be adequate to establish a baseline for *Salmonella* applicable to hogs in the U.S. In the Canadian survey, *salmonellae* were isolated from 17.5 percent of the pork carcasses sampled.

The Canadian study also reported a *Salmonella* frequency of 69.1 percent of the turkey carcasses sampled. However, several U.S. surveys had conflicting results. A study conducted in 1979 showed 6.3 percent of the 79 turkey carcasses sampled were positive for *Salmonella.* Another U.S. survey compared *Salmonella* prevalence in three different establishments. The turkey carcasses positive for *Salmonella* were 13 out of 40 samples (32.5 percent), 6 out of 39 samples (15.4 percent), and 8 out of 40 samples (12.5 percent). Finally, an industry survey conducted from 1987–1988 showed a 15 percent frequency of *Salmonella* on turkey carcasses from the 25 plants that were sampled. The Agency believes these U.S. industry surveys to be the most representative of current conditions and is tentatively proposing to use the figure obtained from the U.S. industry surveys as the proposed baseline for *Salmonella* on turkey carcasses.

The Agency has no data upon which to establish baselines for the other species of food animals subject to mandatory inspection. As such, it is not proposing pathogen reduction target levels for minor livestock species—sheep, lambs, goats, equines—or for minor poultry species—ducks, geese, and guineas—at this time. The minor livestock species together comprise 4–5 percent of all livestock slaughtered, and the minor poultry species comprise only a fraction of 1 percent of domestic birds slaughtered. Assuming that the public risk of foodborne illness from these animals is comparably small, FSIS has decided to focus this rulemaking on the major food species, and defer rulemaking on these minor species. Comment is welcomed on whether FSIS should include these species in its testing program and, if so, on what basis it should do so.

FSIS recognizes that the data currently available to the Agency for determining the current baseline and the appropriate interim target for reduction in *Salmonella* incidence are limited. FSIS is also aware that many meat and poultry companies have been conducting microbial testing, in some cases for many years. The Agency believes that the industry possesses a significant body of data that would help better define the current baseline levels in various products prior to making final decisions on these issues. FSIS strongly encourages the industry and all those who possess relevant data to submit those data to the Agency in response to this proposal and to assist the Agency in adopting appropriate baselines as the reference points for pathogen reduction.

FSIS is also considering and invites comment on alternative approaches to identifying baselines against which pathogen reduction would be measured. One alternative would be to require the use of pathogens other than *Salmonella* as the target organism for certain products. For example, it could be argued that *Campylobacter jejuni/coli* occurs at a greater frequency in poultry than *Salmonella* and as such would be a more pertinent target pathogen. Likewise, according to the available FSIS baseline survey data, beef carcasses have a relatively low incidence of *Salmonella* contamination, suggesting the possibility that other pathogenic microorganisms, such as *Campylobacter jejuni/coli,* might be preferable target organisms for pathogen reduction. FSIS would be prepared to adopt such alternatives if the comments received on this proposal demonstrate that alternative organisms would provide a more effective basis for achieving measurable pathogen reduction in the near term.

Another alternative, discussed further below, would be to use the current performance of a specific establishment as that establishment's baseline for pathogen reduction in lieu of a national baseline.

FSIS also is interested in receiving data showing any correlation between factors other than the species of slaughtered animals and the incidence of pathogenic bacteria. For example, there are suggestions that old animals (e.g., spent hens and culled cows) are more likely than younger animals of the same species to harbor pathogenic bacteria and should be addressed separately.

6. The Interim Targets

FSIS is proposing that each establishment, at a minimum, achieve process control that will bring their incidence of *Salmonella* contamination below the current national baseline incidence of *Salmonella* found on that product within two years of the effective date of this proposed rule.

The baseline levels were chosen as a basis for initial targets in part because they are by definition averages that reflect a distribution of levels among a broad range of establishments. Some establishments have incidences of contamination above the national baseline, while others are achieving rates of contamination below the national baseline. FSIS believes that it is reasonable and feasible to require, as an interim pathogen reduction measure, that all establishments control their processes so that their *Salmonella* incidence is no greater than the current national average.

FSIS is also considering a requirement that, for one or more species, the target for pathogen reduction be some percentage reduction in *Salmonella* below the national baseline, such as a 25 or 50 percent reduction. This option is suggested by statements made by members of industry that many establishments already are achieving a prevalence of contamination well below FSIS's estimated national baseline incidence of *Salmonella* contamination using currently available methods and technologies. In the case of poultry, for example, some companies are reportedly achieving a frequency of occurrence of *Salmonella* contamination as low as 5 percent or less, well below the tentatively identified baseline for broilers and turkeys. The principle underlying FSIS's effort to establish appropriate interim targets for pathogen reduction is that establishments should be moving to adopt process controls and production practices that the industry itself has demonstrated in actual practice are available and effective for reducing the incidence of contamination with pathogenic microorganisms. If reductions 25 or 50 percent below the national baseline are reasonably achievable in the near term for a particular species, all companies should work to achieve them. At the final rule stage, FSIS will adopt specific percentage reductions below the national baseline to the extent they are supported by the administrative record developed in response to this proposal.

FSIS also invites comment on the appropriateness of the proposed two year time period for reaching the interim target following adoption of the final rule. Two years allows ample time for establishments to determine their current performance through the microbial testing FSIS is proposing and implement process controls and interventions that are already available. FSIS may determine on the basis of comments that different time periods, shorter or longer, may be appropriate for one or more species, depending on what is feasible for that species and on the degree of pathogen reduction FSIS adopts as the target. FSIS invites comments on these issues.

7. Requirement for Daily Testing

Each establishment would be expected to collect a minimum of one specimen for testing each day from each slaughter class and/or class of raw ground product, beginning 90 days following publication of the final rule. Once-a-day sampling is based on the natural daily cycle in production processes, starting with daily cleanup. Contamination builds up as operations progress throughout the day. The required sanitation/cleanup returns the level of contamination to essentially zero, thus starting a new cycle. As explained in the next section, FSIS considers one sample a day to be statistically adequate to verify process control.

As alternatives to the one sample per day being proposed in this document, FSIS considered requiring a sampling plan based on establishment production volume, or by lot, which would have meant, for most plants, many more than one sample per species per day. It also considered a sampling plan based on less than one sample per species per day, particularly for small plants. FSIS invites comment on its sampling plan, including the frequency of sampling.

FSIS recognizes that some establishments are currently conducting broader microbial testing than FSIS is proposing, and broader microbial testing will play an important role in an establishment's implementation of HACCP. More than once-a-day testing would have the advantage of providing more rapid analytical verification of process control. However, the Agency is proposing to require only one sample per species per day to achieve the dual purposes of using a statistically valid method and reducing the cost of testing. The Agency believes that maintaining a requirement for species-based testing is needed to provide analytical verification of process control.

As a general matter, single qualitative tests (positive or negative) provide adequate but minimum acceptable information regarding the level of process control. These singular results need to be accumulated over time for process verification. Daily testing (one test per day) was considered to be the minimum sampling required to deliver acceptable sensitivity for detection of process deviations within a realistic timeframe.

FSIS is not proposing at this time to use these testing results for making decisions on the disposition of specific lots of product. The amount of testing FSIS is proposing is not adequate to assure a specific lot is free of *Salmonella*. The purpose of the testing is to verify the performance of an establishment's system of process controls. As explained below, establishments not meeting the target within the specified time will be required to take remedial measures under FSIS inspection.

As proposed, each establishment would develop a written protocol, available for review by Program employees, outlining specimen collection and handling. It would, at a minimum, include:

- Designation of a responsible individual;
- The number of specimens to be collected from each slaughter class and/or species of ground meat and/or poultry;
- Description of random sampling procedure (i.e., how to determine which carcasses are to be sampled to ensure that specimens are representative of that day's production);
- Who will conduct the analysis (e.g., in-house laboratory, commercial laboratory, etc.; and
- Moving sum verification procedure (chart or table).

The designated representative of the establishment would collect the specimen at the end of the production process. For meat this would be prior to the carcass leaving the cooler; for poultry this would be immediately post-chiller; for raw ground meat and poultry, this would be prior to packaging. Samples would be taken as follows:

Poultry: whole bird rinse with the carcass selected after the chiller, at the end of the drip line.

Beef: excised brisket skin tissue, 4 inches (10.2 cm)×4 inches (10.2 cm)×½ inch (1.3 cm) in depth, collected in the cooler, after chilling.

Hogs: excised belly skin tissue, 3 inches (7.6 cm)×5 inches (12.7 cm)×½ inch (1.3 cm) in depth, collected in the cooler, after chilling.

Raw ground meat and poultry products: ½-pound (0.4 kg) sample, collected prior to packaging.

The analytical sample size and the method used would give a result equivalent to the result that would be obtained using the FSIS *Procedure for Isolation and Identification of Salmonella from Food*. (Requests for this document should be sent to the Director, Microbiological Division, FSIS, U.S. Department of Agriculture, Washington, DC 20250.) Samples would be drawn randomly, from all product produced. Samples would be taken for regulatory purposes and, therefore, would be required to meet all of the attributes of an official method (approved for use by Association of Official Analytical Chemists or other recognized scientific body). The method chosen must be verified by in-house data within the testing laboratory.

An establishment would be allowed to test the specimens in its own laboratory or in a commercial/contract laboratory. However, the laboratory that is selected must demonstrate experience in testing meat and poultry for *Salmonella* spp. Either an internal or external laboratory quality assurance/quality control (QA/QC) program with check sample analysis would be required. QA/QC records must be available to FSIS personnel, with FSIS reserving the right to send official samples to the laboratory to verify laboratory capabilities.

The laboratory would record the results and provide the results daily to the establishment, which would enter the results in a chart or table daily to determine whether the process in question is meeting pathogen reduction target levels.

The establishment would provide all the test results at least weekly to Program employees for entry into the FSIS's database. Electronic transmission of test results would be allowed.

8. Determining Compliance With Target Levels

In accordance with the FSIS food safety strategy of articulating what constitutes an acceptable level of food safety performance by a meat or poultry establishment and holding the establishment accountable to that performance, a moving sum statistical procedure is being proposed to evaluate whether establishments are achieving the interim targets for pathogen reduction. The moving sum procedure is a tool for evaluating whether the process control system is functioning and is designed to assess the effectiveness of a system in relation to a specified target level of performance. It focuses on a specific number of days (window) within a production process and evaluates that process to determine whether its performance meets or fails to meet that target level over that period of time.

Using this moving sum procedure, establishments will track the results of end-product testing to evaluate the effectiveness of their production systems for controlling pathogens in relation to the interim target FSIS will be establishing for each specific commodity. This method of evaluation was chosen because it provides an effective means of utilizing the microbiological assessment of end products to verify process control, based on a single sample per slaughter class

and/or class of raw, ground product per day.

FSIS believes the specific approach it is proposing for use of the moving sum procedure will provide an effective means of ensuring that establishments meet the interim targets for pathogen reduction. Any establishment with positive *Salmonella* results at a frequency exceeding that allowed for the product will be readily identified as failing to meet the targets so that remedial measures can be implemented.

As proposed, the microbiological testing laboratory will supply the test results on a daily basis to the establishment. Results would be passed at least weekly to a Program employee for transmission to the headquarters database. Alternatively, the establishment could transmit the data directly to the headquarters database electronically, under the supervision of a Program employee. In addition to being used to verify establishment participation in the program, this information will be used, in addition to baseline data, for national trend analysis.

The establishment would be responsible for entering the results into a moving sum verification table or chart (see sample of moving sum table below). The moving sum is a procedure where results are summed over a predetermined period of time. The moving sum consists of two basic elements, a specified length of time over which results are summed (n) and a maximum number of positives that are allowable within that time frame (AL). These two parameters are based on the target frequency of occurrence of *Salmonella* in that particular commodity and the statistical decision criteria built into the procedure.

An advantage of a moving sum is once the criteria are set, all that is required is a count of the positive results over the most recent window of results.

For example, a chart where the number of days to be summed is 8 (n=8), and the maximum permitted number of positives during that time frame is 3 (AL=3), showing whether the Acceptable Limit is met or exceeded, might look like the following:

Day No.	Test result	Moving sum	Comparison to AL	Days included
1	0	0	Meets	1.
2	0	0	Meets	1, 2.
3	0	0	Meets	1 to 3.
4	1	1	Meets	1 to 4.
5	0	1	Meets	1 to 5.
6	0	1	Meets	1 to 6.
7	1	2	Meets	1 to 7.
8	0	2	Meets	1 to 8.
9	0	2	Meets	2 to 9.
10	0	2	Meets	3 to 10.
11	0	2	Meets	4 to 11.
12	0	1	Meets	5 to 12.
13	0	1	Meets	6 to 13.
14	0	1	Meets	7 to 14.
15	0	0	Meets	8 to 15.

The daily result is recorded as a 1 for a *Salmonella* positive test and a 0 for a negative *Salmonella* test (e.g., the test for day 4 was positive). The value of the moving sum for day 10, for example, is the sum of the daily results for days 3 through 10. This value is merely the number of positives in this window (two). It meets the Acceptable Limit, AL=3.

Several features of moving sum procedures can be noted in the example: (1) There is a startup period (days 1 to 7) in which there are fewer than n=8 results in the sum; (2) a positive affects the moving sum value for n=8 consecutive days; and (3) the moving sum gives equal weight to all days in the window, from the most remote to most current.

FSIS is proposing to specify the moving sum rules for each product class. The chart below specifies the initial time window values (n) and Acceptable Limit (AL) for each product class:

Commodity	Moving sum rules		
	Target (percent positive for *salmonella*)	Window size (n) in days	Acceptable limit (AL)
Steers/Heifers	1	82	1
Cows/Bulls	1	82	1
Raw Ground Beef	4	38	2
Fresh Pork Sausages	12	19	3
Turkeys	15	15	3
Hogs	18	17	4
Broilers	25	16	5

These moving sum rules are based on two assumptions: That the production process is running in-control at the target level specified for the commodity; and that specimens are randomly selected from the end of the production process. They also reflect an effort by FSIS to ensure that an establishment operating consistently within the target will not exceed the Acceptable Limit for positive samples during the window period (and thus trigger remedial action) while providing a high likelihood that establishments regularly failing to meet the target will be detected.

It is important to recognize that this approach to verifying process control in meat and poultry production is designed to assess the effectiveness of a system over time in relation to a specified target level of performance. It is not a means of evaluating and approving individual product lots. The assumptions of an in-control process and randomly selected specimens allow the performance assessment to be separated from production volume considerations.

A number of alternative statistical criteria were considered as the basis for the proposed moving sum procedures, ranging from an 80 to a 99 percent probability of meeting the limit if the process is operating at the target level. The following table shows these alternatives with their corresponding window sizes and Acceptable Limits for *Salmonella* positives. For reasons discussed below, the 80 percent probability was selected.

Probability of passing at target	Target	Window size (in days)	Acceptable limit
80	1	82	1
	4	38	2
	12	19	3
	15	15	3
	18	17	4
	25	16	5
90	1	53	1
	4	28	2
	12	15	3
	15	12	3
	18	14	4
	25	15	5
95	1	36	1
	4	21	2
	12	12	3
	15	10	3
	18	12	4
	25	11	5
99	1	15	1
	4	12	2
	12	8	3
	15	7	3
	18	8	4
	25	9	5

The alternative procedures differ in the probability they give for not exceeding the moving sum limit when a production process is operating at the commodity target. These probabilities range from 80 to 99 percent.

There are at least four considerations involved in selecting a verification procedure: (1) Sampling and testing costs; (2) the nature of the penalties for failing the verification procedure; (3) having a low probability of exceeding verification limits when the producer is meeting the target; and (4) having a high probability of exceeding limits when the producer is not meeting the target. The procedures based on a 99 percent probability of not exceeding the moving sum limit at the target satisfy consideration (3), but do not satisfy consideration (4). Establishment personnel would be very limited in their ability to detect production processes not meeting the target.

There are two ways to improve the ability of the verification procedure to detect when the production process is not meeting the target. One is to increase the number of specimens required to be tested each day, and the other is to lower the probability of passing at the target. In view of the increase in costs to producers that a higher sampling rate would entail and the fact that failing the test does not condemn product (considerations (1) and (2)), FSIS selected the procedures based on an 80 percent probability of passing at the commodity target. The 80 percent probability was selected because it enhanced the chance of detecting marginal performers and provides establishments with an incentive to gear their process controls to achieve frequencies of *Salmonella contamination* well below the proposed interim targets. FSIS retains the discretion to not require remedial measures by establishments that demonstrate they were meeting the interim targets but exceeded the Acceptable Limits by chance.

To further evaluate the moving sum verification procedures, the Agency simulated their performance at percent positive levels greater than the interim target. As an example, the Agency looked at the distribution of the number of days from startup to the first exceedance of the AL for broilers (target of 25 percent) assuming a process percent positive rate of 30 percent. The first exceedance occurred within 22 days in 50 percent of the trials, and it occurred within 70 days in 95 percent of the trials. In other words, a process running at 30 percent positive rate (5 percent above the target of 25 percent) is very likely to be detected within no more than 70 days.

Under the proposed moving sum rules, an establishment operating just at the target would have approximately an 80 percent long-run probability of satisfying (not exceeding) the moving sum limit. Over the long term, the moving sum value will not exceed the AL about 80 percent of the days, assuming that the production process stays on target. The proposed rules also mean that an establishment operating just at the target has a 20 percent chance of exceeding the Acceptable Limit and triggering remedial action. This is consistent with the Agency's objective in establishing interim targets as a first step toward holding establishments accountable for meeting acceptable levels of food safety performance, because, due to the variability in pathogen levels, establishments consistently operating at or just below the target are likely to exceed the target from time to time.

The selection of 80 percent as the criterion for establishing the proposed moving sum rules is intended to provide establishments with an incentive to design their process controls in a manner that will achieve pathogen reduction significantly below the designated interim target. As in any random sampling scheme, there is a chance of actually having positive results, even if the process is meeting the criteria. However, an establishment can decrease its probability of exceeding the AL (by chance alone) by targeting its process to produce product with a lower frequency of positive samples. For instance, the establishment could gear its process controls toward a 20 percent target as opposed to the 25 percent target specified for broilers. This would benefit the establishment by providing a greater assurance of not exceeding the AL, since its own target is lower than the designated one.

A document giving a more detailed explanation of the moving sum verification procedure will be made available by FSIS to those wishing more information on this aspect of the proposal. Requests should be sent to Assistant Deputy Administrator for Science, FSIS, U.S. Department of Agriculture, Washington, DC 20250. FSIS welcomes comments on alternative ways by which the Agency and establishments may ascertain how well process controls are achieving national target levels.

9. Establishment Action Required for Exceeding Target Limits

The establishment will have 90 days from the effective date of the rule to establish microbiological testing regimes. Six months from promulgation of the regulations establishments will be required to track these interim target results using a moving sum verification procedure and report the results to FSIS. Two years after promulgation of the rules, establishments that are not achieving the interim targets for pathogen reduction will be required to take corrective action under FSIS supervision. In such instances, a review by the establishment of its production practices and process controls is required. A written report of the evaluation, including any identified process failures and proposed corrective actions, would be submitted to the

Inspector in Charge within 14 days from the day the process exceeded the limits. This report would have to be updated on a weekly basis until the process is back within the Acceptable Limit.

During the time the results exceed the moving sum limit, sampling should be conducted at a higher rate of at least two specimens per day. This will provide more accurate and timely data for effective decisionmaking. This increased sampling has the advantage that, assuming that the problem causing the initial deviation from the target limit has been identified and corrected, the extra samples per day will shorten the time frame (window) during which the establishment would be considered operating above targets. The sampling rate would return to normal when the moving sum value meets the AL. Additional testing may be conducted by FSIS, at the Agency's discretion, as necessary to assist firms in meeting pathogen reduction targets.

10. Relationship to HACCP

Once an operation has a history of consistent control and is operating within the established limits, improvements in technology and increased understanding of process control can be used to further enhance pathogen reduction efforts. The continuous review of the production process with corresponding improvements should set the stage for implementation of state-of the-art process controls, namely HACCP.

FSIS is aware of and continues to encourage establishments to implement effective HACCP programs as soon as possible. Establishments that can demonstrate that their HACCP process controls produce only products that meet or exceed the proposed targets for pathogen reduction, and have an alternate verification program may, upon approval by the Administrator, continue their current operating procedure in lieu of the proposed verification program.

All establishments that have slaughter operations or produce raw, ground beef or poultry are required to participate in this program unless prior approval is granted by the Administrator, in a situation where an establishment has instituted a HACCP system. That system includes pathogen testing which, in the judgment of the Administrator, meets or exceeds the testing requirements in the proposed regulations.

11. Alternative Approaches to Establishing Pathogen Reduction Baselines and Targets

The principle underlying the proposed approach to pathogen reduction outlined above is that production of raw meat and poultry with an incidence of *Salmonella* at or below the national incidence level is readily achievable with available technology and production methods and that all establishments should be required in the relative near term to perform at this level. This would establish a national standard for food safety performance on which future pathogen reduction efforts could be built. One potential disadvantage of this approach is that it does not take account of the likelihood that current incidence levels of *Salmonella* contamination vary widely. In the case of broilers, for example, FSIS believes that some establishments are already performing well below the 25 percent baseline incidence found in the FSIS survey—at a 5 percent incidence level or lower—while many establishments are performing well above that level. Some of the poorer performing establishments may not be able to achieve reductions to the targeted prevalence of contamination in the near-term. The better performing companies—ones already performing well below the national baseline—may feel economic pressure to relax their pathogen reduction efforts to compete under a standard that is less strict than they are already achieving.

An alternative approach would be to establish the initial baseline for pathogen reduction on an establishment-specific basis and to require significant interim reductions in each establishment from its baseline. Such baselines would be established on the basis of either reliable existing data from that establishment or on a brief required period of sampling and testing in each establishment for the target pathogen.

This approach would have some advantages. It would take account of the likelihood that current performance in terms of incidence of *Salmonella* contamination varies widely. Requiring, for example, a 50 percent reduction from the establishment-specific baseline would ensure that some pathogen reduction is achieved by all establishments and a larger reduction, in absolute terms, would be required by establishments that currently have higher incidences of contamination. This approach might achieve a greater overall reduction in incidence of contamination, depending on the percent reduction required for each establishment and the actual current distribution of incidence rates across all establishments.

The establishment-specific baseline approach has disadvantages. It would be more difficult to administer because it would require the creation of approximately 2,500 establishment-specific baselines, and it would not be based on the principle that there should be a nationally recognized measure of food safety performance, regardless of the establishment in which a product is produced. The establishment-specific approach would also fail to recognize that some establishments are already operating in accordance with the current state of the art and may have difficulty achieving significant additional reduction in the near term.

The latter concern might be addressed by hybrids of the two basic alternatives outlined above. For example, establishments currently above the national baseline could be required to reduce the incidence of contamination to some level at or below the national baseline, while the better performing establishments could be required to maintain their current level of performance, perhaps within some appropriate range.

FSIS invites public comment on these and other possible alternatives to its proposed approach. At the final rule stage FSIS intends to adopt an approach to setting interim targets for pathogen reduction that takes into account its proposal, the alternatives outlined here, and the comments received during the course of this rulemaking.

C. Hazard Analysis and Critical Control Point (HACCP) Systems

1. Background

Overview of Rationale for Adopting HACCP

After having introduced key HACCP concepts and controls into federally inspected establishments through the proposed near-term interventions and microbial testing program discussed earlier in this document, FSIS would secure its long-term strategy for improving the safety of meat and poultry products by requiring that all such establishments adopt HACCP systems. HACCP is a systematic approach to the identification and control of hazards associated with food production that is widely recognized by scientific authorities, such as the NAS and the NACMCF and international organizations, such as the Codex Alimentarius Commission, and the International Commission on Microbiological Specifications for Foods (ICMSF), and used in the food industry to produce product in compliance with health and safety requirements. HACCP provides assurances and documentation that processes used in manufacturing meat and poultry products are in control

and producing safe, wholesome, unadulterated products.

FSIS is proposing these regulations because a system of preventive controls with documentation and verification of successful operation is the most effective approach available for producing safe food. Emphasis by the regulated industry on improving the control of microbiological hazards in raw and cooked products in conjunction with process control will reduce the risk of disease resulting from the presence of pathogenic microorganisms in meat and poultry products.

HACCP is a conceptually simple system by which meat and poultry establishments can identify and evaluate the hazards that could affect the safety of their products, institute controls necessary to keep these hazards from occurring, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine. The HACCP systems mandated in these proposed regulations will be limited to attributes affecting product safety, as opposed to economic adulteration and quality parameters. If these regulations are adopted, FSIS will verify HACCP system operations as part of its program of continuous inspection.

FSIS is proposing to make HACCP mandatory for the meat and poultry industry for the following reasons:

(1) Adoption of HACCP controls by the meat and poultry industry, coupled with FSIS inspection activities designed to verify the successful operation of the HACCP system, will produce a more effective and more efficient system for ensuring the safety of meat and poultry products than currently exists. HACCP appropriately places responsibility on meat and poultry establishments to demonstrate an understanding of hazards and risks associated with their products and an ability to control the processes they use.

(2) A federally mandated HACCP system will provide the basis for a modernized process control system capable of dealing with all the hazards that might be associated with meat and poultry products currently and in the future—biological, physical, and chemical.

(3) The expertise for applying HACCP to meat and poultry processes and products is in an advanced state of development. Considerable progress in applying HACCP to meat and poultry processes has already been achieved by FSIS and other USDA agencies (e.g., the Extension Service). Work has also been done by other Federal agencies, several States, by academic institutions, by industry trade associations and independent industry members.

(4) HACCP has a broad base of support. In March 1994, a variety of constituent interest groups including consumers, the regulated industry, scientists and other professionals, producers, employee representatives, and other Federal and State governmental representatives endorsed the HACCP approach as embodied in the seven principles set forth by the NACMCF.

Meat and poultry industry representatives have urged the Federal government to institute the mandatory use of a HACCP-based production system for their products. In a recent letter, the American Meat Institute (AMI) has petitioned the Agency to begin rulemaking to mandate HACCP.

Members of the International Meat and Poultry HACCP Alliance strongly support implementation of a mandatory HACCP program. The Alliance consists of approximately 30 industry associations, 10 professional associations, 32 university affiliates, 6 service groups, 6 Government representatives and 5 foreign government representatives.

In its 1993 report, *Creating a Government That Works Better and Costs Less,* Vice President Gore's National Performance Review recommended that: ''[USDA] require all food processing establishments to identify the danger points in their processes on which safety inspections would focus * * * also [to] develop rigorous, scientifically based systems for conducting inspections. * * *''

(5) A federally mandated HACCP system of preventive process controls appears to be a prerequisite to continued access to world markets. For example, the United States' largest trading partner, Canada, has announced its intention to implement HACCP for meat and poultry processes by 1996. Australia and New Zealand are also implementing HACCP-based programs.

(6) Use of the limited public resources available to assure the wholesomeness of the meat and poultry supply can be significantly more effective if all meat and poultry establishments are controlling their processes through HACCP systems. HACCP systems focus attention on hazards to product safety and steps critical for their effective control. HACCP systems generate data that can be used to continuously assess whether the process is in control, and, when deviations occur, what was done to correct the problem. These two characteristics of HACCP systems will mean that inspector attention can be directed to the safety related elements of the process and that inspector review can utilize objective measures of how well the controls have been working.

(7) Implementation of mandatory HACCP systems in inspected establishments permits separation and clarification of the differing roles of establishment and inspection personnel. HACCP is an industry process control system. Holding the industry responsible for the development and effective operation of HACCP systems makes it clear that production of wholesome meat and poultry products is industry's responsibility, not the responsibility of the inspection service. The role of the regulatory agency under HACCP is verification that the establishment is controlling its processes and consistently producing complying products.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food and the products made from it unavoidably entail some risk of pathogen exposure and foodborne illness to consumers. However, since pathogens are not visible to the naked eye, consumers have no way to determine whether the food they buy is safe to handle and eat. When foodborne illness does occur, consumers often cannot relate the symptoms they experience to a specific food—or any food—because symptoms may appear after some time has passed. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable pathogenic microorganisms. When consumers cannot trace an illness to any particular food or even be certain it was caused by food, food retailers and restaurateurs are not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors may have little incentive to incur costs for more than minimal pathogen and other hazard controls. The Agency believes that today about as much process control exists as current market incentives are likely to generate. The existence of significant foodborne illness demonstrates the inadequacy of the status quo. Thus, if foodborne illness is to be reduced, there must be

an increase in systematic process control throughout the industry. FSIS believes this need is best satisfied by a mandated HACCP program.

The Agency invites comment on its rationale for mandating HACCP rather than relying on market incentives to induce voluntary adoption of HACCP. FSIS also invites comment on whether market incentives can be increased or harnessed to improve food safety as a supplement or alternative to the measures proposed in this rulemaking. FSIS invites comment specifically on the role label claims about the safety or safety-related processing of meat and poultry products might play in encouraging and responding to market demand for safer food products.

The Principal Hazards Addressed by HACCP

Meat and poultry products may present physical, chemical or biological (including microbiological) hazards to consumers.

Physical hazards may include extraneous materials of various kinds that could be introduced into product during slaughtering and processing operations. Usually, these extraneous materials (e.g., ''buckshot''; barbed wire, glass or metal pieces) are easily prevented from getting into the product at all and can be detected while the product is still in the inspected establishment. Other physical hazards result directly from slaughtering and processing operations (e.g., bone chips and feathers). Random product examinations and finished product standards are presently used to control these hazards.

Chemical hazards might result from residue contamination, improper formulations, or use of compounds not intended for food purposes. The results from the past several years of FSIS's residue-monitoring program suggest that contamination of the meat and poultry supply with violative levels of chemical residues is relatively rare; although FSIS test results cannot be extrapolated conclusively to all chemicals in all products, 0.29 percent of analyses detected violative residues in 1993. Chemical contamination from improper formulations and inadvertent or incorrect use of non-food compounds is usually prevented by in-plant control activities.

The issue of responsibility for primary control of hazards presented by chemical residues was raised by GAO in its recent report, ''Food Safety: USDA's Role Under the National Residue Program Should be Re-evaluated'' (RCED–94–158). GAO reported that while Federal resources for residue control cannot keep pace with the industry's growth, the industry has recognized that it must ensure, and document that its products comply with applicable residue standards.

* * * the Congress may wish to consider[:]

—Requiring FSIS to establish scientific, risk-based HACCP systems with the industry for residue prevention, detection and control;

—Having FSIS shift primary responsibility for day-to-day residue prevention, detection and control to the industry; and

—Requiring FSIS to adopt a regulatory oversight role designed to ensure the effectiveness of the industry's efforts.

FSIS accepts and agrees with the direction of these recommendations and believes that mandatory HACCP for slaughter and processing operations presents the opportunity to make this shift so that the industry is more completely responsible for the safety of its products with respect to the chemical hazards presented by residues, especially animal drugs.

Biological hazards associated with disease conditions in animals are presently addressed by specific FSIS disease inspection techniques. Hazards include such disease conditions as anthrax, tuberculosis, brucellosis, leukosis, cysticercosis, and other septicemic and toxemic conditions. The detection and control of these hazards is accomplished through ante- and postmortem inspection performed by FSIS employees on livestock and poultry. When, upon examination, livestock and poultry display signs or symptoms of disease, they are condemned or subject to restrictions, such as ''passed for cooking only.'' Parasitic conditions are also the subject of inspection procedures.

Several human pathogens of enteric origin do not normally produce signs or symptoms of disease in animals or birds but will produce foodborne illness in humans. These microorganisms are among the most significant contributors to foodborne illness associated with consumption of meat and poultry products, but present inspection techniques are not effective in detecting and controlling the presence of pathogens on raw products.

Processing procedures used to manufacture ready-to-eat products are designed to destroy pathogenic microorganisms and, if properly conducted, are effective. Microbiological testing is used to verify these processing procedures. In 1993, there were 11 voluntary recalls involving 1.7 million pounds of product for bacterial contamination in ready-to-eat products. These recalls were principally the result of detecting *Listeria monocytogenes*, which is frequently a post-processing environmental contaminant, and not an indication of a failure of the heat treatment procedure to produce a pathogen-free product.

As explained in earlier sections of this document, there is a compelling public health need to establish systematic process controls for raw meat and poultry products, to prevent their contamination by pathogenic microorganisms and to reduce contamination when it unavoidably occurs. These proposed rules will, for the first time, mandate adoption of a system of control for all federally inspected meat and poultry establishments, build on the foundation of the food safety initiatives proposed earlier in this document, provide FSIS an effective means to verify that establishments are meeting their food safety responsibility with respect to pathogenic microorganisms, and provide the basis for the science-based inspection system of the future.

Overview of HACCP Principles

The HACCP approach to food safety was first developed by the Pillsbury Company as a means of assuring the safety of foods produced for the U.S. space program. The National Aeronautics and Space Administration (NASA) wanted a ''zero defects'' program to guarantee safety in the foods astronauts would be consuming in space. When NASA and Pillsbury critically evaluated available systems for ensuring food safety, they found that, even when very large numbers of finished product samples were tested, a relatively large percentage of potentially hazardous product could still be accepted. Pillsbury then introduced and adopted HACCP as a system that could provide the greatest assurance of safety while reducing the dependence on finished product sampling and testing. HACCP, by virtue of identifying the hazards inherent in the product and process, and devising preventive measures that could be monitored, would control the process. Pillsbury recognized that HACCP offered real-time control of the process as far upstream as possible by utilizing operator controls and continuous monitoring. Through this approach, Pillsbury dramatically reduced the risk of microbiological, chemical, and physical hazards by anticipation and prevention rather than inspection.

The presentation of the HACCP system by the Pillsbury Company at the 1971 U.S. National Conference on Food Protection led to gradual recognition of the value of the HACCP approach. This

was reflected in the incorporation of the HACCP principles into FDA's regulations for low-acid canned foods in 1973 to address serious botulism problems in the canning industry. During the intervening years, the concepts and rationale for utilizing the HACCP approach have slowly gained acceptance throughout the food industry and scientific community.

The USDA and the Department of Health and Human Services (HHS) established the NACMCF in 1988 at the recommendation of the NAS to advise the two departments on food safety issues. In 1992, the NACMCF endorsed HACCP as an effective and rational means of assuring food safety from harvest to consumption.

The Committee formulated seven principles to be employed in the development of HACCP plans. These principles include hazard assessment, critical control point identification, establishing critical limits, monitoring procedures, corrective actions, recordkeeping, and verification procedures. Under such a system, if a deviation occurs indicating that control has been lost, appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous product does not reach the consumer. A complete description of the seven HACCP principles recommended by the NACMCF can be found in the Committee's March 20, 1992, publication, ''Hazard Analysis and Critical Control Point System.'' As outlined in a later section, FSIS has adopted the seven HACCP principles as articulated by the NACMCF, and is proposing that all HACCP plans include the principles. A discussion of the seven HACCP principles and associated HACCP plan elements follows:

Principle No. 1: Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur, and describe the preventive measures.

The first step in establishing a HACCP system for a food production process is the identification of the hazards associated with the product. NACMCF defined a hazard as any biological, chemical, or physical property that may cause a food to be unsafe for consumption. For inclusion in the list, the hazard must be of such a nature that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food. Hazards that involve low risk and severity and that are not likely to occur need not be considered for purposes of HACCP. Examples of several questions to be considered in a hazard analysis include: (1) Does the food contain any sensitive ingredients? (2) Does the food permit survival or multiplication of pathogens or toxin formation during processing? (3) Does the process include a controllable processing step that destroys pathogens? (4) Is it likely that the food will contain pathogens and are they likely to increase during the normal time and conditions under which the food is stored prior to consumption? (5) What product safety devices are used to enhance consumer safety (e.g., metal detectors, filters, thermometers, etc.)? (6) Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins? and (7) Is the product epidemiologically linked to a foodborne disease?

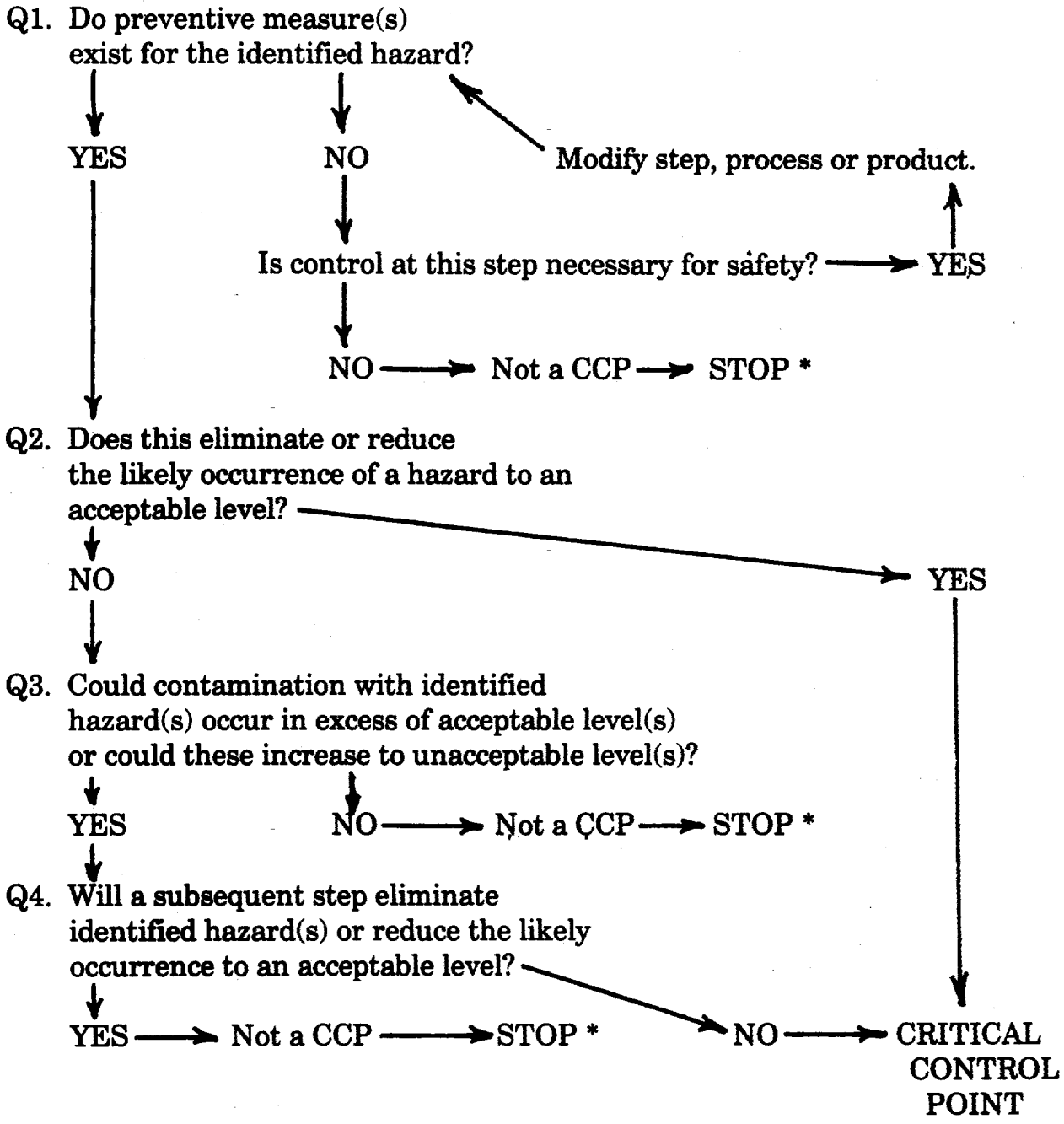
Principle No. 2: Identify the CCP's in the process.

A critical control point (CCP) is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All significant hazards identified during the hazard analysis must be addressed.

The information developed during the hazard analysis should enable the establishment to identify which steps in their processes are CCP's. To facilitate this process, the NACMCF developed a CCP decision tree which can be applied to an identified hazard at each step of the process (see Figure 3, below). The decision tree asks a series of ''yes'' or ''no'' questions to assist in determining whether a particular step is a CCP.

BILLING CODE 3410–DM–P

Figure 3. CCP Decision Tree (Apply at each step of process with an identified hazard.)



* Proceed to next step in the described process.

BILLING CODE 3410–DM–C

Examples of CCP's may include, but are not limited to: cooking, chilling, specific sanitation procedures, product formulation controls, prevention of cross contamination, and certain aspects of employee and environmental hygiene. All CCP's must be carefully developed and documented.

Consistent with the principles of the NACMCF, FSIS is proposing to require that establishments identify CCP's for food safety hazards in their HACCP plans. All three types of hazards (physical, chemical and biological, including microbiological) must be addressed and controlled.

FSIS believes that implementation of mandatory HACCP, in conjunction with related changes described elsewhere in this document, will result in less risk of foodborne illness being associated with these products. Therefore, identification of CCP's throughout the production process for controlling microbial hazards is particularly important.

Principle No. 3: Establish critical limits for preventive measures associated with each identified CCP.

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Another way of considering critical limits is that they serve as boundaries of safety for each CCP.

Critical limits are most often based on process parameters, such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information, such as texture, aroma, or visual appearance in relation to the growth or survival of target pathogens or chemical or physical hazards. Establishment of critical limits should be justifiable in relation to knowledge available from such sources as the meat and poultry regulations or guidelines, literature, surveys, experimental studies, or from recognized experts in the industry, academia, or trade associations.

In accordance with the principles set forth by NACMCF, FSIS is proposing that processors identify critical limits in their HACCP plans that must be met at each CCP to be certain that the hazard is controlled. Critical limits must reflect relevant FSIS regulations, FDA tolerances, and action levels where appropriate. Processing establishments are encouraged to establish critical limits more stringent than those now in FSIS regulations or related documents to ensure that regulatory requirements are routinely met even when deviations occur. If critical limits more stringent than regulatory limits or requirements are set, then the establishment must meet those more stringent limits.

Principle No. 4: Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Monitoring is observations or measurements taken to assess whether a CCP is under control. Monitoring is used to determine when a deviation occurs at a CCP; therefore, monitoring procedures must be effective. There are many ways to monitor CCP critical limits on a continuous or batch basis; however, continuous monitoring is always preferred. When continuous monitoring is not feasible, frequencies must be sufficient to ensure that the CCP is under control. Statistically designed data collection or sampling plans need to be developed in such instances.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Personnel assigned the monitoring activities must be properly trained to report all results, including any unusual occurrences, so that adjustments can be made and any processes or products that do not meet critical limits are identified so that immediate corrective actions may be taken.

Monitoring activities are necessary to assure that the process is in fact under control at each critical control point. Some monitoring procedures could be accomplished by automatic instruments and devices such as time/temperature recording devices. Some monitoring procedures could consist of checks performed, with outcomes recorded. Other monitoring procedures might involve rapid testing technologies that provide feedback within appropriate time frames, for example, the use of quick tests to verify levels of chlorine in poultry chillers.

HACCP requires establishments to systematically monitor, control, and, where necessary, adjust their production processes to meet a specified standard. Process monitoring may necessitate materials or devices to measure, test, or otherwise evaluate the process at critical control points. Examples would be such items as thermometers and test kits.

FSIS is proposing to require that procedures for monitoring each CCP be identified in the HACCP plan. These monitoring procedures should assure that the monitoring systems are capable of detecting process deviations, including product segregation and holding procedures, effect of deviations on product safety, indicators for modification of the HACCP plan, and the establishment employee responsible for monitoring activities.

Principle No. 5: Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

A HACCP system is designed to identify potential health hazards and to establish strategies to prevent their occurrence. However, ideal circumstances will not always prevail in a processing operation and deviations will occur. In such instances, the NACMCF points out that corrective action plans must be in place to: (1) determine the disposition of the non-compliant product and (2) identify and correct the cause of the deviation to regain control of the CCP. Individuals who have a thorough understanding of the process, product, and HACCP plan should be identified and assigned responsibility for making decisions. When appropriate, scientific experts must be consulted to determine disposition of the product.

FSIS is proposing to require that establishments describe in their HACCP plans the corrective actions that will be taken if a critical limit is not met. Corrective actions must be specified in sufficient detail to ensure that no public health hazard exists after these actions have been taken. Although the process of developing a HACCP plan emphasizes organized and preventive thinking about what is occurring as the meat or poultry product is being manufactured, the existence of a HACCP plan does not guarantee that problems will not arise. For this reason, the identification of a planned set of activities to address deviations is an important part of a HACCP plan.

Principle No. 6: Establish effective recordkeeping procedures that document the HACCP system.

The NACMCF points out that an establishment's HACCP plan and all associated records must be maintained on file at the establishment, and provides several examples of records that could be maintained, such as those relating to incoming ingredients, product safety, processing, packaging, storage, and distribution, deviations and corrective actions, and employee training.

A HACCP system will not work unless records are generated during the operation of the plan, and those records are maintained and available for review. One of the principal benefits of a HACCP process control system to both industry and regulatory officials is the availability of objective, relevant data. Thus, FSIS is proposing to require that the HACCP plan provide for a recordkeeping system that will

document the establishment's CCP monitoring, verification activities, and deviation records. FSIS has also concluded that recordkeeping systems are much more effective when they include the actual values obtained, as opposed to terms such as ''satisfactory'' or ''unsatisfactory,'' which reflect a judgment about the values and do not permit trend analysis.

Principle No. 7: Establish procedures to verify that the HACCP system is working correctly.

The NACMCF defines verification as the use of methods, procedures, or tests in addition to those used for monitoring, to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation. Four processes are identified as steps in the establishment's verification of its HACCP system.

The first process is the scientific and technical process to verify that all critical limits at CCP's are adequate and sufficient to control hazards that are likely to occur in their specific process(es). This is commonly referred to as ''validating'' the process.

The second process is to ensure that the HACCP plan functions properly. Establishments should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate management decisions and product dispositions are made when deviations occur.

The third process consists of documented periodic reviews to ensure the accuracy of the HACCP plan. Such reviews should include an on-site review and verification of all flow diagrams, CCPs, critical limits, monitoring procedures, corrective actions, and records maintained.

The fourth and final verification process deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily. This verification can be viewed as an overall process validation and can consist of any and all of the verification activities mentioned above, plus final product testing to demonstrate compliance with regulatory as well as other desired performance standards.

FSIS is proposing to require that the HACCP plan include a set of verification tasks to be performed by establishment personnel. Verification tasks will also be performed by FSIS personnel. However, an important benefit of HACCP is for establishments to take full responsibility for producing a safe product. Thus, it is envisioned that establishments, as well as the regulatory agency, will undertake final product testing as one of several verification activities. Verification tasks provide an opportunity to demonstrate that a well-functioning HACCP system is in fact controlling a process so that safe product is being produced under conditions that minimize preventable risks.

The verification principle also links HACCP with the key element of the FSIS regulatory strategy for pathogenic microorganisms, which is the establishment of public health-oriented targets, guidelines, or standards establishments must meet to engage in commerce. Without some objective measure of what constitutes an acceptable level of food safety performance with respect to pathogenic microorganisms, it would be impossible to determine whether an establishment's HACCP plan is acceptable and functioning effectively. FSIS is taking the first step toward implementation of such objective measures with the proposed interim targets for pathogen reduction, which focus on *Salmonella.* As data become available, these targets will be refined, and possibly expanded in slaughter operations and extended in processing operations, to support the Agency's implementation of HACCP. Verification might well include required microbial testing for all processes and species. Eventually, such testing can be expected to be an integral part of HACCP verification.

FSIS Experience With HACCP

(1) FSIS HACCP Study, 1990–1992.

In 1990, FSIS initiated a study of HACCP that focused on how this system of process control could be applied within the meat and poultry industries and what the implications might be for regulatory inspection activities. This study was not designed to establish the efficacy or benefit of the HACCP approach as a process control system. Recognition of HACCP as a proven method for preventing and controlling food safety hazards has been achieved through practical application of the concepts to food production operations since 1971.

Recognizing that acceptance of HACCP within the meat and poultry industries would be dependent on a broad range of constituent support, the FSIS study involved consultations and public hearings; technical workshops with representatives of industry, academia, and trade associations to develop generic HACCP models; and testing and evaluation of in-plant trials through case studies. In-plant testing involved operational application of generic models for refrigerated foods, cooked sausage, and poultry slaughter in nine volunteer establishments.

The study underscored the significance of the change in roles and responsibilities that use of a HACCP system brings both to the regulated industry and to the inspection service. This finding would later be supported by observations at a Round Table meeting on HACCP in 1994 that successful HACCP implementation will demand a culture change within the inspection service and within the industry. Additionally, the Agency's earlier experiences with HACCP-based regulations, such as those for low-acid canned foods, cooked roast beef, and, more recently, for cooked, uncured patties had demonstrated the advisability of technical collaboration. The study experience confirmed these earlier conclusions that technical collaboration was essential to successful implementation of HACCP.

(2) HACCP Round Table, 1994.

FSIS was proceeding during 1993 to develop a HACCP regulation when a group of concerned constituent organizations requested greater pre-proposal involvement and public consultations prior to publication of proposed regulations. USDA agreed to have a public event at which the application of HACCP in the meat and poultry industry could be discussed. This event became known as the HACCP Round Table.

On March 30 and March 31, 1994, FSIS held a two-day Round Table meeting in Washington, D.C. Participants in the Round Table were primarily selected by a procedure announced in the **Federal Register** on January 13, 1994. Participants included public health officials, representatives from the meat and poultry industry, consumer groups, scientists and professional scientific organizations, producer and farmer groups, USDA and other Federal, State, and local employees. Prior to the Round Table, a steering committee of nine of the Round Table participants determined the key issues to be addressed during the forum. For each key issue, a particular question was developed to focus the deliberations. Each issue, question, and deliberation is summarized below. FSIS's views on those issues addressed by this regulation are covered under ''Discussion of HACCP Proposal'' below. A report on the HACCP Round Table has been published and is available from the FSIS Docket Clerk at the address provided under **ADDRESSES**.

HACCP Plan Approval: What is the best way to ensure that HACCP plans effectively incorporate the seven HACCP principles?

There was broad support for incorporating the seven HACCP principles into HACCP plans. Different perspectives were expressed concerning the means by which this might be achieved. These perspectives ranged from having plans developed by certified experts, to the use of objective baseline data from industry operations, and to the use of generic models. Having and applying generic models and guidelines to plant specific situations was considered desirable.

Training/Certification: What should be the role of FSIS with regard to industry HACCP training?

This question generated discussion on three components: (1) HACCP curricula, (2) training approaches, and (3) certification requirements. The centrality of training to successful implementation of HACCP is reflected in the broad range of perspectives offered. Curricula concerns ranged from the need for uniform training on principles, to the need for specific training on application of the principles within a particular establishment operation, to the need for joint training between inspectors and industry employees. Training approaches touched on the need for training to be both available and affordable, and the potential for training development and delivery to occur within various private sector organizations as well as academia. Certification requirements addressed the alternatives of having HACCP-trained personnel in establishments, having HACCP consultants available on-call, and having some type of certification process for such individuals.

Phase-in: Should the mandatory HACCP requirement be phased-in and, if so, how?

There was broad support for the notion of phasing-in HACCP requirements, since allowing enough time for the HACCP program to develop and grow is deemed critical for its success. Proceeding on a deliberate schedule allows for an orderly transition within the industry and permits adjustments of the regulatory infrastructure to suit the HACCP structure within inspected establishments. A variety of approaches to phase-in and timing were offered. A second point raised was that the phase-in should take advantage of existing HACCP knowledge and expertise, advancing first those industry segments whose process control operations are more closely aligned with HACCP. A third point offered was that the phase-in should provide for a transition or trial period as application of HACCP occurs within a particular establishment.

Measures of Effectiveness: How can it be determined initially, and on a continuing basis, that HACCP plans are working effectively?

Participants discussed the need to develop measures of effectiveness for HACCP plans. These ranged from the use of baseline data on the process, establishment, and product level; to the use of microbial, physical, and chemical guidelines; to the use of in-process, as well as end-product testing; to the openness and accessibility of data and records on selected measures of effectiveness. There was considerable discussion concerning the need for finished product testing to support verification of a HACCP program. The area of greatest controversy was the need for microbial testing and the development of microbial guidelines in conjunction with the need for finished product testing. Different perspectives were offered on these issues, on how such testing could be accomplished, and on the practical limits of detection, sample collection, and testing.

Compliance/Enforcement: What are the best ways to adequately enforce and ensure compliance with HACCP requirements?

Participants presented views on the types of regulatory authority that would be appropriate in a mandatory HACCP system. Viewpoints ranged from those who believed that current enforcement authorities are adequate, to those who stated a need for new authorities (e.g., civil penalties) and those who believed a review of enforcement authorities should be undertaken to reflect the changes in roles and responsibilities between the industry and the inspection service. There was significant discussion concerning deviations from HACCP requirements and how these deviations should be handled, including appropriate enforcement responses to repeated deviations from the HACCP plan. Here, two major points of view were articulated. The first view was that any deviation from a HACCP plan could result in a regulatory remedy (rather than criminal remedy) and that a deviation from a CCP, while a food safety concern, should result in a regulatory response related to the level of severity (in terms of risk to human health) of the deviation. The second view was that any deviation from the HACCP plan constitutes adulteration, hence a violation of law subject to enforcement action. This view holds that, since HACCP is intended to address potentially serious food safety hazards, a deviation is a violation. A final point of discussion on this issue was employee protection from reprisals for reporting food safety hazards (e.g., whistleblower protection for industry employees).

Relationship and Effect of HACCP on Current Inspection Procedures: To what extent will the possible changes in the regulated industry impact on possible changes in the current inspection system?

Discussion on this issue centered on five points: Modification of inspection procedures to take advantage of HACCP plans; advantages and disadvantages of continuing current regulatory programs until HACCP is fully implemented; ways to combine HACCP and the current inspection system; the extent to which changes in industry will affect changes in inspection; and the potential effects of HACCP on small establishments. Modification of inspection procedures to take advantage of HACCP plans generally follow NACMCF recommendations that regulatory verification of HACCP plans can be accomplished in lieu of, rather than adding to, existing procedures. This would permit reallocation of inspection resources to food safety concerns and away from quality attributes and aesthetic concerns. HACCP should not invite an arbitrary reduction in the inspection force and the numbers of inspectors should not be tied to HACCP implementation. The potential effects of HACCP on small establishments were noted, along with the view that some accommodation during implementation should be afforded to these establishments.

All issues raised and discussed during the HACCP Round Table were taken into account in formulating this proposal.

FSIS Experience With Process Control

(1) Current Application of Hazard Analysis to Meat and Poultry Processing.

The principle of hazard analysis has been utilized to prevent foodborne illness associated with specific meat and poultry products and to support regulatory process control for certain voluntary procedures. The examples discussed below represent FSIS's early efforts using hazard analysis to identify CCP's in a production process and to establish stringent regulatory requirements for controlling production processes. Whereas the earlier regulations were prescriptive, the current proposal is performance based, and holds the industry fully responsible for conducting the hazard analysis and identifying the CCP's and critical limits associated with producing products that minimize the risk of foodborne illness.

(a) Low-Acid Canned Foods

The low-acid canned food industry has had a remarkably good record over the past 50 years, during which more than 1 trillion cans of commercially canned foods were consumed. Beginning in 1970, however, botulinum toxin and *C. botulinum* were found in commercially canned product produced under the jurisdiction of both FDA and USDA. From 1970 until 1990, nine incidents of botulinum outbreaks occurred, resulting in death on six occasions. The products implicated included mushrooms, peppers, salmon, boned turkey, chicken vegetable soup, tuna, and bean salad.

In response to the botulism outbreaks, the canning industry identified CCPs that must be controlled and monitored to ensure that canning operations produce safe canned foods. For products under its jurisdiction, FDA in 1973 codified the CCPs into a good manufacturing practice regulation for thermally processed low-acid canned foods packed in hermetically sealed containers(21 CFR 110).

Since FDA's promulgation of that regulation (revised in 1978), the threat of botulism in canned product has been greatly reduced. While sporadic incidents continue, investigations of such incidents have attributed the causes to establishments' failure to comply with the regulation rather than inadequacies in the regulation.

To address problems in the canned meat and poultry industry, in 1986 FSIS promulgated HACCP-based low acid canned food regulations similar to those of the FDA. CCPs identified in those regulations were incorporated into the Agency's Performance Based Inspection System, so that inspectors' tasks include verification of establishments' compliance with the regulations. Incidents of foodborne illness involving canned meat and poultry products that occurred following the publication of the rules have been attributed to establishments' noncompliance with the regulations.

(b) Commercially Processed Cooked Roast Beef

Five outbreaks of salmonellosis associated with the consumption of commercially processed cooked beef products occurred in the northeastern United States from 1975 until 1981. These outbreaks resulting from five different serotypes of *Salmonella*, caused up to 200 reported cases of illness per incidence.

FSIS responded to the outbreaks by supervising the voluntary recall and destruction of thousands of pounds of affected product on a case-by-case basis. Additionally, whole, intact, cooked roast beef products from several establishments were sampled and found positive for salmonellae. As a result of the outbreaks, it became apparent that salmonellae contamination of cooked beef products needed to be addressed on an industry-wide basis.

In 1977, FSIS promulgated a regulation requiring that all cooked beef products be prepared by ''a cooking procedure that produces a minimum temperature of 145 degrees F in all parts of each roast'' to destroy any salmonellae that might be present. This regulation was amended in 1978 to provide alternate cooking times and temperatures to preserve the rare appearance of the product but still destroy all salmonellae. (See 9 CFR 381.17.)

During the summer of 1981, eight additional outbreaks of the disease were linked to the consumption of roast beef produced by four separate establishments in the northeastern United States.

Epidemiologic investigations revealed that inadequate cooking times and temperatures were not the major problems. A new regulation was implemented in 1983 that addressed the necessary handling, processing, cooling times and temperatures, and storage requirements to ensure the wholesomeness of cooked roast beef.

In total, the changes that evolved in the roast beef regulations represented a HACCP approach in identifying the CCP's in roast beef processing that must be monitored and controlled by an establishment to ensure production of unadulterated product. These HACCP-based CCP's have subsequently been incorporated into the FSIS-PBIS system for scheduling inspectors' tasks in establishments that produce cooked roast beef. Since 1983, no confirmed salmonellae outbreaks have been traced to commercially prepared roast beef.

(c) Uncured Cooked Meat Patties

In response to recent outbreaks of foodborne illness caused by *E. coli* 0157:H7, FSIS promulgated a rule dealing with the heat-processing, cooking, cooling, handling, and storage requirements for uncured meat patties. HACCP principles were used to identify CCP's, critical limits, and corrective actions; as a result, cooking times and temperatures, cooling requirements, sanitary handling and storage practices, and requirements for the handling of heating or cooling deviations were established. The CCP's identified in that rule have been incorporated into the Agency's PBIS for scheduling inspector tasks to ensure establishments' compliance with the regulations.

The ''Heat Processing Procedures, Cooking Instructions, Cooling, Handling and Storage Requirements for Uncured Meat Patties'' (8/2/93 at 58 FR 41151) incorporated HACCP concepts (CCPs, critical limits, corrective actions, etc.) associated with the manufacture of uncooked, partially cooked, char-marked, comminuted products.

(d) Current Process Control Systems

The development and implementation of standardized process control procedures, such as Total Quality Control (TQC) systems and Partial Quality Control (PQC) programs have been part of an effort to focus the responsibility for compliance on the processing establishment. FSIS first began approving industry operated quality control programs in the mid 1970's. The QC policy evolved throughout the late 1970's until in 1980 when it was codified in 9 CFR 318.4 and 381.145 providing a regulatory basis for FSIS policies for PQC and TQC. At present, there are over 9,000 approved PQC programs in operation in inspected establishments and 361 approved and operating TQC systems.

TQC systems are defined by regulation as plans or systems for controlling product after antemortem and postmortem inspection throughout all stages of preparation adequate to result in product being in compliance with the regulations (9 CFR 318.4(c) and 381.145(c)). This definition had traditionally been interpreted to mean that an establishment's TQC system must include control for all aspects of a process. By regulation, PQC programs may be approved for controlling the production of individual products, individual operations within the establishment, or parts of operations (9 CFR 318.4(d) and 381.145(d)).

In processing establishments, most approved PQC programs are designed to control economic and quality aspects of meat and poultry products, such as net weight and label claims. Such PQC programs are generally voluntary or are a condition of label approval. A smaller number of procedures operate to control product wholesomeness factors and are mandated in current regulations. These include the production of cooked roast beef (§ 318.17), mechanically deboned product (§ 319.5), and irradiated poultry product (§ 381.145). In addition, some PQC programs are approved as alternative procedures to regulatory requirements such as handling thermal processing deviations (§§ 318/381.308) and finished product inspections (§§ 318/381.309) of shelf stable canned

meat and poultry products. In slaughter establishments, PQC programs are designed to control economic, quality, and some product wholesomeness aspects of production. Such programs include finished product standards, preoperational sanitation and carcass presentation. All slaughter PQC programs are voluntary.

Preventive systems of process control have been formally employed in the slaughter of broilers and Cornish game hens since 1983, and in the slaughter of turkeys since 1984. These process control approaches are integral features of inspection systems known as the New Line Speed (NELS) inspection system for broilers and cornish game hens, and the New Turkey Inspection System (NTIS) for turkeys (9 CFR 381.76). Forty-five establishments operate under NELS today, and 27 establishments operate under NTIS.

Under these slaughter process control systems, the establishment demonstrates compliance with regulatory requirements by identifying the points in the slaughter process that are important to regulatory compliance. The establishment then sets realistic standards for these points, and observes them often enough to detect deviation from a standard before non-compliance occurs. The establishment also identifies action it will take if a standard is not met. The written program and the generated records of observations and actions are evidence of the degree of process control and regulatory compliance. By reviewing and evaluating establishment records and verifying them with process observations as necessary, FSIS inspection personnel ensure an establishment is meeting its responsibility to produce safe and wholesome product.

The principal difference between slaughter process control systems in place in NELS and NTIS establishments today, and the proposed HACCP system is the focus of the systems. NELS and NTIS were designed not only to address safety hazards associated with raw poultry carcasses, but quality factors as well. The proposed HACCP system focuses on hazards associated with safety of product.

International Efforts on HACCP

Between 1990 and 1992, a working group of the Codex Committee on Food Hygiene developed a guideline document that covered the principles and application of HACCP to all sectors of the food chain from producer to consumer. The Codex Alimentarius Commission in 1993 adopted the HACCP document that now serves as a benchmark for countries to incorporate HACCP principles into their food industries. The seven HACCP principles adopted by the Codex Alimentarius Commission are identical to those proposed in this rule with the exception that HACCP principles six (i.e., recordkeeping) and seven (i.e., verification) are reversed.

In 1993, Agriculture Canada implemented a Food Safety Enhancement Program, which is designed to encourage the adoption of HACCP principles across all agri-food processed commodity groups and shell eggs. The food industry will be required to control and monitor its manufacturing process and maintain records at CCP's. FSEP will also provide a means to help government inspectors prioritize their responsibilities and focus their attention on CCP's in the process to ensure the production of safe food. Full implementation of the FSEP program is scheduled to be completed by September 1996.

Recently, the European Union (EU) adopted two Directives that made reference to the HACCP system. One Directive (93/43/EEC) focuses on the hygiene of foodstuffs and specifies that food business operations must identify and control any step in their process critical for ensuring food safety using the HACCP system. The other Directive (92/5/EEC) is one specific to meat products, which also embraces HACCP principles. These Directives were adopted on June 14, 1993 and February 10, 1992, respectively. EU members have up to 30 months from the date of adoption to implement the provisions of the Directives into national law. Detailed guidelines are now under development for meat products.

New Zealand has also been proactive in adopting HACCP principles in the food industry. Through the publication of *Guide to the Implementation of Hazard Analysis and Critical Control Point Systems in the Meat Industry*, the Ministry of Agriculture and Fisheries provided: (1) a generic model from which an understanding of the HACCP approach to food safety can be obtained; (2) a guide to the application of HACCP systems, especially in the case of raw foods; and (3) specific examples of application.

Adopting a HACCP system could potentially enhance international trade opportunities for the United States. Although enhancing trade has no direct effect on public health, participation in international trade in food products is critical to the U.S. economy. The United States is by far the world's major food exporter, with exports of raw agricultural and processed food products of over $40 billion per year. The United States also imports a substantial quantity of food products each year from many countries around the world. HACCP will improve FSIS's ability to monitor imports and thus ensure greater confidence in their safety. Also, HACCP is becoming the world-wide standard to ensure the safety of food and will thus serve as the basis for harmonizing U.S. food safety regulations with those of other nations.

The Uruguay Round Negotiations under the General Agreement on Tariffs and Trade (GATT) has resulted in further focus on this area. The Agreement on the Application of Sanitary and Phytosanitary Measures states the desire of member countries including the United States, to further ''* * * the use of harmonized sanitary and phytosanitary measures between members, on the basis of international standards, guidelines, and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission * * *''. This trend toward harmonization coupled with the current recommendations of the Codex Alimentarius Commission encouraging the international use of HACCP, provide further support for FSIS's proposal for a mandatory HACCP program for the production of all meat and poultry products.

FSIS Guidance on Development of HACCP Plans

FSIS believes that it can facilitate development of HACCP plans in various ways without compromising the principle that these are industry process control plans and, as such, plan development is the responsibility of the regulated establishment. Therefore, FSIS has underway a series of planned assistance efforts, which will continue and be completed over the next 6–12 months.

(a) Generic Models: FSIS has published the generic models developed at Agency workshops and will publish generic models developed by NACMCF as they become available. An example, the ''Generic HACCP for Raw Beef,'' is provided in the Appendix.

FSIS has categorized in this proposed regulation all processes carried out in the establishments it regulates. Because FSIS pilot-testing has shown generic plans to be useful to establishments as they develop plans specific to their own processes and products, FSIS will publish and make widely available a generic model for each of the nine process categories at least six months in advance of the due date for each process category. FSIS believes that use of

generic plans will assist in assuring the basic level of uniformity necessary to have inspection activities based on establishment HACCP plans, and that the provision of generic models will help to communicate the level of detail expected in the elements of the plan. FSIS also believes that generic models can help identify the kinds of hazards that should be considered at various CCP's, without interfering with the establishment's hazard analysis.

(b) NACMCF Materials: FSIS is publishing and will make widely available guidance materials developed by NACMCF describing the optimum steps to be followed in developing HACCP plans. In addition, FSIS is currently exploring the most effective and economical approach to developing a HACCP videotape.

(c) Computer Packages: FSIS is aware of commercially available software programs that might assist food processors in developing HACCP plans. FSIS has made a commitment to work with companies developing these programs to make them more applicable to meat and poultry processes.

2. Discussion of HACCP Proposal Regulatory Considerations

Process control is neither FSIS's responsibility nor a shared responsibility between the Agency and industry. Each USDA inspected establishment must assume full responsibility for making safe and wholesome products. FSIS is responsible for assuring that products in marketplace distribution are unadulterated, wholesome, and accurately labeled. From a public health perspective, the more that industry process controls anticipate and prevent problems, the less likely products produced under such systems are to become adulterated.

HACCP is not an inspection system; it is an industry process control system that provides opportunities to make inspection more effective. Currently, FSIS performs inspection by having inspectors generate information about the establishment's production process and environment to evaluate the conditions under which meat and poultry products are being produced. This activity permits oversight of establishment efforts at the time of inspection. In contrast to this relatively small amount of information, HACCP records will enable inspectors to see how the establishment's processes have operated on a continuing basis over time. The Program employee will be able to determine whether problems have occurred and, if so, how they were addressed.

In addition to providing a greater quantity of information and in effect extending the scope of regulatory observations, the presence of functional HACCP plans for all products and processes will also produce more relevant data. This is because the monitoring and recordkeeping requirements of a HACCP plan are organized around identified hazards, CCP's, critical limits, and the actions taken to ensure that defects are corrected before they become a risk. Finally, HACCP systems will yield data that are more objective and more scientific.

(1) Definitions

For the purposes of this discussion and within this proposed rule, FSIS has adopted some definitions of terms related to HACCP and HACCP systems from the NACMCF in the publication titled ''Hazard Analysis and Critical Control Point System,'' dated March 20, 1992; these definitions are noted by ''*''. Other definitions are specific to FSIS and its activities.

Corrective action. Procedures to be followed when a deviation occurs.*

Criterion. A requirement on which a judgment or decision can be based.*

Critical Control Point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*

Critical Control Point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.*

Deviation. Failure to meet a critical limit.*

HACCP. A hazard analysis and critical control point system (HACCP) that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.*

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to meat and poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

HACCP system. The result of the implementation of the HACCP plan.*

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.*

Hazard Analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.*

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.*

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's are identical, except that optional operations or CCP's, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, meat, meat byproduct, or meat food product, poultry, or poultry food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees, which satisfies the following: consists of at least three days, one day devoted to understanding the seven principles of HACCP, one day devoted to applying these concepts to this and other regulatory requirements of FSIS, and one day devoted to beginning development of a HACCP plan for a specified process.

Responsible Establishment Official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.*

(2) HACCP Plans

(a) Basis of Required Elements

The question of adherence to the seven principles of HACCP as defined by the NACMCF has been considered by FSIS since it began HACCP activities.

FSIS has determined that the scientific and conceptual integrity of HACCP as articulated by NACMCF is critical to its success and to public acceptance of inspection systems based on it. FSIS believes that each principle is important to achieving the objectives of HACCP and that the support of the scientific, technical, and industry communities for HACCP rests on its overall integrity. Furthermore, the external advice from such bodies as NAS and GAO recommending HACCP implementation assumed adoption of all seven principles. Therefore, the Agency has determined that its regulatory requirements will be founded on HACCP principles as articulated by NACMCF. Comments are invited on this fundamental premise of the FSIS proposed regulation.

(b) Required Elements

FSIS is proposing to require that inspected establishments develop HACCP plans that include: identification of the processing steps that present hazards; identification and description of the CCP for each identified hazard; specification of the critical limit, which may not be exceeded at the CCP and, if appropriate, a target limit; description of the establishment monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded and the individual responsible for taking corrective action; description of the records that will be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Critical limits currently a part of FSIS regulation or other requirements must be met. FSIS invites comment on permitting approval of alternative procedures if sound scientific reasons and data are provided.

FSIS is proposing that the HACCP plan be signed by the responsible establishment official as an indication of his or her accountability for the plan. Comment is invited on the merits of such a requirement as a method of ensuring and demonstrating establishment commitment to, and formal adoption of, the plan.

(3) Overview of Plan Content and Format; Consistency With FDA

FSIS is aware that a large number of food producing companies are regulated by both FDA and USDA. Earlier this year, FDA proposed to mandate HACCP for seafood processors (59 FR 4142, January 28, 1994). In formulating the proposal presented in this document, FSIS has tried to assure conceptual uniformity and consistency with FDA on the practical details to the greatest extent possible. However, differing statutes are administered by the two agencies and each species—livestock, birds and fish and shellfish—differ significantly.

In many important respects, the FSIS and FDA HACCP programs are fully consistent. The same underlying principles of HACCP form the foundation of the two programs. Both programs have the goal of improving the microbial profile of regulated food products and, thereby, reducing the incidence of foodborne illness that might be associated with these foods.

Both programs require that establishments: develop HACCP plans that address the health and safety aspects of their processes; have access to at least one HACCP-trained individual; and recognize and carry out their responsibility to control sanitation as a prerequisite to HACCP.

In addition, both regulatory programs are similar in that operational success is the mechanism for acceptance of establishment HACCP plans; verification tasks of all types will be conducted by regulatory officials; and FSIS and FDA will attempt to provide assistance to establishments through the development of guidance materials or generic models from which industry efforts can begin.

FSIS is recommending that the format used in its generic models and those of the NACMCF be followed by all establishments; however, Agency personnel will be flexible in this matter and consider alternative formats that ensure that both establishment and inspection personnel can readily identify the hazards, the CCP's and the specific critical limits, plus actions and records that should be associated with each. The generic models are to provide guidance, not serve as blueprints, and not substitute for process controls. FSIS proposes to publish and make widely available both its generic models and the NACMCF models. Comments are invited on this approach.

FSIS is proposing to require that each inspected establishment have and implement a HACCP plan that is specific to each kind of meat or poultry processing activity conducted in that establishment. Establishments coming under inspection after the implementation date appropriate for the process(es) to be conducted will be required to develop their HACCP plans in conjunction with the application for the grant of inspection. FSIS acknowledges that such establishments may need some practical experience operating under their HACCP plan to finalize their plans. FSIS invites comments on whether new establishments coming under inspection should be granted a reasonable amount of time, for example, six months, to finalize their HACCP plans under commercial conditions.

(4) Sanitation as a Prerequisite to HACCP Plan Development

FSIS believes that there are certain prerequisites that must be met before successful HACCP plan development can be accomplished. An important foundation is the successful control of the cleanliness and sanitation of the facilities and equipment, and adequacy of employee sanitation and hygienic practices necessary in producing meat and poultry products. FSIS is proposing that this be accomplished through Standard Operating Procedures for sanitation. (See ''Near-term Interventions'' section of ''DISCUSSION OF REGULATORY PROPOSALS,'' above).

These proposed regulations reflect the decision that HACCP plans should address food safety factors only. FSIS invites comment on this approach.

(5) Participation of HACCP-Trained Individuals

The Agency believes that establishments will vary widely in their familiarity and experience with HACCP. All establishments will need to have access to persons who have been trained in HACCP and its application to meat and poultry production processes. Some establishments have already chosen to secure HACCP training for their staff or to secure consulting services. Others must accomplish this before they begin the hazard analysis that will initiate their plan development process. FSIS will consider an individual who has successfully completed a recognized HACCP training course, as defined in §§ 326.1 and 381.601, to be a HACCP-trained individual.

A recognized HACCP course would consist of at least three days: one day devoted to understanding the seven principles of HACCP; one day devoted to meshing these concepts with this and other regulatory requirements of FSIS; and one day devoted to development of

a HACCP plan for a specified process. As discussed below, the Agency expects that many organizations will be knowledgeable about such courses and may serve as legitimate sources of such training. It is the responsibility of the establishment sending its employee(s) to a particular training course to ascertain that the course meets the minimum requirements described above.

FSIS is aware that, through industry-sponsored training courses, several hundred industry employees have already received the necessary training. It is not expected that such training needs to be repeated. Individuals who previously received HACCP training should be able to supplement their knowledge through guidelines and informational materials made available by FSIS, NACMCF, professional associations, and trade associations. FSIS invites comments on this approach for supplementing knowledge levels of previously trained individuals. In cases where a consulting expert serves as the HACCP-trained individual for an establishment, it is the responsibility of the establishment to assure that this individual has the requisite training.

FSIS is also proposing that the HACCP-trained individual participate in the hazard analysis and subsequent development of the HACCP plans, and assist in addressing product safety in situations where there have been deviations from critical limits and judgment is needed to determine the adequacy of the response. HACCP-trained individuals must also be available to establishments to participate in plan modification and revalidation. FSIS does not believe it needs to prescribe details about the hours or days on which the HACCP-trained individual is to be on establishment premises, or what should be done in establishments having multi-shift operations, other than to require that the HACCP-trained individual be available to the establishment to accomplish the prescribed role. FSIS is proposing that the establishment have on file the name and a brief resume of the HACCP-trained individual on whom it is relying.

The Agency has determined that a HACCP-trained individual must be employed by each establishment. This individual will be responsible for addressing and performing functions related to hazard analysis, plan development, plan validation, review and assessment of critical limits, and responses to deviations. The HACCP trained individual will be pivotal in an establishment's ability to successfully assure process control in an operational HACCP system. The Agency recognizes that employment of a HACCP trained individual could also be accomplished through acquisition of the services of a HACCP consultant. The Agency does not intend to be overly prescriptive by specifying the conditions of employment between the establishment and the HACCP trained individual. It is, however, the determination of the Agency that the services of a HACCP-trained individual able to carry out the activities described above is essential to successful operation of a HACCP system. Comments are invited on this approach.

This proposed requirement for involvement by a HACCP-trained individual is an alternative to requiring that there be such an individual in each establishment. FSIS recognizes that, for many establishments, securing HACCP expertise by training one employee in a recognized HACCP course is the best means to meet this requirement. Comments are invited on this approach.

(6) Hazard Analysis

FSIS believes that success in HACCP plan development is founded on a hazard analysis that is thorough and forces the establishment to critically think about and analyze its processes. Guidance materials prepared by the NACMCF for carrying out Principle 1 address this issue. Especially for establishments without HACCP experience, this is a critical and challenging first step. Because FSIS is concerned that each establishment properly begin its application of the concepts of HACCP, the Agency is proposing to specify a time frame prior to the due date for any HACCP plan, during which hazard analysis should be conducted.

The proposed time frame is six months; this means that six months before any HACCP plan is required to be completed, establishments should begin the hazard analysis process. Activities constituting the hazard analysis include: accurately and completely describing product composition, developing a flow diagram, listing of all hazards associated with each processing step, and collecting of necessary scientific data to assess and validate the effectiveness and variability of process controls. During the six-month hazard analysis period, there should be regular meetings between inspection personnel and the establishment HACCP team on the subject of the hazard analysis.

Once the hazard analysis has been completed, it is expected that identification of CCP's will begin and the activities related to the remaining principles will be carried out so that the plan can be ready and validated by the due date.

In only one circumstance will Program employees be expected to report on the progress of these establishment activities with respect to plan development; that is, if there has been no effort to initiate hazard analysis, and the subsequent application of remaining HACCP principles, at least one month prior to the due date for the HACCP plan. FSIS believes that, in such a circumstance, there is a considerable likelihood that the plan will be insufficient and that regulatory action will be necessary. Therefore, Program employees will report such a situation through their supervisory channels. FSIS invites comment on this particular feature of the proposed implementation schedule.

(7) Establishment-Specific HACCP Plan Acceptance

The question of HACCP plan acceptance has been long and thoroughly considered by the Agency. In reviewing various options, the Agency has maintained several objectives:

- Any acceptance system should not include a requirement that HACCP plans be physically forwarded to the Agency and remain in its possession at one or a few central locations.
- The acceptance system must accommodate varying establishment-specific HACCP plans for similar products, but maintain uniformity on basic standards.
- The acceptance system should involve Agency in-plant Program employees to the maximum extent possible, after they have been provided the requisite education and training in HACCP.

The Agency gave serious consideration to requiring formal plan acceptance prior to full plan operation, either by formal FSIS approval or by an ''expert'' computer system. However, advice from colleagues at FDA suggested that any system of acceptance prior to operational validation was likely to be administratively complex and irrelevant to successful implementation. Therefore, the Agency has decided that plan acceptance will not be a one-time administrative event but a process. Successful process control, as evidenced by the existence of a plan having all the features required by the seven principles plus the capacity of the plan to result in production of complying products, will mean that the plan is acceptable.

Inspection activities will be designed to verify that the plan has all the required features, that the plan and the

records it generates are a reflection of what has occurred during processing of products, that deviations have elicited appropriate responses, and that continually complying products have been produced. Whenever any of these conditions are not met, the plan will be judged to need revision and revalidation.

In essence, establishment-specific HACCP plans will be developed, reviewed, and validated at the establishment level on a continuing basis, with activities by both establishment and Program employees. This has emerged as the most viable and efficient approach for both the Agency and industry.

Responding to Deviations From Critical Limits

FSIS is proposing to require that deviations from critical limits trigger a prescribed set of actions by an establishment.

First, under this proposed provision, product affected by the deviation from the critical limit must be segregated and held until the significance of the deviation can be determined. Second, the establishment must make the necessary determination of the effect of the deviation on product safety. This determination must be made in consultation with a HACCP-trained individual and any other subject-matter experts needed to deal with the deviation in question. In consultation with this person or team, the establishment should also determine whether the deviation reveals the need to modify either the process itself or the HACCP plan.

Finally, FSIS is proposing to require that establishments record all steps taken in response to a deviation from a critical limit and include that information as part of the HACCP record. Documentation of deviations should be brought to the attention of FSIS personnel.

HACCP Recordkeeping

Maintenance of accurate HACCP records is fundamental to a HACCP system and is the cornerstone of its usefulness to regulators. Therefore, FSIS is proposing to require that these records contain certain necessary information; that the records be systematically reviewed by the establishment; that the records be maintained for a specific period of time; and that FSIS Program personnel be given access to these records.

First, FSIS is proposing that the records involving measurements during slaughter and processing, corrective actions, verification check results, and related activities contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The purpose of this proposed requirement is to assure that both the establishment and the regulator can readily link a record to a product and the period during which the product was processed. FSIS is also proposing to require that the information be recorded at the time that it is observed and that the record be signed by the operator or observer.

Second, FSIS is proposing to require that the HACCP records associated with the product to be shipped be reviewed by an establishment employee other than the one who produced the record, before the product is distributed in commerce. The purpose of this review is to verify that the HACCP system has been in operation during the production of the product, that it has functioned as designed, and that the establishment is taking full responsibility for the product meeting applicable food safety regulatory requirements. If a HACCP-trained individual is on-site, that person should be this second reviewer. The reviewer should sign the records. FSIS program personnel will be performing similar reviews of HACCP records on a regular basis, but their oversight cannot be substituted for the establishment's review.

Third, FSIS is proposing that HACCP records generated by the establishment be retained on site for at least one year and for an additional two years on-site or at another location. HACCP records will be necessary in the revalidation process. Further, FSIS' experience with other recordkeeping requirements indicates this is a manageable time frame. FSIS invites comments on the appropriateness of these records retention requirements.

Finally, FSIS is proposing to require that HACCP plans and records be available for review and copying by program personnel at reasonable times. Industry records are reviewed by Program personnel as part of their assigned tasks. Comprehensive records access is necessary to permit verification of all aspects of a HACCP system. However, FSIS does not intend to routinely copy or take possession of such records. It is the Agency's intent to generate its own records of its verification tasks and results rather than duplicate the records of the establishment. Data collection instruments for program employee verification tasks are being developed and will become the Agency's verification record that the HACCP system is functioning as intended.

Extensive copying of records is anticipated only in cases where there was evidence of non-compliance with requirements or deviations from critical limits that resulted in product safety problems. In such instances, complete access to all pertinent records would be necessary. FSIS invites comments on this issue.

Training

There is significant interest by the Agency in HACCP training for Agency and industry personnel. FSIS takes full responsibility for the training of its own personnel within time frames that permit the orderly implementation of HACCP. The Agency's interest in HACCP training for the regulated industry is based on the need to assure that both industry and Agency personnel are receiving training that is founded on a single vision of HACCP and how it is to operate.

Two areas concerning training requirements were considered by the Agency in determining how training for HACCP-trained individuals should be evaluated: The availability of training and whether to require acceptance or accreditation for training programs.

Upon review the Agency determined that there are a number of options for the industry when selecting the appropriate training course for their employee(s). Among these are courses offered by industry trade associations, such as AMI, the National Food Processors' Association, and others. Academia also offers courses in HACCP principles and application. Groups such as the HACCP Alliance, The National Center for Food Safety and Technology, and accredited universities are among the available sources for HACCP training. Private consultants and consulting firms also offer HACCP training. Other available resources include a list of HACCP courses prepared by USDA's Extension Service. These training sources are all available to the regulated industry although the cost, length, and to some extent, the content of these courses differ. Recognizing that there are differing needs for technical knowledge and ability to pay for these courses among the regulated industry, FSIS has determined that each responsible establishment official should be responsible for deciding which provider of training best meets the establishment's needs.

A second concern is whether the Agency should stipulate that the courses taken by a HACCP-trained individual be subject to acceptance or accreditation. This accreditation could be conducted by the Agency, by an outside body (e.g.,

scientific body or professional association) under the auspices of an industry-sponsored accreditation system, or a decision to require no accreditation for courses could be adopted. An outside source for accreditation could be created by the industry as is the case in thermal processing where a nationally recognized course is offered by industry. A scientific body or a professional association could serve such a function.

FSIS considered the implications of serving as an accrediting body for HACCP training courses. This option afforded three choices. First, the Agency could provide accreditation review of all available HACCP courses. This could be accomplished by contracting out the function. Second, the Agency could provide this service to the regulated industry through staff resources. This would require a significant diversion of Agency resources from regulatory activities to servicing the industry by approving a large volume of requests for review of HACCP courses. Third, FSIS could publish a periodic list of unacceptable HACCP courses based on the training received by HACCP-trained individuals in establishments with proven histories of poor performance. This would serve only to identify those courses the Agency determined through establishment performance to be inadequate preparation for a HACCP-trained individual.

To assure that training is timely, to reduce cost requirements for the Agency and industry, and to assure that a wide range of options is available to the industry, the Agency has tentatively concluded that the adequacy of courses for a HACCP-trained individual should be evaluated by each responsible establishment official. FSIS is not proposing to establish an accreditation process to evaluate training courses, because the Agency believes that its evaluation of the establishment's HACCP performance is the most resource-efficient means to reveal any training deficiencies or mistakes in the course selections made by the establishment. The Agency is soliciting comment on this approach and will consider other viable options for ensuring appropriate training of industry personnel.

Implementation Schedule

Since mandatory HACCP was first considered by FSIS, the Agency has been considering the significant issues surrounding orderly implementation. Public discussions regarding phase-in have alternated between the need for caution in implementing so significant a change too quickly and a sense of urgency because of the food safety benefits associated with HACCP. The time frame for implementation in these proposed regulations attempts to balance these competing concerns. The first phase-in of a process begins 12 months from the publication of the final rule and ends at 36 months. This balanced phase-in approach will permit the regulated industry time to accomplish the training of personnel and adjust their activities to include necessary HACCP activities.

FSIS proposes to establish a timetable for phasing in HACCP based on industry production process categories. In identifying process categories for phase-in of mandatory HACCP, the Agency has taken a number of factors into account. These include the knowledge of areas where controls similar to HACCP presently exist; consideration of all activities conducted by regulated establishments; consideration of the wide variety of products produced by the regulated industry that are difficult to sort into separate product categories; and the nature of changing and constant product development activities conducted by the industry. Also in keeping with the process control principles inherent in HACCP, FSIS has selected process as the basis for phase-in, rather than product category. The Agency has identified process categories that appear to encompass all the processes of the regulated industry. They are:

01 Raw, Ground: This category includes ground red meat (beef, pork, sheep, etc.), ground poultry, all mechanically separated species, and mechanically deboned poultry.

02 Raw, Other: This category includes all red meat species and poultry classes not fully cooked including non-intact muscle products (shaped, formed, separated, etc.), all intact raw muscle products including processed (injected, coated, breaded, tenderized, etc.) and all cut, or boned product both bone-in and boneless.

03 Thermally Processed/ Commercially Sterile: Included in this category are retortable pouches and canned meat and poultry products.

04 All Other Shelf Stable, Not Heat Treated: This category includes all products that are shelf stable including dried, controlled by water activity, pH, dehydrated, freeze dried, fermented, and products that meet the requirement for a maximum pH of 4.6, for example freeze dried soup or meals, shelf stable salami, jerky, or dried beef.

05 Fully Cooked, Not Shelf Stable: This includes all keep refrigerated or frozen products including those that are sliced and packaged, and products prepared by central kitchens, for example cooked sausage, hams, frozen fully cooked beef patties, pizzas.

06 All Other Shelf Stable, Heat Treated Product: This includes rendered products, for example lard and oils.

07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked Product: This category includes ready-to-cook poultry, cold smoked and products smoked as a trichinae treatment, partially cooked, battered, breaded, char-marked, batter set, and low temperature rendered products, for example partially cooked patties and nuggets, partially defatted beef, ready-to-cook barbecued chicken, mettwurst, etc.

08 Non-Shelf Stable, with Secondary Inhibitors: This includes products that are irradiated, fermented, salted, and brine treated, for example, oriental sausages, pressed duck, and irradiated poultry.

09 Slaughter: This includes all red meat species, all poultry classes, and all voluntarily inspected species and classes.

Special considerations for phasing HACCP into small establishments are discussed below.

The proposed effective dates for each category are expressed in relation to publication of a final HACCP regulation; the six month Hazard Analysis period is to precede the effective date for each process category.

In determining the phase-in sequence for these categories, four options were considered.

The first proposed phase-in option considered is based on the public health and safety risk inherent in the production process. Risk considerations dictate that raw ground product be in the initial implementation period, followed by slaughter since these processes result in products that have been shown to pose the greatest risk for foodborne illness. The process categories were then ranked according to the food safety process controls applied during the manufacturing process. This option would have phased-in Shelf Stable, Heat Treated and Thermally Processed/Commercially Sterile processes in the final groups. Those processes include areas in which significant interventions take place during production to assure product safety.

The second option considered the controls that currently exist in regulation mandating critical control points and critical limits related to health and safety. This method would have phased-in those processes where the greatest process control experience and regulatory standards exist for the earliest implementation dates. The

burden for the development of a HACCP plan and hazard analysis would not have been as great for these establishments due to past experience. This option would initially have phased-in processes such as Thermally Processed/Commercially Sterile and end with Raw, Ground; Raw, Other, and Slaughter processes. Phase-in would occur in an inverse order from the first option considered.

The third phase-in scenario considered by the Agency utilized an evaluation of the number of establishments producing products covered by a process and the known volumes of industry production for each of these processes. In this option, process category Raw, Other would have been implemented first since this comprises a large sector of industry production both by volume and the number of producing establishments. The second process for phase-in would have been slaughter, since again, this comprises a large portion of the regulated industry both in the number of establishments and the volume of product produced. Thermally Processed/Commercially Sterile would have been the final process phased-in under this option since this process constitutes a small segment of the regulated industry both in the number of producing establishments and the volume of production.

The fourth option for phase-in, and the one proposed by the Agency, incorporates considerations from each of the above-discussed options, beginning with the processes that constitute the greatest public health risks, combining some other processes where the volume of production in the regulated industry is lower, using the option for processes where a large body of experience and regulatory criteria presently exist, and combining these for the existing time frame of total implementation over a 1-to-3-year period from the publication of a final HACCP regulation. In all options considered, the category encompassing small establishments will be phased-in last. FSIS selected the fourth option because it takes into consideration production, experience with process control, and public health risk. FSIS invites comments on the proposed phase-in schedule.

The Agency envisions that, upon the required implementation date for phase-in, establishments will be completely ready to operate their HACCP system and that FSIS will conduct inspection activities according to HACCP principles, including verification and validation, to ensure that the HACCP system as operating is acceptable.

The proposed phase-in schedule 4 is as follows:

Final rule plus 12 months: Raw Ground; Thermally Processed/ Commercially Sterile; and all Other Shelf Stable, Heat Treated Products.

Final rule plus 18 months: All Non Shelf Stable, Heat Treated, Not Fully Cooked; all Other Shelf Stable, Non Heat Treated.

Final rule plus 24 months: Fully Cooked, Non Shelf Stable; all Non Shelf Stable with Secondary Inhibitors.

Final rule plus 30 months: All Slaughter; all Raw Other Product.

Final rule plus 36 months: Small Establishments.

Special Consideration for Small Establishments

FSIS believes that planned technical assistance activities offer benefits to small establishments. Among these are the provision of generic models from which to begin HACCP plan development and the provision of other guidance material. Additionally, FSIS is proposing that small establishments, regardless of the processes performed and products produced, be permitted 36 months from the date of publication of the final rule in the **Federal Register** to complete plan development. In determining which establishments should be eligible for this implementation schedule, FSIS considered three ways of defining ''small.'' The object was to distribute the economic burden equitably among various segments of the industry.

(1) Defining ''small'' on the basis of units produced (number of head slaughtered, number of birds slaughtered, or pounds of product produced). Because of the difficulty of making meaningful economic comparisons among unlike species and processes, the Agency decided against defining small establishments on the basis of production volume.

(2) Defining ''small'' according to the number of establishment employees. The Agency rejected this approach because the number of employees is not a good indicator of the ability of the establishment to undertake additional financial burdens.

(3) Definitions based on annual sales in dollars. This simple, across-the board measure appears both reasonable, simple, and fair. For this reason, the Agency selected this approach, rather than either of the others discussed, alone or in combination.

For the purposes of HACCP implementation scheduling, FSIS is proposing that small establishments be defined as those with annual production valued at or below $2.5 million. Defining a small business as one with a maximum of $2.5 million in annual sales allows the maximum time for compliance with the HACCP requirement for a significant number of establishments, with approximately one-third of all establishments falling into the ''small'' category. Further, using the amount of $2.5 million the percentage of slaughter establishments considered small is roughly the same as the percentage of processing establishments falling into this category. The proposed definition of a small establishment will not significantly affect achievement of the Agency's food safety objectives, because slaughter and processing establishments in this category together account for less than one percent of annual meat and poultry production in the United States.

FSIS invites comment on its approach to defining small establishments.

Regulatory Oversight of the HACCP System

The NACMCF has specifically addressed the subject of the roles of regulatory agencies with respect to establishments in which HACCP is the system of process control for food safety (''The Role of Regulatory Agencies and Industry in HACCP''). FSIS is in general agreement with that discussion, especially the part that emphasizes that, with respect to food safety, establishments must operate effective HACCP systems and the government role should focus on verification that HACCP plans are working as intended. If the regulatory agency were to take on hazard identification, determination of CCP's or critical limits, responsibility for corrective actions or monitoring responsibilities, it would be undermining the need for the establishment to assume full responsibility for the processing of safe product through the HACCP system of process control.

Verification procedures the Agency might use include:

(1) Review of the HACCP plan;
(2) Review of CCP records;
(3) Review of deviations and responses to deviations;
(4) Visual inspections of operations to see if CCP's are under control;
(5) Random sample collection and analysis (including microbial testing);
(6) Review of critical limits;
(7) Review of written records of establishment verification tasks;
(8) Revalidation of HACCP plans including on-site observations and complete records review.

FSIS intends to review and revise existing inspection tasks to assure that

they are focused on the CCP's for each of the processes that will be controlled by HACCP plans. These revised tasks will be incorporated into the PBIS and become part of regular assignments for program personnel.

Public Access to Records

There is a broad policy question about public access to establishment records generated under HACCP. Some groups believe that any records used by regulatory agencies for making a determination about the safety of meat and poultry products produced should be made public to the maximum extent possible. Others take the position that such broad-scale access compromises establishments' rights to protect sensitive commercial information from business competitors.

FSIS believes that public access to any records which it generates itself and any establishment records copied by FSIS as part of its verification tasks would be governed by the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the implementing regulations of USDA (7 CFR Part 1, Subpart A). FOIA exempts particular commercial and financial information from mandatory release by government agencies. As a preliminary matter, it appears that at least some elements of HACCP plans and monitoring records would be considered commercial information of the kind exempt from disclosure. FSIS is committed to meeting fully the public disclosure objectives and requirements of the Freedom of Information Act.

It should be noted that the FOIA presumes that the governmental agency has both possession and control of the record. Therefore, when information is obtained from an establishment and is maintained by FSIS, that information becomes an agency record subject to FOIA. As previously discussed, the Agency is not proposing that HACCP plans be submitted for approval. HACCP plans which have been accepted by virtue of successful process controls will be on file in the establishment and available for review by FSIS program personnel. Therefore, the information maintained by the establishments, including monitoring records, would not be subject to a FOIA request. However, if during validation of an establishment's HACCP plan, or during an investigation of an alleged violation, HACCP records are obtained from an establishment, those records become agency records subject to FOIA.

FSIS invites public comment on the issue of whether broader public accessibility to an establishment's records is in the public interest, and, if so, to what extent the records should be required to be disclosed.

Relationship to Other Process Control Systems

To eliminate duplication, redundancy, and confusion, FSIS is considering proposing that the mandatory HACCP plan become the only Agency recognized process control system for health and safety aspects of the processes/products of each establishment. Those portions of existing TQC systems or PQC programs that address health and safety issues would be encompassed within the mandatory HACCP plan. Those aspects of an establishments operations that are not health-and-safety related and, therefore, not covered by the HACCP plan would be monitored by tasks assigned through PBIS at frequencies determined by the demands of HACCP verification activities. Comments are invited on this approach.

Enforcement

The enforcement provisions would require that establishments have verified HACCP plans for their processing operations by the dates specified for the establishment and process. As noted, the HACCP requirements would be phased in by having different effective dates—12 months, 18 months, 24 months, 30 months, or 36 months from the date the final rule is published, depending on the establishment and the product(s) being produced.

Establishments that fail to have a verified HACCP plan in place for a processing operation by the date required for that operation would have its inspection for that process suspended. Similarly, new establishments and establishments applying for inspection of new processing operations would be denied inspection services after those dates unless and until a HACCP plan is in place for that process.

The enforcement provisions also provide that, once adopted, HACCP plans would still be subject to verification by FSIS. If a HACCP plan is found by FSIS to be invalid, inspection would be suspended from existing operations, pending correction of the HACCP plan.

A HACCP plan might be found invalid for one or more of three reasons: (1) The HACCP plan does not meet the essential requirements set forth in the regulation; (2) HACCP records are not being maintained as required by the regulation and/or the plan, preventing validation of the plan and/or verification of process controls as may be required, and (3) a processing failure results in the production of adulterated product.

Suspension of all or a part of an establishment's inspection services will be made under rules of practice, proposed in Part 335 of the Federal meat inspection regulations and Subpart W of the poultry products inspection regulations, requiring notice by FSIS to the establishment of the reasons for the suspension. The notice also would specify the processing operations affected (if not the entire establishment) and the corrective action(s) required before inspection service would be resumed.

While inspection is suspended, the facilities identified in the suspension notice could not be used for the production of meat or poultry products. Furthermore, if product produced prior to the suspension were suspected of being adulterated, such product would be retained at the establishment pending disposition by the Program, and if already shipped, such product would be subject to recall as necessary to protect public health.

A suspension would be lifted and inspection service restored upon the designated Program official providing written acknowledgement of receipt of a modified plan, coupled with a detailed validation of that plan by a HACCP-trained individual. The modified plan must have been developed in consultation with that HACCP-trained individual. In the case of suspension caused by a processing deficiency resulting in production of adulterated product, a written testing plan would also be required. The plan must provide for the testing of finished product produced under the modified plan for chemical or microbial characteristics, as appropriate, to demonstrate that the process under the modified plan would correct the identified problem.

Failure to prepare a valid HACCP plan as specified in the notice, by the time specified in the notice, will result in service on the establishment of a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service will be refused or withdrawn pending resolution of any hearing.

Failure to adhere to a modified HACCP plan, and, if applicable, testing plan, resulting in a repeat of the suspension for the same or a related deficiency, would in addition to the requirement for another modified plan, require a Program review of the establishment's performance under other provisions of the inspection laws before inspection would be restored.

Recurring violations of fundamental HACCP requirements would be viewed as indicating an increased likelihood that other violations of inspection requirements exist and that additional enforcement actions may be required by FSIS.

Finally, in the event the Administrator finds that HACCP records have been deliberately falsified, the Agency would in addition to any suspension in effect, issue a complaint for withdrawal of inspection from the establishment and would refer the case to the Department of Justice for criminal prosecution.

3. Illustrations of the Application of HACCP

The HACCP approach to process control is systematic and establishment specific. The generic models prepared by FSIS and NACMCF to assist federally inspected establishments to develop HACCP plans would serve as guides for the processes described earlier in this document. In order to clarify these concepts, some examples are included to explain the contrast in operations conducted under the HACCP system from those conducted under the traditional mode of industry operation. Since each HACCP system is developed by an individual establishment to fit with its process(es), the following examples are meant to serve only as illustrations, and are not intended to serve as prescriptive blueprints for a specific HACCP plan.

When developing a HACCP plan, all aspects of a food's production must be considered. The development of a HACCP plan begins with the identification of the product, its distribution, and the intended consumer of the product. A hazard analysis is conducted, and the plan is developed by identifying critical control points, monitoring procedures, critical limits, and the remainder of the seven principles discussed earlier in this document.

The HACCP system places the responsibility for production of a safe and unadulterated product with the industry. The HACCP approach allows the establishment to focus on the process as it is occurring. If contamination is occurring, it should be immediately identified, allowing for prompt corrective action as well as providing an opportunity to determine the cause and take action to prevent a future recurrence of the problem. In a non-HACCP approach, the establishment may not discover contamination until much later in the process, if at all, resulting in delays, the possibility of producing and distributing unsafe product, and difficulty in implementing preventive measures.

The following are illustrations of the application of existing generic models and how they can be used by an establishment.

The HACCP System for Beef Slaughter

For beef slaughtering establishments, a generic HACCP plan which reviews the processing steps of slaughter operations can provide general guidance for developing an establishment's specific plan. The goal of HACCP for slaughter operations is to prevent, eliminate, or reduce both the incidence and levels of microorganisms pathogenic to humans. While beef slaughter operations do not include a lethal treatment (e.g., thermal process) that ensures the elimination of pathogenic microorganisms, a number of the processing steps can be controlled to minimize microbiological hazards.

A beef slaughter establishment performing a hazard analysis of its operation may identify several hazards, particularly enteric pathogens, such as *Salmonella*. CCP's where *Salmonella* contamination might occur can be identified and then controlled by establishing critical limits, monitoring those limits at an appropriate frequency, and taking corrective actions when deviations occur. Recordkeeping and verification procedures would also be identified for these CCP's in the establishment's specific HACCP plan.

For example, the intestinal tracts of animals can harbor large populations of enteric pathogens, such as *Salmonella*, even though the animals themselves are asymptomatic. As the slaughtered animals are eviscerated (removal of the intestinal tract and other organs), there is potential for spreading the *Salmonella* from the intestinal tract to the carcass, operator, or equipment, if the intestines are accidentally cut. Therefore, evisceration would be considered a CCP in a HACCP plan for beef slaughter.

Critical limits for the evisceration CCP might be zero percent occurrence of the following defects for a single carcass: fecal material, ingesta, urine or abscesses. The establishment employee(s) working at evisceration would monitor by observing carcasses for contamination defects and would take corrective actions if the critical limits were exceeded. Corrective actions might include: immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, a reduction in line speed, sanitization of evisceration tools in 180°F water, and sanitization of contaminated clothing in 120°F water or appropriate sanitizer.

Records resulting from this CCP might include a random post-evisceration carcass examination log. Verification might consist of supervisory review of records and operations, and random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.

In a non-HACCP approach, the establishment may discover contamination from evisceration much later in the process, causing delays before the contamination is removed and making implementation of preventive measures difficult.

Removing the hide from cattle is a major source of microbial contamination during the slaughtering process. Cattle entering the slaughter establishment carry with them microbial populations indicative of what occurred during the care and handling of the live animals. *Salmonella* and other types of bacteria can be spread during the skinning process through contact with hide, hands, and various pieces of equipment. Therefore, skinning would be a CCP in a beef slaughter HACCP plan.

Methods for control of contamination at skinning might include adequate training of the person doing the skinning to minimize contamination, including pulling the hide down and out from the carcass as opposed to upward and away; positive reinforcement through appropriate supervision; and proper cleaning and sanitization of equipment and carcass contact surfaces.

Monitoring at this CCP might include observation of the effectiveness of the skinning process for each carcass. Ways to ensure this is working would be to set critical limits. Critical limits for skinning might include less than or equal to 20 percent of carcasses with dressing defects.

If this critical limit is exceeded, corrective actions would be required. These could include: immediate trimming of defects on carcasses, additional establishment employees added to the slaughter line, and/or a reduction in line speed.

Records resulting from this CCP might include a random post-skinning carcass examination log. Verification might consist of a supervisory review of records, examination of random carcasses after skinning is complete using a sampling plan sufficient to assure process control, and reviewing control charts to confirm that sampling frequency is sufficient to detect 20 percent defect criteria. Additionally, baseline data might be established for expected bacterial numbers. Periodic

follow-up analyses and trend analysis might be performed to verify process control.

Other possible CCP's in beef slaughter are described in the ''Generic HACCP for Raw Beef'' (see Appendix).

The HACCP System for Poultry Slaughter

The current systems of postmortem inspection for poultry share elements of a HACCP system approach, such as critical limits, monitoring, corrective action plans, recordkeeping, verification tasks, critical limits or tolerance levels, monitoring tasks, corrective actions, and recordkeeping. However, these components are not arranged in the highly organized systematic manner that is evidenced in a HACCP system.

Major differences between a HACCP system and the present poultry slaughter systems are hazard identification and analysis, and the specific identification of critical control points which are not a part of current poultry slaughter systems. The progression to a HACCP system in poultry slaughter would cause some significant changes to emerge. These changes would include more industry involvement and responsibility for control of processes executed to produce an end product that is safe, wholesome, and unadulterated.

Under HACCP, the establishment would define processing steps where control can be exerted to effectively prevent, eliminate, or reduce food safety hazards. Because *Salmonella* is a significant microbial hazard in raw poultry, establishments would be expected to target measures that prevent contamination and control the growth of *Salmonella* throughout the slaughter process.

For example, under a HACCP system, the establishment may set criteria for maximum permissible levels of *Salmonella* in a flock presented for slaughter. CCP's for control of this enteric pathogen may include requiring that flock health records be reviewed, that the level of *Salmonella* on each flock brought for slaughter be monitored, and that corrective action be taken when appropriate levels are not met.

At evisceration, critical limits would be set for fecal or other intestinal contamination present on the carcass. Monitoring would be conducted at a set frequency, the results would be recorded after observing the carcasses, and corrective action would be taken if the limits were exceeded.

In addition, control of *Salmonella* may include targeting the chlorine level in the rinse water required for automatic evisceration equipment, the level of antimicrobial treatment in the chiller, and/or the temperature of the chill water. These would constitute CCP's identified by the establishment.

Critical limits would be set based on allowable levels and types of antimicrobials used, monitored by testing at appropriate frequency, and recorded in a log or other record.

Corrective action taken may include more frequent changes of chill water, better temperature control to preclude the growth of pathogens, or use of an alternate antimicrobial rinse.

Currently, some establishments rely on FSIS personnel to detect contamination by visual examination of the carcass or by using chiller water temperatures as an indicator of less than satisfactory conditions. This would occur as a result of end product examination. The HACCP approach requires the establishment to implement effective preventive measures.

Industry would follow a similar protocol for all points in the poultry slaughter process where a potential hazard can be prevented, eliminated, or reduced to an acceptable level. This demonstrates CCP's in an establishment-controlled HACCP system.

The HACCP System for Cooked Sausage

For the development of a HACCP plan, an establishment producing a cooked sausage must evaluate the entire manufacturing process. The focus of a HACCP plan on the prevention of food safety hazards requires defining where unsafe conditions can occur, setting target limits, and defining corrective action.

Cooked sausage is a broad category which includes frankfurters (hot dogs and wieners), vienna sausage, bologna, knockwurst, braunschweiger (liver sausage), and similar products. In this example, assume that the establishment produces bologna.

Because HACCP is a hazard prevention process control system, processing hazards must now be identified. The finished product—bologna—is a fully cooked product that can be consumed without further safety treatment (i.e., cooking).

Consequently, raw materials (meat and other ingredients) must be handled to reduce the opportunity for microbiological growth. CCP's requiring limits would include ensuring that incoming ingredients are adequately packaged to prevent contamination, and perishable ingredients are kept within temperature limits that assure their safety.

Cooking is considered a primary kill step in processed products where microbiological hazards can be controlled. Critical limits must be set by an establishment to assure that the product has been sufficiently heat treated to preclude the growth of pathogenic microorganisms. The manufacturer of a poultry bologna may set 160 °F as the critical limit for the internal temperature and test a set amount of product, recording the internal temperature, time the temperature was recorded, and the lot number and size.

If the product does not meet the critical limit set by the establishment, corrective action can be instituted that could include recooking the lot of product or chilling and reworking the lot into subsequent production.

The cooling process is another example of a CCP in the processing of a cooked sausage product. Improper chilling after the lethal heat treatment is applied can result in the growth of microorganisms (particularly vegetative spores) which may have survived the heating process. Improper chilling will permit the growth of these microbes and render the product unsafe.

The HACCP approach would ensure that an establishment targets chilling as a CCP, sets critical limits including time and temperature parameters (e.g., 5 hours to reach and maintain 40°F internally), monitors the temperature at frequent intervals, records the results, and takes appropriate corrective action if the critical limit is exceeded. Corrective action might include recooking the lot of product and recooling.

In addition to microbial hazards, physical and chemical hazards must be identified. The use of nitrite in cooked sausages serves two functions—color development and some protection against the outgrowth of anaerobic organisms. Under HACCP, an establishment would set a critical limit for nitrite in the product, monitor the formulation of each batch of product produced, record the exact amount of each ingredient used, and take appropriate corrective action if the limit were exceeded. Corrective action might include the addition of other ingredients, such as meat, to offset the addition of excess nitrite.

Therefore, it becomes the responsibility of the establishment under HACCP to identify CCP's, monitoring procedures, and corrective action that specifies what would happen to product that is or may be affected and what would happen to prevent the violation from recurring. Finally, all HACCP plans must identify the documentation that would occur to

verify that the process is operating appropriately.

D. Effective Dates

The proposed requirements for Sanitation SOP's, antimicrobial treatments, cooling standards for livestock carcasses, and microbial testing would be effective 90 days after the date of the final rule's publication in the **Federal Register**. This would afford those establishments not yet performing the proposed interventions the time to make necessary adjustments. Minimal preparation would be required to begin microbial testing. The requirement to begin tracking test results in accordance with the moving sums process-control procedures and reporting the results to FSIS would be effective 6 months after promulgation of the final rule. FSIS is proposing to hold establishments accountable for meeting the interim targets for pathogen reduction beginning 2 years after promulgation of the final rule.

The 6-month Hazard Analysis period would begin no less than 6 months before the HACCP phase-in date, as set forth for each of nine process categories and for small establishments, as provided in the proposed 9 CFR 326.7 and 381.607.

FSIS invites comment on these proposed effective dates.

III. Other Issues and Initiatives

A. Legal Authority

The Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) and the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) were enacted to protect the health and welfare of consumers by assuring that meat and poultry products distributed in commerce are ''wholesome, not adulterated, and properly marked, labeled and packaged'' (21 U.S.C. §§ 451 and 602). The term ''adulterated'' is defined in the Acts to include any meat or poultry product that is ''unsound, unhealthful, unwholesome, or otherwise unfit for human food'' (21 U.S.C. §§ 453 (g)(3) and 601(m)(3)). Meat and poultry products that bear or contain any poisonous or deleterious added substance which may render them injurious to health, and meat and poultry products that bear or contain inherent substances in sufficient quantity to ordinarily render them injurious to health are also ''adulterated'' within the meaning of the Acts (21 U.S.C. §§ 453(g)(1) and 601(m)(1)).

The term ''adulterated'' is also defined to include meat and poultry products that have been ''prepared, packed, or held under insanitary conditions whereby [they] may have become contaminated with filth, or whereby [they] may have been rendered injurious to health'' (21 U.S.C. §§ 453(g)(4) and 601(m)(4)). The FMIA specifically authorizes the Secretary to ''prescribe the rules and regulations of sanitation under which establishments shall be maintained'' and to refuse to allow meat or meat food products to be labeled, marked, stamped, or tagged as ''inspected and passed'' if the sanitary conditions of the establishment are such that the meat or meat food products are rendered adulterated (21 U.S.C. § 608). Similarly, the PPIA requires all official establishments to be operated ''in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary'' and authorizes the Secretary ''to refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section'' (21 U.S.C. § 456).

In addition to this specific authority, the Secretary has broad authority under both Acts to promulgate rules and regulations necessary to carry out the Acts (21 U.S.C. § 463, 621).

Based on these statutory provisions, FSIS is proposing that establishments take affirmative action, including adherence to sanitation standard operating procedures, the application of antimicrobial treatments and microbial testing, the adherence to cooling requirements for livestock carcasses, and the development and adherence to HACCP plans, to reduce the occurrence and levels of pathogenic bacteria on meat and poultry products and to protect the health and welfare of consumers. FSIS is also proposing, based on these statutory provisions, to establish interim targets for quantitative reductions in the incidence of contamination of meat and poultry with microbial pathogens. These actions to protect public health and improve the safety of meat and poultry products are authorized by the various provisions of the Acts referenced above.

B. Improving Food Safety at the Animal Production Stage

There is wide agreement that ensuring food safety requires taking steps throughout the continuum of production, slaughter, processing, distribution, and sale of livestock and poultry carcasses and meat and poultry products to prevent hazards and reduce the risk of foodborne illness. The U.S. food safety continuum begins on the farm. From there, animals are transported to markets and then to slaughtering establishments.

While FSIS is proposing significant enhancement in its regulatory oversight of FSIS-inspected slaughter and processing establishments, improving food safety at the animal production stage would require a different approach. Many producers recognize the need to play an active role in reducing microbiological and chemical hazards that originate on the farm. FSIS will work with producers and others to develop and foster implementation of food safety measures that can be taken on the farm and prior to the animals entering the slaughter facility to reduce the risk of harmful contamination of meat and poultry products. Within this context, the voluntary application of HACCP principles can be useful in establishing the CCP's within the farm management and live animal transportation arenas where pathogenic organisms can enter the food chain.

HACCP principles can be utilized also to structure voluntary national animal health programs that focus on risk reduction and producer incentives to reduce the prevalence of a given pathogen. Such voluntary programs can be built upon similar, successful food safety efforts presently in use. These include industry-sponsored quality assurance programs, such as the Milk and Dairy Beef Quality Assurance Program, a ten-point grassroots education effort by the National Milk Producers Federation and the American Veterinary Medical Association; pork and beef quality assurance programs developed by the National Pork Producers Council and the National Cattlemen's Association; the American Veal Association's quality assurance program; the GMP guidelines developed by the National Broiler Council and several quality assurance efforts by the United Egg Producers; the chemical-residue avoidance program of the National Turkey Federation; and the flock health-certification program of the American Sheep Industry Association. All these programs focus on actions that individual producers can take to improve the quality and safety of the products they market. These programs provide a foundation for building future on-farm food safety initiatives.

There may also be a link between on-farm control measures and the proposed mandatory implementation of HACCP in FSIS-inspected meat and poultry establishments. For example, establishments may determine that the external cleanliness or degree of external contamination of animals with pathogenic microorganisms at the time the animals enter the slaughter

establishment is a critical control point. This would require that the establishment and the producer work together to ensure that an appropriate critical limit has been met. This possible linkage between in-plant mandatory HACCP and the control practices of producers simply reflects the reality that improving the safety of meat and poultry products will require cooperative action across the entire food system from production on the farm all the way to the consumer. The expertise and commitment of the producer community will be critical to making real progress.

FSIS invites comment on the role it can best play to improve food safety at the animal production stage. Because FSIS resources in this area are limited, the private sector must continue and perhaps expand its efforts and initiatives. One role FSIS expects to play is as a facilitator of research and other activities designed to define problems and opportunities for improvement and develop animal production technologies and practices that can improve food safety. FSIS intends to work closely with academic researchers, other government agencies, producer groups, and consumer organizations to help shape an appropriate research agenda and devise effective on-farm food safety strategies.

FSIS also intends to work closely and cooperatively with producers and with State health and agricultural officials when outbreaks of foodborne illness necessitate investigations to trace a safety problem to its origins which may in some cases be at the animal production stage. Such investigations are a problemsolving tool intended to assist public health authorities in controlling an ongoing food safety problem and finding means to prevent or reduce the likelihood of occurrence of the problem in the future. Traceback investigations are resource-intensive and difficult to conduct. They require cooperation among government agencies at all levels and with the animal production and processing industries. FSIS invites comment on the appropriate role of traceback investigations and how they can best be conducted and used to improve food safety.

C. Transportation, Distribution, Storage, Retail

Just as food safety hazards can arise before animals enter the slaughterhouse so too can they arise after meat and poultry products leave FSIS-inspected slaughter and processing establishments. The transporter, the wholesaler, the retailer, and the food service industry are important links in the chain of responsibility for food safety that extends from the farm to the consumer. FSIS has historically focused on the manufacturing of meat and poultry products, but the Agency's public health mandate requires that it also work with the animal production, transportation, distribution, and retail sectors to implement effective prevention strategies and ensure that the whole system is working effectively to prevent food safety problems.

FSIS and FDA share authority and responsibility for overseeing the safety of meat and poultry products after they leave FSIS-inspected facilities. In accord with the Administration's National Performance Review, FSIS and FDA have agreed to work together to ensure effective oversight and the adoption of preventive approaches through the chain of transportation, distribution, storage, and retail.

FSIS exercises regulatory oversight of meat and poultry products in transportation, storage, and distribution channels through the activities of about 130 compliance officers who conduct a nationwide monitoring program to prevent adulterated or misbranded product from reaching consumers. FDA also conducts regulatory activities in this sector. In addition to monitoring retail food safety programs at the State level, FDA provides technical assistance to States in the form of a uniform code (the *Food Code* discussed below) that prescribes appropriate food handling practices in distribution and retail channels.

FSIS and FDA will review their respective programs to determine how they can, considering all of the resources being devoted to this sector, reconfigure the program or initiate activities to increase program effectiveness. Two specific areas of review will be transportation of product in commerce and handling and preparation of food products by retail stores, restaurants, and institutions.

In the area of transportation, FSIS is currently working with FDA on the development of guidelines for conveyances used to transport food products. FSIS and FDA have agreed to:

- Ask a group of experts to provide systematic information on the hazards and controls that currently exist;
- Develop practical standards of performance for establishments and carriers with respect to the transport of food;
- Develop a list of Good Manufacturing Practices and options for encouraging their use;
- Initiate joint rulemaking to establish appropriate standards to ensure the safety of meat and poultry products and other foods during transport;
- Work with the Department of Transportation to implement the National Food Safety Transportation Act, and investigate whether additional authority is needed to carry out the shared food safety mission of FDA and FSIS.

In the area of retail distribution, FSIS has worked closely with FDA in the recent updating of the Food Code, a set of model ordinances that serve as a guide for State and local authorities who have primary responsibility for the regulation of retail stores and restaurants. FSIS and FDA will continue to work on making the code comprehensive, focusing on areas of greatest concern, and using existing FDA mechanisms such as seminars, workshops, and evaluations for getting the word out in a timely manner on important changes and assuring good understanding of the practices involved. FSIS and FDA will collaborate in presenting issues to the Conference for Food Protection and in responding to the Conference's recommendations, on which the States vote. In addition, the two agencies will work together to facilitate State audits, and to provide assistance for whatever changes the audit results indicate.

FSIS and FDA will also work together to encourage State adoption of the *Food Code* as a means to ensure that consistent, science-based food safety standards are being observed at the retail level across the country.

D. Health-Based Standards for Pathogenic Microorganisms

Overview

As explained elsewhere in this document, the FSIS food safety regulatory strategy rests on articulating what constitutes an acceptable level of food safety performance by meat and poultry establishments and holding establishments accountable for achieving that level of performance. The proposed HACCP regulations will provide the framework for adoption by all meat and poultry establishments of the science-based preventive controls that will be necessary to achieve the food safety objectives established by FSIS.

As an initial step toward articulating an acceptable level of food safety performance and reducing the frequency and degree of contamination of meat and poultry products with pathogenic microorganisms, FSIS is proposing to require reductions in the incidence of one pathogenic microorganism of significant public health concern,

Salmonella, based on what is achievable in the near term with available science and technology. FSIS may in the future adjust the interim targets for *Salmonella* downward, as experience warrants, and may consider adopting similar technology-based interim targets for other pathogens.

As explained earlier in this document, FSIS also intends to pursue over the long term development of science-based food safety performance standards that are based on what is necessary and appropriate to protect public health. This is the approach typically taken in the regulation of chemical residues in food: tolerances are established that limit the amount of residue that can be lawfully present based on an assessment of what limit is necessary to ensure the safety of the food. For certain cooked, ready-to-eat products, and more recently in the case of *E. coli* 0157:H7 in raw ground beef, FSIS has determined that pathogens at any level pose a safety concern and legally adulterate the product, in effect setting a zero tolerance for such pathogens.

Other than *E. coli* 0157:H7 in raw ground beef, a potential hazard that survives traditional cooking practices followed by many people, FSIS has not taken this approach with pathogenic microorganisms contaminating raw meat and poultry products. FSIS has relied in part on the fact that proper and generally accepted cooking practices kill most pathogens present in most raw products. It is also believed that for some important pathogens, such as *Salmonella, Staphylococcus aureus* and *Bacillus cereus*, some minimum number of organisms may be required to pose a significant threat of illness, although there is much scientific uncertainty in this area and susceptibility to illness varies among individuals.

The task of establishing science and public-health based food safety performance standards for meat and poultry products, such as by identifying levels of specific pathogens that pose a threat to public health and requiring that those levels not be exceeded, raises difficult scientific and public health policy issues. These include determining the nature of the hazard posed by particular pathogens and the actual threat to health posed under various conditions of exposure to the pathogen—an inquiry commonly referred to as risk assessment. In setting such standards, it also must be determined how protective the standard is to be: how strong must the assurance of safety be? Is any degree of risk acceptable? How can potential risks be managed by quantitative limits, labeling or some combination of measures? Addressing these public health policy issues is sometimes referred to as risk management.

FSIS invites public comment on the utility of health-based food safety performance standards and the issues involved in developing them. FSIS also intends to hold one or more public meetings to explore this topic with interested persons and experts in the industry, scientific, consumer and public health communities. Details on the time, place, and agenda for such meetings will be published in a future issue of the **Federal Register**. While the public health policy issues in this area are difficult and important, it is necessary first to consider the scientific basis for setting health-based food safety performance standards. The following paragraphs describe the current state of knowledge in this area and some of the scientific issues that need to be addressed.

Quantitative Risk Assessment for Microbial Pathogens

Integral to development of public health-based food safety performance standards is an understanding of the relationship between bacterial levels and the incidence of disease. The likelihood that an exposure to a foodborne pathogen will produce a disease response in an individual is dependent on the pathogenicity of the microorganism, the level of exposure (i.e., number of microorganisms ingested), and the susceptibility of the host. Qualitative and quantitative consideration of these factors is the basis for conducting a microbial risk assessment.

Pathogenicity describes the overall disease-causing capability of a microorganism. The inherent potential for a microorganism to cause disease is associated with one or more genetic characteristics (i.e., virulence factors). The virulence of a species is reflected in the levels of the microorganism that are needed to colonize a host and produce an infection or toxigenic response, as well as the severity (i.e., medical consequences) of the disease. However, pathogens must always be considered in the context of their host, since disease processes are dependent on host/pathogen interactions. In any population, individuals will have a varied response to any specific pathogen. This includes both the levels of the pathogen needed to elicit an infection or morbidity, and the extent and duration of symptoms. Typically, there will be a distribution of susceptibilities as a function of the levels of ingested pathogen.

This distribution of the host and pathogen characteristics means that the potential for infection must be treated as a probability function. This approach is replacing the older concept of minimum infectious dose, which fails to take into account the distribution of susceptibility within the host population. As the number of pathogen cells to which the host population is exposed increases, there is a corresponding increase in the probability of infection among the population.

The amount of data on the quantitative dose-response relations for human and various foodborne pathogens is severely limited. However, available data do allow estimation of infection rates for many foodborne pathogens. In many instances this may be sufficient since, barring exceptional pathogenic resistance or host susceptibility, the key data for a microbial risk assessment in foods are estimates of exposure (i.e., the numbers of pathogens ingested by consumers) and their correlation with infection rates.

A key limitation on the application of risk assessment techniques to microbial food safety issues has been that, unlike most chemical toxins, the levels of bacteria in food are not constant. They can change drastically as the result of growth or inactivation. The ability to run risk assessment scenarios to study the potential impact of changing food processing or food preparation protocols is dependent on acquiring a reasonable estimate of the levels of a pathogen consumers are ingesting. The ability to estimate exposure is, in turn, dependent on being able to estimate (1) The probability that the pathogen is present in the food ingredients, (2) the initial levels of the pathogen that can be expected if the microorganism is present, and (3) how these levels are likely to change as a result of operations associated with the processing, preparation, and storage of the food. While there are still methodological limitations, recent advances in predictive microbiology and the systematic collection of baseline data on the presence of pathogenic bacteria in foods have begun to allow the first quantitative microbial risk assessments.

In the case of some significant foodborne illness sources, such as contamination of raw poultry with *Salmonella* and *Campylobacter*, the illness is more often caused not by direct consumption of the contaminated food but by cross-contamination of other foods during handling and preparation. FSIS is not aware of research having been done to correlate levels of specific

pathogens in raw meat or poultry with the risk of cross-contamination and consequent illness. Whether experimentally derived or acquired through correlation of community disease rates and pathogen levels in meat or poultry, FSIS would be interested in reviewing any available data. At the same time, recognizing the key nature of such data, FSIS is committed to working with the CDC and the research community to obtain the necessary information.

Finally, quantitative risk assessment for pathogenic microorganisms is complicated by the wide variability in susceptibility to particular pathogens among individuals and groups of individuals in the population. It is well known, for example, that the young and the elderly are at significantly greater risk of serious illness or death from consumption of *E. coli* 0157:H7 than the general population. Any person with a weakened or compromised immune system, whether due to age or illness, is generally more vulnerable to foodborne illness associated with pathogenic microorganisms. Thus, in developing the scientific basis for risk assessment, attention must be paid to these subpopulations so that any resulting health-based standard will be adequately protective of the population as a whole.

Future Activities

FSIS intends to work closely with the Centers for Disease Control and Prevention, the Food and Drug Administration, other public health agencies, academic scientists, and the industry and consumer communities to develop the scientific basis for microbial risk assessment and the creation of health-based performance standards for pathogenic microorganisms. FSIS recognizes that the scientific issues are difficult and that it may not be possible in the near term to establish health-based standards for all pathogens. It is important to begin this effort, however, because, as progress is made in the near term toward pathogen reduction on the basis of available technology, it will be increasingly important to know what constitutes an acceptable level of food safety performance from a public health perspective. Health-based performance standards can provide an incentive for further improvement and progress in reducing pathogenic microorganisms and an indication of the point beyond which further reduction would be unlikely to yield a public health gain.

FSIS will seek to stimulate—and to a limited extent conduct and support—the scientific research needed to develop quantitative risk assessment methods and databases for pathogenic microorganisms. This will likely include laboratory research, in-plant studies and community-based epidemiological studies to evaluate health outcome in meat and poultry inspection. FSIS intends to use the public meetings mentioned above to canvass the current state of knowledge in this area and encourage development of a coherent research agenda that can contribute to progress in this important area.

E. FSIS Technology Strategy

Overview

FSIS has a longstanding interest in the technologies used in meat and poultry establishments. The facilities, equipment, and processes used during slaughter and processing of meat and poultry can significantly affect the safety, quality and wholesomeness of the finished product. The safety of the product can be affected adversely by the wrong technology, such as equipment whose food contact surfaces cannot be adequately cleaned, or by misuse of a technology, such as a chemical sanitizer or preservative that is used above established safe limits.

There are also many technologies that can be used in meat and poultry establishments to help protect product from physical, chemical, and biological, especially microbiological, hazards. These include laboratory and in-plant methods to test for chemicals, animal drugs and bacteria; technologies for preventing harmful contamination by pathogenic microorganisms; chemicals or physical treatments that can be applied to carcasses to reduce pathogens; and equipment to verify pathology diagnoses.

FSIS currently regulates virtually all substances, processes, and pieces of equipment found in meat and poultry establishments that might affect the safety, quality, or wholesomeness of the product, through either prior approval on a plant-by-plant basis or publication of generic approvals or lists of approved items. The principle objectives FSIS pursues with these mechanisms are to ensure that the technology does what it is claimed to do (especially if the claim is safety related) but does not jeopardize the safety or wholesomeness of the product, cause or contribute to economic adulteration, interfere with FSIS inspection, or jeopardize the safety of inspectors.

Recently, members of the regulated industry have complained that the Agency's control mechanisms, especially its prior approval processes, stifle innovation and may retard technological progress that can improve food safety in such important areas as pathogen reduction. At the same time, representatives of consumer groups have expressed concern that technologies claimed to be effective for pathogen reduction and other important food safety purposes be proven effective for that purpose and that the scientific processes used by FSIS to evaluate technologies be more open to public scrutiny and participation.

FSIS believes that the development and proper use of technology can contribute significantly to improving the safety of the food supply, especially with regard to reducing the threat posed by pathogenic microorganisms; and can, in general, improve the Agency's ability to carry out its mission. The FSIS food safety strategy depends heavily on establishing food safety objectives for the meat and poultry industry, which in turn provide an incentive for industry to innovate to meet those objectives. To make this strategy work, FSIS must not be an obstacle to beneficial innovation.

Therefore, FSIS is reviewing its current policies and procedures governing review and approval of in-plant technologies with the intention of simplifying them to the maximum extent possible, while ensuring that important safety and efficacy issues are considered. FSIS invites comment on its technology strategy, including the issues and activities outlined below. FSIS also intends to convene one or more public meetings to gain further input on how it can improve its role in fostering and overseeing the implementation of new technologies to improve the safety of meat and poultry products. Some of the Agency's current perspectives and activities in the area of technology development and evaluation are outlined below.

Current Perspectives and Activities

As a general rule, the development of technologies required to produce safe and wholesome products is a responsibility of the meat and poultry industry and allied enterprises, such as equipment designers and manufacturers, pharmaceutical companies, analytical laboratories, manufacturers of non-food compounds, and many others. Innovative technologies are continually developed by these entities to enhance productivity and profitability in the meat and poultry industry. FSIS believes that industry innovation can also be directed to improving food safety if the right incentives exist. FSIS intends as part of its long-term food safety strategy to increase the incentive for such innovation by establishing

public health-driven targets, guidelines, or standards that establishments will be held accountable for meeting. This should have its greatest impact in slaughter establishments, where such targets, guidelines, or standards do not generally exist today.

FSIS will focus its own limited technology development efforts on tools that can assist the Agency in detecting and evaluating food safety hazards or addressing other issues within its statutory responsibility, such as economic adulteration. These efforts have traditionally included, and will continue to include, the development of sensitive and reliable analytical methods and diagnostics that can assist the Agency in verifying the safety of meat and poultry products and detecting product characteristics of regulatory interest. FSIS will also continue its efforts to develop tools that it can use to advance its food safety mission but that require long-term commitment to develop, such as various computer models on pathogen behavior. In these cases, the Agency has (1) carried out its own technology development efforts, as it did in developing quick tests for antibiotics and species identification; (2) secured the assistance of the Agricultural Research Service and Cooperative State Research Service, as it has done with computer modeling of pathogen growth under various times and temperatures; and (3) occasionally, supported specific work by academic institutions or other private entities through use of competitive bidding processes, as it did recently by awarding more than $700,000 in contracts for development of methods to detect pathogenic microorganisms.

The resources available to FSIS for such technology development activities are very limited. Moreover, FSIS has found that there is often considerable interest within the regulated industry in using technologies that were originally developed by FSIS. FSIS intends to explore mechanisms for stimulating private sector investment in analytical methods and other technologies that can assist the Agency in its regulatory role but that also can assist the industry in carrying out its food safety responsibilities.

FSIS believes that its primary role with respect to new in-plant technologies developed by industry should be to ensure that the technologies do not interfere with inspection, threaten the safety of the product, or violate other statutory standards, such as those concerning economic adulteration.

In some circumstances, the FSIS evaluation of a new technology may need to consider the efficacy of the technology, that is, its success in accomplishing its intended objective. For example, if FSIS has a regulatory requirement for the use of an antibacterial treatment, as is proposed elsewhere in this document, the Agency will take an evaluative interest in whether a specific treatment in fact has the intended and required effect. In addition, if a company intends to make a marketing claim for a process or technology used in an establishment—such as a claim that its product is ''pathogen free''—FSIS will require a demonstration that the claim is valid.

On the other hand, in circumstances where industry interest in the technology is not based on required or claimed health and safety effects, but on a productivity concern, FSIS interest will be limited to ensuring that relevant safety questions have been addressed.

When FSIS makes significant decisions about the safety or effectiveness of an in-plant technology, it must ensure that its decisions are scientifically sound and open to appropriate public scrutiny and participation. An example of how this can be achieved is the approach taken in an earlier section of this document to inviting public comment on the possible antimicrobial treatments that might satisfy the proposed requirement that all meat and poultry establishments adopt at least one antimicrobial treatment. FSIS invites comment on this approach and other means for ensuring that its scientific decisions are sound and open to public scrutiny.

During the past several years, staffs in the Agency have begun efforts that would permit technological change to proceed more readily from the development to the implementation stage. The Facilities, Equipment and Sanitation Division has explained many of the principles and criteria that it uses to make decisions in publicly available documents so that they can be readily understood and used by companies as they plan changes in their physical plants. The Microbiology Division has provided public notice about the circumstances under which it will formally evaluate analytical methods that may be useful in the FSIS program, and it has negotiated a Memorandum of Understanding with the AOAC Research Institute that will permit manufacturers of test kits designed for use by the industry to have their technologies evaluated for that purpose. The Processed Products Inspection Division has developed guidelines to be used in preparing various required QC programs. The Slaughter Inspection Standards and Procedures Division has developed and made available protocol guidelines so that companies that want to conduct in-plant demonstrations of antimicrobial treatments will know what is necessary to secure Agency approval.

Providing clear guidance of this kind assists companies in meeting the Agency's requirements and will continue to be an important part of FSIS's effort to improve its technology review function. As outlined below, however, FSIS intends to take a number of additional steps to help foster development, appropriate review, and prompt implementation of beneficial new technologies, especially those that can help improve the safety of meat and poultry products.

Future Agency Activities

As already noted, FSIS is reviewing all of its existing systems of prior approval or other procedural requirements that are now in place regarding the development and implementation of technologies in meat and poultry establishments. The Agency intends to eliminate, streamline, or otherwise modify its systems and procedures, as appropriate, to ensure that its legitimate oversight obligations are met without unduly delaying the introduction of beneficial new technologies or imposing unnecessary burdens on establishments seeking to adopt such technologies.

One approach FSIS is considering is a simplified single-stop approval mechanism for industry-wide application of proven pathogen reduction technologies, once necessary laboratory and in-plant trials have been completed and the data have been evaluated. The generic approvals FSIS recently granted for use of hot water and organic acids in conjunction with the final carcass wash in beef slaughter establishments could provide a workable model for expediting the adoption of pathogen-reducing technological developments. The Agency's scientific evaluation would be for the purpose of ensuring that efficacy is demonstrated, that conditions of use are specified so the technology can be widely replicated, and that verification techniques are available. Once this scientific evaluation has been completed on a generic basis, approval for industry-wide use without further constraints, such as plant-by-plant review, could be granted by the Administrator or his/her designee. FSIS invites comment on this approach, including what public process would be appropriate in making such decisions.

FSIS is also establishing a single point of contact in the Agency regarding technology development and implementation. This will be the newly constituted office of technology development in the Science and Technology Program. This office will serve as the initial point of contact for all inquiries about technology development, and it will help coordinate evaluations that involve multiple divisions in the Agency so that responses to inquiries will be timely and complete.

This office will also coordinate development of, and make available to interested parties, a single guideline for experimental protocols to be submitted to the Agency prior to commencing an in-plant study of a new technology. Some new technologies need to be evaluated in in-plant trials to determine their safety and effectiveness before they can be appropriately evaluated by FSIS. The Agency does not intend to impede those trials, but it must be assured that they produce data that will be adequate to address the Agency's concerns. Thus, one important element of the guideline will be a description of the information that must be submitted to satisfy the Agency's basic safety concerns. For those circumstances in which the Agency will be evaluating the efficacy of a technology, the guideline will provide detailed information about the Agency's expectations for data offered to demonstrate efficacy. This information will address such areas as the quality of the experimental design, the necessary quantity and quality of data, the plan for data analysis, and other relevant elements.

Finally, FSIS intends to interact publicly with the regulated industry and all interested parties to foster the development of beneficial new food safety technologies and to improve how the Agency plays its role in this critical area. In areas where FSIS is engaged in technology development of its own to advance its regulatory objectives, the Agency intends to identify research that is needed to support its efforts. FSIS is also interested in learning more about the opportunities that exist for improving food safety through the adoption by establishments of scientifically sound processes and technologies in both slaughter and processing operations, and the Agency seeks public input on its effort to improve its systems for reviewing and approving new technologies. As a first step, FSIS intends to hold a public meeting on these topics during the comment period on the regulations proposed elsewhere in this document. Details on the time, place and agenda for this meeting will be published in a future issue of the **Federal Register**.

F. FSIS Inspectional Roles

The current FSIS program, as described in Part I of this document, is fundamentally an inspection program. It is a program designed to ensure through inspection that proper sanitary practices are observed, that organoleptically detectable defects, including diseased and contaminated carcasses, are excluded from the food supply, and that other requirements and standards related to safety, economic adulteration, and misbranding are met.

The long-term FSIS food safety strategy and the HACCP proposal set forth in this document will bring about substantial change in industry practice and in the FSIS program, as the Agency clarifies and reinforces the industry's responsibility for producing safe food, prepares to play its oversight role to ensure companies are implementing HACCP properly, and works to ensure that all participants in the food system—producers, processors, distributors and retailers—are meeting their food safety responsibilities.

With these changes, inspection of products and practices will remain central to the FSIS program. HACCP verification will necessarily expand the roles in-plant inspectors will be called upon to play, and HACCP will enhance the contribution in-plant inspection can make to ensuring the safety of food. In addition, the need to address food safety across the continuum from the farm to the consumer, as discussed in the preceding sections of this document, raises the question of the role FSIS inspectional oversight should play outside of slaughter and processing establishments.

Although the demands that will be placed on the FSIS inspection force by HACCP and other elements of the Agency's food safety strategy will develop over the next two to four years, it is important that FSIS begin considering now the future roles of the FSIS inspection program and how FSIS can maximize the contribution its inspectors make to ensuring the safety of the food supply. One of the Agency's most important challenges and obligations is, by means of training and a clear definition of roles and responsibilities, to prepare its workforce to meet the demands of the future.

In the course of developing the food safety strategy and regulatory proposals set forth in this document, FSIS has consulted with the National Joint Council (NJC) of Food Inspection Locals of the American Federation of Government Employees, which represents the Agency's food inspectors, as well as organizations representing the Agency's veterinarians (National Association of Federal Veterinarians (NAFV)) and technical and supervisory personnel (Association of Technical and Supervisory Personnel (ATSP)). The Agency will continue this consultation throughout the pathogen reduction and HACCP rulemaking process. FSIS also intends to work closely with the bargaining unit and the employee organizations in formulating a plan for the optimal utilization of the Agency's inspectional workforce, and FSIS will comply fully with its obligations under the Basic Agreement with the NJC to bargain on matters that impact inspectors.

The Agency's employees and their representatives are strongly committed to ensuring the safety of the food supply and building the best possible food safety program. They have a critically important expertise and perspective that must be brought to bear in developing optimal roles and responsibilities for FSIS employees.

Many of the current roles of FSIS inspectors are controlled by the statutory mandates for: (1) Carcass-by-carcass inspection in slaughter establishments; (2) continuous FSIS inspectional presence in all processing establishments; and (3) inspectional responsibilities for non-safety wholesomeness and economic adulteration. FSIS is committed to carrying out these existing mandates. Moreover, changes in FSIS inspectional roles will be constrained by the level of resources available to support the inspection program. Nevertheless, some of the inspectional issues FSIS expects to be addressing are outlined below.

FSIS recognizes that food safety begins at the original point of production of the food animal—the farm—and can be affected at every step along the way, including each step of animal production and transportation leading to delivery of the animal to the slaughterhouse. Many in the agricultural producer community have recognized the potential for applying quality assurance principles, including HACCP, on the farm to prevent the introduction of potential food safety hazards at their source. Although the Agency welcomes this initiative, FSIS does not currently have and does not anticipate on-farm inspectional authority.

As discussed in Part I, the first point of FSIS inspection is the antemortem inspection that occurs just before animals enter the slaughter process. It is appropriate to consider whether FSIS should broaden its antemortem inspectional oversight of conditions

under which animals are held in the period immediately before slaughter within its current authority. This is a period during which the health of the animal and its external cleanliness and degree of external microbial contamination can be affected in a way that may adversely affect food safety.

The FSIS in-plant inspectional role will certainly be affected by adoption and implementation of HACCP. As explained above in the portion of this preamble relating to the HACCP proposal, FSIS inspectors will be playing a verification role to ensure that appropriate HACCP plans are in place, are being implemented properly by the establishment, and are achieving the desired food safety results. This role will require increased activity by FSIS inspectors in the areas of records review, visual process verification, and product sampling. FSIS inspectors will, in some cases, have to develop new skills to carry out these activities within the HACCP framework. FSIS will be focusing on the specific additional tasks FSIS inspectors should be performing under HACCP and the training and skills that will be required.

FSIS is considering, in concert with FDA, the need for additional standards and Federal oversight to ensure that food is handled safely during transportation and distribution from processing establishments to the retail level. In the case of meat and poultry products, it is critical that products be shipped and stored in sanitary conditions and, in many cases, under refrigeration. If Federal standards are developed in this area, FSIS will have to consider what the role of Federal inspectors should be in ensuring such standards are met. No Federal agency would have the inspectional resources to inspect on a regular basis all of the hundreds of thousands of trucks, trains, vessels, planes, and storage/distribution facilities in the United States. FSIS will be considering whether there is an appropriate role for a targeted approach to inspection or random surveillance inspection, perhaps in collaboration with State and local food safety authorities, that would help ensure that safe practices are being observed at these critical stages of the food safety continuum. FSIS is interested in determining whether technologies, such as recording thermometers or temperature indicators on refrigerated trucks, could be adopted to enhance the roles of some relatively limited, periodic inspectional oversight and enable FSIS inspectors to work effectively in this area with inspectors from FDA and from counterpart agencies at the State and local levels.

At the retail level, FSIS intends to work closely with FDA and State and local officials and will continue to rely primarily on State and local authorities for inspectional coverage of restaurants, grocery stores and other conventional retail outlets. FSIS will be exploring how FSIS inspectors and field compliance officers can better collaborate with State and local food safety inspectors and other officials.

The FSIS inspection program for imported products relies on review of foreign inspection systems and exporting establishments to ensure that their approaches to food safety are equal to the U.S. approach, coupled with limited reinspection of incoming product at the U.S. border by FSIS inspectors. FSIS currently reinspects approximately 10 percent of import shipments, relying largely on organoleptic inspection techniques. Foreign establishments exporting to the United States will be required to adopt the pathogen reduction measures and HACCP requirements FSIS imposes on domestic establishments pursuant to this rulemaking. As HACCP develops, FSIS will be considering what effect adoption of HACCP should have on the nature and frequency of import inspection, including whether microbial testing should be incorporated, whether the periodic inspections FSIS currently conducts of foreign establishments should change, and how FSIS could best gain assurance on a continuing basis that establishments exporting to the United States are properly implementing appropriate HACCP plans.

Finally, some groups advocate amendment of the FMIA and PPIA to alter or repeal the current requirements for carcass-by-carcass and continuous inspection in meat and poultry establishments. This is necessarily an issue Congress would have to decide. As discussed in Part I of this document, carcass-by-carcass and continuous inspection play an important role in ensuring sanitation compliance is maintained, excluding diseased animals from the food supply, and detecting and removing other defects, such as fecal contamination, which are directly related to food safety. FSIS believes that, under any model of inspection, these objectives must continue to be met if food safety is to be ensured and the legitimate expectations of the public concerning the safety and quality of the food supply are to be satisfied.

Some propose that, with or without any statutory change in the carcass-by-carcass and continuous inspection mandates, establishments take more initiative in these areas. FSIS must consider how FSIS inspectors could verify with an acceptable degree of confidence that functions currently performed by a Federal inspector are being performed consistently, with the same rigor and effectiveness, by establishment employees. If establishment employees take on such functions currently performed by FSIS employees, consideration will have to be given as to whether ''whistleblower'' protection, which would shield them from retaliation of any kind for reporting problems, should be extended to them.

In general, under its proposed pathogen reduction and HACCP regulatory initiatives, FSIS will be considering what new inspectional tools and techniques FSIS should adopt to oversee the safety of meat and poultry products in a regulatory environment where greater responsibility for safety is being placed on establishments and their employees.

FSIS invites comment on these issues and on all aspects of how FSIS can best make use of its inspectional resources to improve the safety of meat and poultry products, both within currently inspected establishments and throughout the continuum from the farm to the consumer.

IV. Economic Impact Analysis and Executive Orders

A. Executive Order 12866

This proposed rule has been determined to be economically significant and was reviewed by OMB under Executive Order 12866.

Summary: Preliminary Regulatory Impact Assessment HACCP and Related Near-Term Initiatives Produce Net Benefit to Society

FSIS has prepared a Preliminary Regulatory Impact Assessment (PRIA) that evaluates the costs and benefits of a mandatory HACCP regulatory program and related near-term initiatives for all meat and poultry establishments under inspection. The PRIA concludes that mandating HACCP systems would result in net benefits that far exceed industry implementation and operation costs. Mandatory HACCP Program implementation at a cost of $2 billion over 20 years is projected to produce a direct reduction in foodborne illness with public health benefits estimated at $6–24 billion over 20 years.

The proposed near-term requirements, which would be incorporated into HACCP, would target pathogen reduction on carcasses and raw product, currently the products with the least systematically controlled hazards. The

benefits are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* 0157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes*. The minimization of risk from these pathogens which can contaminate meat and poultry during slaughter and processing would produce a 90 percent reduction in the foodborne illness attributed to these pathogenic microorganisms. Ten percent of contamination occurs after the product leaves the manufacturing sector.

Industry costs to develop, implement, and operate HACCP processing control systems are estimated to total $2 billion over 20 years. The proposed regulation would redistribute costs in a manner more acceptable to societal values which have always given priority to eliminating controllable diseases. Establishments that now have good processing controls would have relatively few implementation costs, while establishments that have little or no process control would need to spend more for compliance.

Market Failure Justifies Regulation of Pathogens

Since all raw meat and poultry products contain microorganisms which may be pathogens, raw food unavoidably entails some risk to consumers of pathogen exposure and foodborne illness. The presence and level of this risk cannot be determined by a consumer since pathogens are not visible to the naked eye. The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable either.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen controls. The widespread lack of information about pathogen sources means that businesses at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product.

The science and technology required to reduce meat and poultry pathogens is well established, readily available, and commercially practical. FSIS has concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention. The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS has determined to be unacceptable. A Federal regulatory program that reaches every level of meat and poultry processing for commerce is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP regulatory program is the only means to attain this goal.

Alternatives

Process Control Regulatory Strategy

FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination of food products and lower the risk of subsequent foodborne illness.

The process control regulatory strategy was evaluated using five factors for effectiveness:

1. Controls production safety hazards;
2. Reduces foodborne illness;
3. Makes inspection more effective;
4. Increases consumer confidence; and
5. Provides the opportunity for increased productivity.

Using these factors, FSIS has determined that mandatory HACCP provides the greatest effectiveness.

FSIS examined six other process control approaches before determining that mandatory HACCP was the most effective means for industry to eliminate pathogens in meat and poultry:

1. Status quo;
2. Intensify present inspection;
3. Voluntary HACCP regulatory program;
4. Mandatory HACCP regulation with exemption for very small establishments;
5. Mandatory HACCP regulation only for ready-to-eat products; and
6. Modified HACCP—negative records only.

Each of these alternatives was assessed using the five effectiveness factors for process control presented in the previous section. None was determined to meet all five criteria; each was found to be flawed in meeting one or more of the target factors.

The full text of the Preliminary Regulatory Impact Assessment is published as a supplement to this document.

B. Executive Order 12778

This proposed rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the FMIA and PPIA from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different from, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements on State-inspected products and establishments that are at least equal to those required under the FMIA and the PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

C. Effect on Small Entities

The Administrator, Food Safety and Inspection Service, has determined that this proposed rule will have a significant economic impact on a substantial number of small entities. For purposes of this proposal, a small entity is defined as an establishment with a sales volume of meat and/or poultry products of no more than $2.5 million per year. Based on this criterion, as of November 1994, there are 6,827 small slaughter and/or processing establishments that would be affected by this proposed rule. This analysis assumes that 5 percent of these small establishments or 341 establishments are currently operating under all the proposed requirements. Therefore, for these 341 establishments, this proposed rule would impose no additional costs.

For the remaining 6,486 small establishments, costs would be incurred as follows:

Near-Term Requirements

1. Sanitation Standard Operating Procedures

Establishments would be required to develop a written plan addressing the required operating procedures, monitor

the plan, record the results of monitoring, and store any records generated under the operating procedures. Establishments would also be required to train one or more individuals to carry out the operating procedures. Costs for this activity are estimated at $50.4 million.

2. Use of an Antimicrobial Treatment

Establishments would be required to use an antimicrobial treatment on all meat and poultry carcasses. Of the 1,923 small slaughter establishments, it is estimated that approximately 70 percent now apply an antimicrobial treatment to meat and/or poultry carcasses. Therefore, for these establishments, no additional costs should be incurred. For those establishments that do not now use an antimicrobial treatment, costs are estimated at $2.7 million.

3. Time/Temperature Requirements

Establishments would be required to provide written plans for complying with the proposed time, temperature, and monitoring requirements for carcasses and raw meat products, or with alternative procedures which would be permitted under this proposal. The written plan would include the establishment's designated control points, corrective actions, and, when applicable, the name of the processing authority. Some establishments may decide to hire a processing authority to develop such plans, while others may prepare their own plan. If an establishment chooses to follow alternative procedures, the establishment must hire a processing authority to develop the alternative procedures.

The refrigeration requirements set forth in this proposed rule may result in costs associated with purchases of refrigeration facilities. Although all establishments must have cooler rooms and most have refrigerated vehicles for shipping product, some small establishments may not have existing refrigeration facilities that would meet the proposed refrigeration requirements. The number and size of refrigeration units that may be required would depend on cooler room sizes and slaughter volumes of individual establishments.

Establishments would be required to monitor the temperatures of carcasses and raw meat products throughout their operations to ensure compliance with their plan, and maintain ongoing monitoring records for the previous 6 months. Costs for time/temperature requirements are estimated at $28.8 million.

4. Microbiological Testing for *Salmonella*

Each establishment that slaughters livestock or poultry or produces raw, ground meat or poultry products would be required to collect and test one specimen of product per day at the end of the production process. The specimen would be tested for the presence of *Salmonella* (the target organism). Testing could be conducted in the establishment's own laboratory or in a commercial/contract laboratory. Results of the testing would be recorded daily. Costs for this activity are estimated at $91.1 million.

As a general matter, this approach to process control verification testing provides a very efficient means of determining whether a slaughter establishment is consistently achieving the interim target for pathogen reduction. Many slaughter establishments currently conduct voluntarily, for a variety of purposes, significantly more frequent microbiological testing, and for many establishments the cost of testing a single sample per species per day will be relatively small (approximately $30–35 per sample) in relation to the volume of a day's production.

For some small FSIS-inspected establishments, however, microbiological testing may be entirely new, and the cost of testing will be more significant in relation to the volume of production. For example, some specialty slaughter plants may slaughter only a few head of livestock per day and may slaughter multiple species, thus requiring multiple tests, despite a low volume of production.

FSIS has considered the potential impact of its proposed microbiological testing requirement on small businesses. FSIS is considering alternatives to minimize the burden on small establishments while still achieving the goal of verifying that the establishment's process control is achieving the interim target for pathogen reduction.

One alternative would be to allow certain small establishments additional time to prepare for and begin testing. FSIS is proposing that testing begin 90 days after publication of the final rule. By extending this period for small establishments, such establishments would have additional time to prepare for the testing and to find an efficient means of accomplishing it. In addition, as the testing gets underway in most establishments and the demand for efficient testing increases, FSIS expects that the market will respond by producing increasingly economical test methods for use by establishment personnel and increasingly low-cost laboratory services for establishments that choose to contract outside the establishment for microbiological testing.

Another alternative for reducing the cost burden on small establishments would be to require less than daily testing to verify process control. For example, every-other-day testing could reduce costs by half. This would extend the time required to detect that any establishment is not achieving the target and to begin corrective measures.

FSIS invites comment on whether special consideration should be given to small establishments to reduce the cost burden of testing and on the alternatives outlined above, as well as any other possible alternatives. FSIS is particularly interested in comment on the criteria that should govern eligibility for such special consideration. As discussed above, for the purpose of allowing small establishments the maximum 3-year period to comply with the proposed HACCP regulation, FSIS is proposing to define a ''small'' establishment as one with annual sales of $2.5 million or below. FSIS invites comment on whether this would be the right criterion for any special relief regarding testing or whether an alternative criterion, such as the number of head or a different dollar volume of sales, should be used.

Long-Term Requirement

Implementation of HACCP Systems

Establishments would be required to develop and implement HACCP systems. Costs to develop, implement, and monitor HACCP plans for small establishments are estimated to be $157.6 million. FSIS has determined that it is reasonable to allow small establishments additional time to meet the proposed HACCP requirements. Therefore, small establishments would have 36 months from the publication date of the regulation to implement their HACCP plan(s).

D. Paperwork Requirements

The paperwork requirements in the current proposal, namely records and plans, represent an alternative to the current process of inspection. The industry's documentation of its processes, first in a plan and thereafter in a continuous record of process performance, is a more effective food safety approach than the sporadic generating of information by an inspector. It gives inspectors a much broader picture of production than they can generate on their own and gives them time to perform higher priority

tasks. At the same time it gives the managers a better view of their own process and more opportunity to adjust it to prevent safety defects.

To produce this documentation, all industry managers must learn about the options and methods for making their processes safer, which they do not have to do if the inspector appears to be the only one responsible for finding defects. Therefore, while the proposal contains increased paperwork burden, it is balanced by a reduction in the number of face-to-face contacts between management and the inspector that are required to assure the process is being controlled, so that the opportunity for better control is accompanied by an increase in productivity for both inspectors and managers.

In order not to increase the paperwork burden unnecessarily, the Agency has not required that plans be submitted for prior approval. In addition, the Agency is considering changing some existing prior approval programs, which would further reduce the paperwork burden on industry.

As part of establishments' sanitation requirements, each establishment would develop and maintain an SOP that would be used by inspection personnel in performing verification tasks. The SOP's would specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. As part of the SOP, establishment employees(s) would record results of daily sanitation checks on a checklist at the frequencies stated in the SOP. The checklist would include both preoperational sanitation checks and operational sanitation checks. This checklist would be made available to Program employees, upon request.

As part of the time and temperature requirements, establishments would develop, implement, and place on file a written plan to meet the time and temperature requirements. The plan would include the establishments designated control points where temperatures would be measured; monitoring procedures; how recordkeeping activities would be performed; standards for control points (e.g., cooling rate, holding temperature, and shipping temperature); corrective actions; and, when applicable, the name of the processing authority.

Establishment employees would also have to maintain records that report the maximum temperature of carcasses and raw meat and poultry products throughout the establishment's operations on a daily basis with the frequency of monitoring based on the establishment's size and type of operation. These records would be required to be maintained on file for 6 months after the temperature measurement, and the records would be made available to Program employees, upon request. Additionally, the shipping establishment would be required to record the date and time of shipment of product on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying the shipment.

As part of microbiological testing, each establishment would develop written procedures outlining specimen collection and handling. An establishment may test the specimens in their own laboratory or in a commercial/contract laboratory. Either an internal or external QA/QC program with check sample analysis would be required. QA/QC records must be available to Program employees, upon request.

The laboratory would supply the results on a daily basis to the establishment. The establishment would be responsible for entering the results daily into a statistical process control chart. The data and chart would be available for review by the Inspector in Charge upon request.

The establishment would notify the Inspector in Charge if the results of the testing exceed the process control limits. In such instances, a complete review by the establishment of the production process would be required. A written report of the evaluation, including the reason for process failure and proposed corrective actions, would be submitted to the Inspector in Charge within 14 days from the day the process exceeded the limits. This report would be updated on a weekly basis until the process is in control.

For the implementation of HACCP, the establishment would maintain on file the name and a brief resume of the HACCP-trained individual(s) who participates in the hazard analysis and subsequent development of the HACCP plans. Establishments would develop written HACCP plans that include: Identification of the processing step(s) presents hazard(s); identification and description of the CCP for each identified hazard; specification of the critical limit which may not be exceeded at the CCP, and, if appropriate, a target limit; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records which would be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Critical limits which are currently a part of FSIS regulations or other requirements must be included.

Establishments would keep records for measurements during slaughter and processing, corrective actions, verification check results, and related activities that contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The information would be recorded at the time that it is observed, and the record would be signed by the operator or observer.

The HACCP records would be reviewed by an establishment employee other than the one who produced the record, before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be this second reviewer. The reviewer would sign the records. Lastly, HACCP records generated by the processor would be retained on site for at least 1 year and either on site or in a nearby location for an additional two years.

The paperwork and recordkeeping requirements contained in this proposed rule have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Send written comments to: Office of Management and Budget, Desk Officer for FSIS, Office of Information and Regulatory Affairs, Room 3208, New Executive Office Building, Washington, DC 20503, and to the Clearance Officer, Room 404–W, Administration Building, Washington, DC 20250.

Imports and Exports

The proposed rules will affect importers and exporters of meat and poultry to the U.S. The inspection statutes require that imported product be produced under an inspection system that is equivalent to the U.S. inspection system. The equivalence of a country's system must be established by the United States before product can be exported to the United States. The notion of equivalence has been clarified under the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary measures. Under the WTO all members have an obligation to apply the principle of equivalence on importing countries. Equivalence determinations are based on scientific evidence and risk assessment methodologies.

In light of the WTO emphasis on the use of science to determine equivalence, a number of countries are moving toward implementation of HACCP systems.

HACCP and the related near-term initiatives proposed in this document represent science-based regulation.

Upon implementation of these regulations, FSIS will review other countries' meat and poultry systems to ensure that exporting countries have adopted comparable measures, which would entitle them to continue exporting product to the United States. As other countries improve their regulations by adopting provisions comparable to those proposed in this document, it is expected that U.S. exports will similarly be affected.

FSIS is soliciting comments from all interested parties on how the proposed rule would affect international trade. FSIS believes that these improved scientific measures will facilitate trade.

Comments

Interested persons are invited to submit written comments concerning this proposal and the PRIA. Written comments should be sent in triplicate to Diane Moore, Docket Clerk, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 3171–S, Washington, DC 20250. Any person desiring an opportunity for an oral presentation of views as provided by the Poultry Products Inspection Act should make such request to the appropriate party listed under **FOR FURTHER INFORMATION CONTACT** so that arrangements can be made for such views to be presented. A record will be made of all views orally presented. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's office from 8:30 a.m. to 1:00 p.m. and 2:00 p.m. to 4:00 p.m., Monday through Friday.

Copies of documents listed under ''References,'' below, are available for public inspection in the FSIS Docket Room, USDA, 14th and Independence Avenue, SW, Room 3175, South Agriculture Building, Washington, DC 20250.

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VI. Proposed Rules

List of Subjects

9 CFR Part 308

Meat inspection, Sanitation.

9 CFR Part 310

Antimicrobial treatment, Microbial testing, Reporting and Recordkeeping requirements.

9 CFR Part 318

Meat inspection, Reporting and Recordkeeping requirements, Reinspection, Processed products, Microbial testing.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 325

Meat inspection, Reporting and recordkeeping requirements, transportation.

9 CFR Part 326

Hazard Analysis and Critical Control Point (HACCP) systems, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 327

Imported products, Hazard Analysis and Critical Control Point (HACCP) systems.

9 CFR Part 381

Sanitation, Antimicrobial treatment, Microbial testing, Reinspection, Processed products, Reporting and recordkeeping, Hazard Analysis and Critical Control Point (HACCP) systems, Imports, Transportation.

For the reasons set forth in the preamble, 9 CFR chapter III is proposed to be amended as follows:

PART 308—SANITATION

1. The authority citation for part 308 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 308.3 would be amended by redesignating paragraphs (b) through (i) as paragraphs (c) through (j), and adding a new paragraph (b) to read as follows:

§ 308.3 Establishments; sanitary conditions; requirements.

* * * * *

(b) The establishment shall develop and maintain written Sanitation Standard Operating Procedures (Sanitation-SOP's) which must be available to program employees for verification and monitoring. Sanitation-SOP's shall at a minimum detail daily sanitation procedures to be conducted before and during operations, to prevent direct contamination or adulteration of product(s). Sanitation SOP's must also identify plant officials responsible for monitoring daily sanitation activities, evaluating the effectiveness of SOP's, and initiating corrective actions when needed.

(1) A ''U.S. Rejected'' tag will be attached to the applicable equipment, utensil, room or compartment if a program employee determines that the establishment has failed to adhere to the sanitation SOP's specifically required by FSIS regulations. No equipment, utensil, room or compartment so tagged shall be used until reinspected and found acceptable by a Program employee.

(2) The establishment owner or operator shall be responsible for the establishment's adherence to the SOP's, as well as for all sanitary requirements specified elsewhere in these regulations. Preoperational procedures prescribed in the Sanitation-SOP's must be completed before the start of operations.

(3) The establishment shall develop and maintain a daily record of completion of all sanitation Standard Operating Procedures. Daily records, including any deviations from regulatory requirements and corrective actions taken shall be maintained by the establishment for a minimum of 6 months.

* * * * *

PART 310—POSTMORTEM INSPECTION

3. The authority citation for part 310 would continue to read as follows:

Authority: 21 U.S.C. 601–695, 7 CFR 2.17, 2.55.

4. Part 310 would be amended by adding §§ 310.24 and 310.25 to read as follows:

§ 310.24 Treating carcasses to reduce bacteria.

(a) *General.* Raw livestock carcasses shall be treated at least once at any point during the slaughter and dressing operation, but prior to entering the cooler to reduce levels of bacteria on carcass surfaces.

(b) *Treatment methods.* Official establishments may use any of the following treatment methods to reduce bacteria, provided that equipment has been approved under § 308.5, and that operation of the method results in full compliance with the Act and this subchapter.

(1) Any chlorine compound approved by the Administrator and administered to raw, uncooled whole livestock carcasses or major carcass portions at 20 to 50 parts per million (ppm) in the intake water at the final wash. The chlorinated water must contact all carcass surfaces. The Administrator will prepare a list containing compounds approved for use in official establishments. A copy of the list may be obtained from the Compounds and Packaging Branch, Produce Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700.

(2) Hot water applied such that the temperature of the water at the carcass surface is ≥165 °F (≥74 °C) for ≥10 seconds. The hot water must contact all carcass surfaces.

(3) Any antimicrobial compound listed in the table in § 318.7(c)(4) and permitted for use on livestock products may be used under the conditions specified therein. The antimicrobial compound must be administered so that it contacts all carcass surfaces.

(4) Any antimicrobial compound previously approved for use in livestock or livestock products as a food additive or processing aid by the Food and Drug Administration and listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 182, or 184 may be used, provided the owner or operator has received approval for such use from the Administrator in accordance with § 318.7(a) of this subchapter. Any such antimicrobial compound must be administered so that it contacts all carcass surfaces.

(c) *Exemptions for exported product.* Product designated for export only to a country which will not accept product exposed to the antimicrobial treatment installed in the establishment will be exempted by the inspection program from the requirement for antimicrobial treatment if the product is properly identified, segregated, and labeled.

§ 310.25 Microbial testing.

(a) *General.* (1) *Incidental sampling.* In the event of an outbreak of foodborne disease or other evidence of a threat to public health attributable to a meat or meat food product, the Administrator will conduct a sampling and testing program as may be required. Carcasses at official establishments may be included in such a sampling and testing

program. Procedures and protocols will vary, depending on the pathogen of concern and other circumstances.

(2) *Rountine sampling.* (i) All establishments which have slaughter operations or produce raw, ground meat or raw sausages are required to collect a minimum of one sample for testing each day from each slaughter class and/or species of ground meat. Establishments shall test the samples for *Salmonella* species. The results of the analysis shall be provided to FSIS, as well as to the establishment. The results of the analysis shall be entered by the establishment in a moving sum verification chart or table as provided in paragraph (d)(2) of this section for review by Program employees.

(ii) Establishment must evaluate and improve their process controls when their performance, as indicated by the number of positive samples over a specified time, exceeds established acceptable limits.

(iii) Establishments which have adopted a Hazard Analysis and Critical Control Point system documenting that product being produced meets or exceeds the established targets for pathogen reduction may, upon approval by the Administrator, continue their current operating procedure in lieu of the proposed testing verification program set forth in paragraph (a)(2)(i) of this section.

(b) *Sample collection.* (1) Each establishment shall prepare written procedures outlining specimen collection. Procedures shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to Program employees for verification that it is being followed.

(2) The establishment will designate an employee or agent to collect the specimen, as follows:

(i) Samples from raw carcasses must be taken from chilled product in the cooler, or if to be used for further processing without cooling, prior to such further processing. Samples will be excised brisket skin tissue, 4 inches (10 cm) × 4 inches (10 cm) × ½ inch (1 cm) for beef and belly skin tissue, and 3 inches (7 cm) × 5 inches (12 cm) × ½ inch (1 cm) for hogs.

(ii) Samples from raw, ground or comminuted meat products should be taken prior to packaging. Samples will be ½ pound (0.4 kg).

(c) *Analysis.* (1) An establishment may test the specimens in its own laboratory or in a commercial/contract laboratory. However, the laboratory which is selected must demonstrate experience in testing meat and poultry for *Salmonella* spp. Either an internal or external quality assurance/quality control (QA/QC) program with check sample analysis is required. QA/QC records must be available to FSIS personnel and FSIS reserves the right to send official check samples to the laboratory to verify laboratory capabilities.

(2) The method used for analyzing a sample for *Salmonella* must be one of the following:

(i) The method published by FSIS in the current edition of the Microbiology Laboratory Guidebook. A copy of this method may be obtained from Microbiology Division, Science and Technology, FSIS, Washington, DC 20250.

(ii) Any method for *Salmonella* species recognized by the Association of Official Analytical Chemists or other scientific body that may be approved by the Administrator for this purpose. The analytic method used must be accepted by this third party authority as being at least as sensitive as the method used by FSIS for official samples.

(d) *Reports and recordkeeping.* (1) The designated laboratory or establishment employee will record the results and supply them on a daily basis to the establishment. The establishment will provide the results, at least weekly, to Program employees. The results may be electronically transmitted.

(2) The establishment will be responsible for entering the results into a moving sum verification chart or table. The moving sum process verification chart or table will be maintained by the establishment for each type of production (slaughter class and/or species of ground product). This table or chart will consist of a moving sum of results (i.e., a moving count of positives) that is updated with each new result. The moving sum procedure is determined by width of window (n) in terms of number of days' results to include, and maximum acceptable number of positive samples during that time frame or the Acceptable Limit.

(i) An example of a moving sum process control chart with the corresponding decision about process acceptability is given below. In the example, the window is 8 days (n=8), and the maximum number of positives permitted in that window is 3 (AL=3).

Day No.	Test result	Moving sum	Comparison to AL	Days included
1	0	0	Meets	1
2	0	0	Meets	1, 2
3	0	0	Meets	1 to 3
4	1	1	Meets	1 to 4
5	0	1	Meets	1 to 5
6	0	1	Meets	1 to 6
7	1	2	Meets	1 to 7
8	0	2	Meets	1 to 8
9	0	2	Meets	2 to 9
10	0	2	Meets	3 to 10
11	0	2	Meets	4 to 11
12	0	1	Meets	5 to 12
13	0	1	Meets	6 to 13
14	0	1	Meets	7 to 14
15	0	0	Meets	8 to 15

Note: Thus, the moving sum value for day 10 is the sum of the results in the 8 day window ending that day; it can be calculated simply by counting the number of 1's in the daily result column on days 3 through 10.

(ii) The chart below specifies the initial values of width of windows (n) and Acceptable Limit (AL) for each product class.

Commodity	Moving sum rules		
	Target (percent positive for *Salmonella*)	Window size (n) in days	Acceptable limit (AL)
Steers/Heifers ...	1	82	1
Raw Ground Beef	4	38	2
Cows/Bulls	1	82	1
Hogs	18	17	4
Fresh Pork Sausages	12	19	3

(e) *Corrective action.* (1) Establishments failing to meet Acceptable Limits will be presumed to have process control deficiencies. In such instances, a complete review by the establishment of the production process is required. A written report of the evaluation, including the reason for process failure and proposed corrective actions, will be submitted to the Inspector in Charge within 14 days from the day the process exceeded the limits. This report shall be updated on a weekly basis until the moving sum procedure indicates the process is in control.

(2) During the time the results fail to meet the Acceptable Limits, sampling should be conducted at a rate of two specimens or more per day. The sampling rate will return to normal when the establishment meets Acceptable Limits indicating the process is in control.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

5. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

* * * * *

6. Part 318 would be amended by adding a new § 318.25 to read as follows:

§ 318.25 Temperatures and chilling requirements for carcasses and raw meat products.

(a) *Definitions:*

Processing authority. A person or organization having expert knowledge of food processing procedures, having access to facilities for evaluating the safety of such procedures, and designated by the establishment to perform certain functions as indicated in this section.

Raw meat product. Any meat, meat food product, or meat byproduct that has not received treatment, such as cooking, to make it ready to eat.

Ready-to-eat-process. Any process, such as cooking, applied to a raw meat product that effectively inactivates infective pathogenic hazards that may be in or on the product.

Ready-to-eat product. Any food that is safe for human consumption without additional treatment.

(b) *Time and temperature requirements.* (1) All carcasses and raw meat products from such carcasses shall be cooled to surface temperatures of 50°F (10°C) or below within 5 hours and 40°F (4.4°C) or below within 24 hours from the time the carcasses exit the slaughter floor, unless such product immediately enters a ready-to-eat process or is part of a hot-boning operation, as prescribed in paragraph (b)(2) of this section. Raw product removed from the carcass on the slaughter floor not entering a ready-to-eat process or hot-boning operation, e.g., livers, hearts, and heads with cheek meat, shall be placed in a chiller within 1 hour of removal from the carcass.

(2) Establishments that separate raw meat from the bone before cooling the carcasses (hot-boning) shall cool such raw meat until it reaches an internal temperature of 50°F (10°C) or below within 5 hours of initial separation, and 40°F within 24 hours, except that raw meat from a hot-boning operation may enter a ready-to-eat process at the establishment within 5 hours of initial separation.

(3) Carcasses or raw meat products received at official establishments shall register an internal temperature of 40°F or below.

(4) Establishments shall maintain carcasses or raw meat products in their possession or under their control at a temperature of 40°F or below. Product may not be released into commerce unless chilled to this temperature.

(5) Establishments may use a processing authority to develop time and temperature limits microbiologically equivalent to those provided in paragraphs 318.25 (b)(1) through (b)(4). Any such time and temperature alternatives must be included in the establishment's written plan, as provided in § 318.25(c) of this section.

(c) *Temperature monitoring and written plans.* (1) Establishments shall monitor the temperature of raw meat at the control points as set forth in the establishment's written plan required by paragraph (c)(3) of this section. Establishments shall make the temperature monitoring records available to the Program employees and shall retain records up to 6 months after the temperature measurement or until such time as may otherwise be specified by the Administrator.

(2) To demonstrate compliance with the time and temperature requirements set forth in this section, establishments shall use temperature measuring devices readable and accurate to 2°F (0.9°C).

(3) Establishments shall develop, implement, and place on file a written plan for complying with the time and temperature requirements set forth in this section. Establishments shall make their plans and records, created under the plans, available to Program employees upon request. Each plan shall identify the establishment's control points, i.e., points designated in the production process after the chilling procedure where temperatures are measured; monitoring procedures, including frequency within a day's operation; records; standards for the control points, including cooling rate and holding temperature; corrective actions, including a system for separating and identifying noncomplying products; and, when applicable, the name of the processing authority.

PART 320—RECORDS, REGISTRATION, AND REPORTS

7. The authority citation for part 320 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

8. Section 320.1 would be amended by adding new paragraphs (b) (11), (12), (13) and (14) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(11) Standard operating procedures (SOP's) for sanitation, and daily records, as prescribed in § 308.3 of this subchapter.

(12) Temperature control plans and records, as required by § 318.25 of this subchapter.

(13) A written protocol for sampling raw product for pathogen testing, as required by § 318.25 of this subchapter.

(14) HACCP plans and records, as required by part 326 of this subchapter.

9. Section 320.3 would be amended by adding new paragraphs (c), (d) and (e) to read as follows:

§ 320.3 Record retention period.

* * * * *

(c) The Sanitation Standard Operation Procedures for Sanitation shall be retained as required in § 308.3.

(d) Temperature monitoring plan and records shall be retained as required in § 318.25(e)(1).

(e) Record of HACCP plans and systems, shall be retained as required in § 326.6(d).

10. Section 320.6 would be amended by revising paragraph (a) to read as follows:

§ 320.6 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, antimicrobial treatments, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection thereat, as may be required by the Administrator in special cases.

* * * * *

PART 325—TRANSPORTATION

11. The authority citation for part 325 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

12. Section 325.9 would be added to read as follows:

§ 325.9 Shipment of carcasses and raw meat products.

(a) Carcasses and raw meat products, as defined in § 318.25 of this subchapter, shall have an internal temperature of 40°F or below when loaded on vehicles for shipping. Such products that are shipped from an official establishment to another official establishment shall arrive at the receiving establishment at an internal temperature of 40°F or below.

(b) The date and time of shipment of carcasses and raw meat products from an official establishment to another official establishment shall be recorded on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying a shipment.

13. A new part 326 would be added to read as follows:

PART 326—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

Sec.

326.1 Definitions.
326.2 Development of HACCP plan.
326.3 HACCP principles.
326.4 Implementation of the HACCP plan.
326.5 Operation of HACCP system.
326.6 Record review and maintenance.
326.7 Enforcement.

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 326.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Criterion. A requirement on which a judgment or decision can be based.

Critical control point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical control point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.

Deviation. Failure to meet a critical limit.

HACCP. A hazard analysis and critical control point (HACCP) system that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.

HACCP system. The result of the implementation of the HACCP plan.

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to meat processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.

Hazard analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCPs are identical, except that optional operations or CCPs, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, meat, meat byproduct, or meat food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees which satisfies the following: consists of at least 3 days, 1 day devoted to understanding the seven principles of HACCP, 1 day devoted to applying these concepts to this and other regulatory requirements of FSIS, and 1 day devoted to beginning development of a HACCP plan for a specific process.

Responsible establishment official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of safe and wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.

§ 326.2 Development of HACCP plan.

(a) Every official establishment shall develop, implement, and operate a HACCP plan, as set forth in paragraph (d) of this section, for each process listed below conducted by the establishment.

Categories of Processes for HACCP:

01 Raw-Ground
02 Raw Other Inclusive
03 Thermally Processed/Commercial Sterile
04 All Other Shelf Stable, Not Heat Treated
05 Fully Cooked—Not Shelf Stable
06 All Other Shelf Stable, Heat Treated
07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked
08 Non-Shelf Stable, w/Secondary Inhibitors
09 Slaughter, All Meat Species

(b) At a minimum, the HACCP plan(s) shall be developed with the assistance

of a HACCP-trained individual employed by the establishment, whose name and resume is on file at the establishment, and who is knowledgeable of each process conducted by the establishment. The person(s) developing the plan shall be knowledgeable of HACCP and the associated recordkeeping procedures, and shall be capable of: identifying the hazards of the establishment's process and understanding the source of such hazards; establishing relevant CCP's throughout the process; and developing appropriate critical limits, monitoring procedures, corrective action procedures, verification procedures and their frequency, and operating procedures to implement the HACCP plan.

(c) Prior to the initiation of the Hazard Analysis phase for HACCP plan development, each establishment shall have on file a copy of its procedures for maintaining adherence to recommended Standard Operating Procedures for sanitation as set forth in § 308.3.

(d) The development of the HACCP plan shall consist of two stages: a Hazard Analysis, as provided under Principle 1 in § 326.3(a); and the development of the remainder of the HACCP plan for each specific process, as defined in § 326.2(a), including activities designed to ensure that the HACCP plan as developed is valid. These steps shall be completed over a period not to exceed 6 months prior to the phase-in date of the process category as prescribed in § 326.7, or upon application for the grant of inspection, or when a new process is intended for implementation.

(1) The HACCP plan should be in a format that is similar to the National Advisory Committee on Microbiological Criteria for Foods and FSIS generic models to ensure that both the establishment and program employees can readily identify the requirements in §§ 326.2(c) and 326.3.

(2) Each HACCP principle, as prescribed in § 326.3, must be included in the HACCP plan.

§ 326.3 HACCP principles.

The following principles and their associated components shall be included in each HACCP plan:

(a) *Principle No. 1.* A hazard analysis shall be conducted to identify biological (including microbiological), chemical, and/or physical properties of raw materials and processing steps that may cause a product or products to be unsafe for consumption. A list of steps in the process where potentially significant hazards may occur and the preventive measures to be taken shall be prepared. Hazard analysis should take into consideration factors such as: ingredients; physical characteristics and composition; processing procedures, microbial content of the product or products; facility and equipment design; packaging; sanitation; conditions of storage between packaging and the end user; intended use; and intended consumer. All identified hazards associated with each step in the process must be listed and its significant risk and severity evaluated. The preventive measures to control the identified hazards must be listed. The steps in application of this principle shall, at a minimum, include:

(1) A flow chart describing the steps of each process and product flow in the establishment; and

(2) Identification of the intended use and consumers of the product based upon normal use by the general public or a particular segment of the population.

(b) *Principle No. 2.* Identify the CCP's in the process using a decision tree and the information derived from § 326.3(a). CCP's shall be identified for purposes of product safety only. They must include physical, chemical, and biological (including microbiological and residue) hazards; must encompass the health and safety process control points required by FSIS regulations, or their equivalents; and must be specified for each identified hazard.

(c) *Principle No. 3.* Establish specific critical limits for preventive measures associated with each identified CCP. Critical limits which are a part of other portions of relevant regulations must be included.

(1) All critical limits shall meet or exceed any requirement set forth in this subchapter pertaining to a specific process and which are currently a part of FSIS regulations or other FSIS requirements.

(2) The responsible establishment official shall ensure that the critical limits are sufficient to control the identified hazards through a validation process consisting of verification and monitoring activities.

(d) *Principle No. 4.* Establish CCP monitoring requirements. Establish specific procedures for using the results of CCP monitoring to adjust and maintain process control.

(1) The responsible establishment official shall ensure that establishment employees are assigned to monitor each CCP effectively, as determined by Hazard Analysis.

(2) When monitoring is not possible on a continuous basis, the monitoring interval established shall reliably indicate that the hazard can be controlled as demonstrated by process validation performed during the Hazard Analysis and plan development.

(3) All records and documents associated with CCP monitoring shall be dated and signed or initialed by the person(s) conducting the monitoring.

(e) *Principal No. 5.* Establish corrective action(s) to be taken when monitoring indicates that there is a deviation from an established critical limit.

(1) The corrective actions shall describe the step(s) taken to identify and correct the cause of noncompliance to assure that the CCP is under control, ensure that no safety hazards exist after these actions, and define measures to prevent recurrence.

(2) Corrective actions shall include a determination of the effect of the deviation(s) on product safety; how noncompliant product will be handled, including segregation and holding procedures; a definition of lot size; whether the deviation indicates a modification or revision of the HACCP plan is required, and time frames for modification or revision of the HACCP plan.

(f) *Principal No. 6.* Establish effective recordkeeping and systematic review procedures that document the HACCP system. The required records are specified in § 326.6.

(g) *Principal No. 7.* Establish procedures for verification by a HACCP-trained individual that the HACCP system is functioning effectively to ensure product safety and process control. This is the plan validation process and therefore includes methods, procedures, or tests in addition to those used for monitoring. Such validation shall ensure:

(1) The adequacy of the critical limits at each CCP;

(2) The continuing effectiveness of the establishment's HACCP plan and system, including taking into account changes in product volumes, procedures, personnel, and product use;

(3) The accuracy of the HACCP plan through the completion of all seven principles and their associated actions including revalidation whenever significant product, process, deviations, or packaging changes require modification of the plan; and

(4) The evaluation of product safety in situations where the establishment identifies deviations from critical limits, all steps taken in response to a deviation, and the adequacy of the corrective response.

§ 326.4 Implementation of the HACCP plan.

(a) Upon completion of the Hazard Analysis and development of the HACCP plan, a responsible establishment official shall review and approve the written plan by signing it.

(b) Upon completion of the Hazard Analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended, ensuring the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions. During this initial HACCP plan validation period, the establishment shall conduct repeated verifications and meet frequently with Program employees to assure the HACCP system is functioning as intended, which shall include a review of the records generated by the HACCP system.

(c) When an ingredient change, product reformulation, manufacturing process or procedure modification, equipment change, or any other such change requires modifications to the establishment's HACCP plan, the responsible establishment official, in consultation with a HACCP-trained individual employed by the establishment, shall ensure that the HACCP plan is modified to reflect such changes. The development of the modified HACCP plan shall be conducted in accordance with §§ 326.2 and 326.3.

§ 326.5 Operation of HACCP system.

(a) The establishment's HACCP system, as set forth in the establishment's HACCP plan, shall be operated with the advice and guidance of a HACCP-trained individual, as defined in § 326.1.

(b) The responsible establishment official shall be held responsible for the operation of the HACCP system to ensure compliance with the Act and regulations thereunder. In all respects, however, the Administrator shall continue to provide the Federal inspection necessary to carry out the provisions of the Act.

§ 326.6 Record review and maintenance.

(a) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the time recorded, and the record shall be signed or initialed by the establishment employee making the entry. Prior to shipping product produced under each process, the establishment shall review, on a defined, systematic basis, all processing and production records associated with the HACCP plan to ensure completeness, to determine whether all critical limits were met and, if appropriate, corrective action(s) were taken, including proper disposition of product. This review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by the HACCP-trained individual, or the responsible establishment official.

(b) The following records supporting the establishment's HACCP plan shall be maintained:

(1) The written HACCP plan including all portions of the Hazard Analysis as prescribed in this part;

(2) Records associated with the monitoring of CCP's, which include the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), identity, or slaughter production lot; and date the record was made; and

(3) Records associated with supporting documentation for the Hazard Analysis, development of the selected CCP's, critical limits, frequency of monitoring and verification procedures, and corrective actions taken.

(c) All such records shall be made available to any Program employee upon request. A deviation from a critical limit shall be brought to the attention of the appropriate Program employee promptly.

(d) All records shall be retained at the establishment at all times, except that records for monitoring CCP's, corrective actions, and verification procedures shall be retained at the establishment for no less than 1 year, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees.

§ 326.7 Enforcement.

(a) *Implementation*. (1) The following establishments shall meet the requirements of this part by the date prescribed:

(i) Estabishments that conduct the following categories of processes shall comply by [insert date 12 months after publication of final rule]: Raw, Ground (including mechanically separated (species)); Thermally Processed/ Commercially Sterile; and All Other, Shelf Stable, Heat Treated.

(ii) Establishments that conduct the following categories of processes shall comply by (insert date 18 months after publication of final rule): Non-Shelf Stable, Heat Treated, Not Fully Cooked; and Shelf Stable, Not Heat Treated.

(iii) Establishments that conduct the following categories of processes shall comply by [insert date 24 months after publication of final rule]: Fully Cooked, Non-Shelf Stable; and Non-Shelf Stable, with Secondary Inhibitors.

(iv) Establishments that conduct the following categories of processes shall meet the requirements of this part by [insert date 30 months after publication of final rule]: Raw, other; and Slaughter, all livestock.

(v) Small entities that generate less than $2.5 million dollars of product per year shall comply by [insert date 36 months after publication of final rule].

(2) Any establishment that obtains Federal inspection on or after the effective date(s) for the process category(ies) to be conducted shall conduct a Hazard Analysis, and shall develop and validate its HACCP plan(s), as set forth in § 326.2(d) of this part, concurrent with the grant of inspection. Process analysis, as set forth in § 326.4(c), shall commence after obtaining Federal inspection to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(3) Any establishment that institutes a new process requiring development of a HACCP plan on or after the applicable effective date(s) of this regulation shall conduct all activities required for hazard analysis, development, and validation of its HACCP plan(s) for the process category(ies) as set forth in § 326.2(d) of this part, before commencing production and shall conduct process analyses, as set forth in § 326.4(b), to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(4) Commencing with the applicable effective date(s), the Program shall refuse new inspection services requested for, or, using the procedures in § 335.33, suspend inspection services from establishments or specific processes within establishments not having HACCP plans.

(b) *Verification*. The Program shall verify that HACCP plan(s) are effective and validated, and otherwise in compliance with this regulation. Such verification and process validation may include:

(1) Reviewing the HACCP plan,

(2) Reviewing the CCP records,

(3) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs,

(4) Conducting verification activities to determine whether CCP's are under control,

(5) Reviewing the critical limits,

(6) Reviewing other records pertaining to the HACCP plan or system,

(7) Random sample collection and analysis to determine the safety of the product, and/or

(8) On-site observations and records review for revalidation of HACCP plans.

(c) *Suspension, correction of invalid plans.* (1) If the Program finds a HACCP plan to be invalid, inspection service for the process covered by the HACCP plan will be suspended using the procedures in § 335.33. The processing facilities identified shall not be used for production of meat or meat food product pending completion of the specified corrective action(s), as prescribed (c)(3) of this section and written acknowledgement thereof by the designated Program official. Products produced by the process prior to the suspension suspected of being adulterated shall be retained at the establishment pending disposition by the Program, and if such product has been shipped, it shall be subject to voluntary recall as necessary to protect public health.

(2) A HACCP plan may be found invalid if:

(i) The HACCP plan does not meet the requirements of this part,

(ii) HACCP records are not being maintained as required to validate the plan or verify process control under the plan, or

(iii) A processing failure results in production of adulterated product.

(3) Invalid HACCP plans must be corrected by:

(i) Submission to the designated Program official of a written, detailed verification by a HACCP-trained individual that a modified HACCP plan has been developed in consultation with that individual and that, as modified, the plan corrects the deficiencies found, and

(ii) In the case of a processing deficiency resulting in production of adulterated product, submission to the designated Program official of and adherence to a written plan for finished product produced under the modified HACCP plan to be tested by an external laboratory for chemical or microbial characteristics, at the establishment's expense, as appropriate to demonstrate that the process under the modified HACCP plan corrects the identified problem.

(4) If the establishment fails to adhere to the modified HACCP plan and, if applicable, the testing plan, resulting in a subsequent suspension of the same process for the same or a related deficiency, the designated Program official will, upon receipt and before acknowledgement of any subsequent modified plan(s) under paragraph (c)(3) of this section, also review the establishment's performance under the inspection regulations generally and make a written recommendation to the Administrator whether any additional inspection or enforcement measures may be required.

PART 327—IMPORTED PRODUCTS

14. The authority citation for Part 327 would continue to read as follows:

Authority: 21 U.S.C. 601–695, 7 CFR 2.17, 2.55.

15. Section 327.2 would be amended by redesignating paragraph (a)(2)(ii)(*h*) as (a)(2)(ii)(*i*) and by adding a new paragraph a(2)(ii)(*h*) to read as follows:

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(*h*) Development and maintenance of a Hazard Analysis and Critical Control Point (HACCP) system pursuant to part 326 of this subchapter in each certified establishment;

* * * * *

16. Subpart E of part 335 would be redesignated as subpart F, and a new subpart E would be added to read as follows:

Subpart E—Rules Applicable to the Suspension of Inspection for Failure To Have a Validated HACCP Plan

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 335.33 Refusal or suspension of inspection service for failure to comply with HACCP requirements.

(a) In any situation in which the Administrator determines that an establishment which is applying for inspection or receiving inspection under Title I of the Federal Meat Inspection Act does not have a valid HACCP plan as required by § 326.7, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as ''inspected and passed.'' The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal to inspect and pass the meat or meat food products and the reasons therefor, and the action which the Administrator deems necessary to have a valid HACCP plan. In the event of oral notification, written confirmation shall be given, as promptly as circumstances permit, to the applicant or operator of the establishment in the manner prescribed in § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any applicant or operator of an establishment so notified fails to take the necessary action to have a valid HACCP plan within the period specified in the notice, the Administrator may issue a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service shall be refused or withdrawn from such establishment pending final determination in the proceeding.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

17. The authority citation for Part 381 would continue to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

Subpart H—Sanitation

18. Section 381.45 would be revised to read as follows:

§ 381.45 Minimum standards for sanitation, facilities and operating procedures in official establishments.

The provisions of §§ 381.45 through 381.61, inclusive, shall apply with respect to all official establishments.

(a) The establishment shall develop and maintain written Sanitation Standard Operating Procedures (Sanitation SOP's) which must be available to program employees for verification and monitoring. Sanitation SOP's shall, at a minimum, detail daily sanitation procedures to be conducted, before and during operations, to prevent direct contamination or adulteration of product(s). Sanitation SOP's must also identify plant officials responsible for monitoring daily sanitation activities, evaluating the effectiveness of SOP's, and initiating corrective actions when needed.

(1) A ''US Rejected'' tag will be attached to the applicable equipment, utensil, room or compartment if a Program employee determines that the establishment has failed to adhere to the Sanitation SOP's specifically required by paragraph (a) of this section. No equipment, utensil, room, or compartment so tagged shall be used until reinspected and found acceptable by a Program employee. The establishment shall maintain daily records for a minimum of 6 months.

(2) The establishment owner or operator shall be responsible for the establishment's adherence to the SOP's, as well as for all sanitary requirements specified elsewhere in these regulations.

Preoperational procedures prescribed in the Sanitation SOP's must be completed before the start of operations.

(3) The establishment shall develop and maintain a daily record of completion of all sanitation Standard Operating Procedures. Daily records, including any deviations from regulatory requirements and corrective actions taken, shall be maintained by the establishment for a minimum of 6 months.

(b) [Reserved]

Subpart I—Operating Procedures

19. Section 381.66 would be amended by revising paragraph (b) to read as follows:

§ 381.66 Temperatures and chilling and freezing procedures.

* * * * *

(b) *General chilling requirements*—(1) *Definitions:*

Processing authority. A person or organization having expert knowledge of food processing procedures, having access to facilities for evaluating the safety of such procedures, and designated by the establishment to perform certain functions as indicated in this section.

Raw poultry product. Any poultry or poultry byproduct that has not received treatment, such as cooking, to make it ready to eat.

Ready-to-eat process. Any process, such as cooking, applied to a raw poultry product that effectively inactivates infective pathogenic hazards that may be in or on the product.

Ready-to-eat product. Any food that is safe for human consumption without additional treatment.

(2) *Time and temperature requirements.*

(i) All poultry and poultry products that are slaughtered and eviscerated in the official establishment shall be chilled immediately after processing to reach surface temperatures of 50 °F (10°C) or below within 1.5 hours and 40°F (4.4°C) or below within 24 hours from the time that the carcasses exit the slaughter line, unless such product immediately enters a ready-to-eat process or a hot-boning operation, as prescribed in paragraph (b)(2)(ii) of this section. Raw product removed from the carcass on the slaughter line, such as giblets, shall be placed in a chiller within 1 hour of removal from the carcass.

(ii) Establishments that separate raw poultry from the bone before cooling the carcasses (hot-boning) shall cool such raw poultry until it reaches an internal temperature of 50°F (10°C) or below within 1.5 hours of initial separation, except that raw poultry from a hot-boning operation may enter a ready-to-eat process at the establishment within 1.5 hours of initial separation.

(iii) Carcasses or raw poultry products received at official establishments shall register an internal temperature of 40°F or below.

(iv) Establishments shall maintain raw poultry carcasses and products in their possession or under their control at a temperature of 40°F or below. Product may not be released into commerce unless chilled to this temperature.

(v) Establishments may use a processing authority to develop time and temperature limits microbiologically equivalent to those provided in paragraphs 381.66(b)(2)(i) through (b)(2)(iv). Any such time and temperature alternatives must be included in the establishment's written plan, as provided in § 381.66(b)(3) of this section.

(3) *Temperature monitoring and written plans.* (i) Establishments shall monitor the temperature of raw poultry at the control points as set forth in the establishment's written plan required by paragraph (b)(3)(iii) of this section. Establishments shall make the temperature monitoring records available to Program employees and shall retain records up to 6 months after the temperature measurement or until such time as may otherwise be specified by the Administrator.

(ii) To demonstrate compliance with the time and temperature requirements set forth in this section, establishments shall use temperature measuring devices readable and accurate to 2°F (0.9°C).

(iii) Establishments shall develop, implement, and place on file a written plan for complying with the time and temperature requirements set forth in this section. Establishments shall make their plans and records, created under the plans, available to Program employees upon request. Each plan shall identify the establishment's control points, i.e., points designated in the production process after the chilling procedure where temperatures are measured; monitoring procedures, including frequency within a day's operation; records; standards for the control points, including cooling rate and holding temperature; corrective actions, including a system for separating and identifying noncomplying products; and, when applicable, the name of the processing authority.

* * * * *

20. Subpart I would be amended by adding a new § 381.69 to read as follows:

§ 381.69 Treating carcasses to reduce bacteria.

(a) *General.* Raw poultry carcasses shall be treated at least once at any point during the slaughter and dressing operation, but prior to entering the chiller to reduce levels of bacteria on carcass surfaces.

(b) *Treatment methods.* Official establishments may use any of the following treatment methods to reduce bacteria, provided that equipment has been approved under § 381.53, and that operation of the method results in full compliance with the Act and this part.

(1) Any chlorine compound approved by the Administrator and administered to raw, unchilled whole poultry carcasses or major carcass portions at 20 to 50 parts per million (ppm) in the intake water at the final wash. The chlorinated water must contact all carcass surfaces. The Administrator will prepare a list containing compounds approved for use in official establishments. A copy of the list may be obtained from the Compounds and Packaging Branch, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700.

(2) Hot water applied such that the temperature of the water at the carcass surface is ≥165°F (≥74°C) for ≥10 seconds. The hot water must contact all carcass surfaces.

(3) Any antimicrobial compound listed in the table in § 381.147(f)(4) and permitted for use on poultry products may be used under the conditions specified therein. The antimicrobial compound must be administered so that it contacts all carcass surfaces.

(4) Any antimicrobial compound approved for use in poultry or poultry products as a food additive or processing aid by the Food and Drug Administration and listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 182, or 184 may be used, provided the owner or operator has received approval for such use from the Administrator in accordance with § 381.147(f)(2) of this part. Any such antimicrobial compound must be administered so that it contacts all carcass surfaces.

(5) If the application or use of an antimicrobial treatment is determined by the Inspector in Charge to not conform to approved parameters, the establishment shall make necessary adjustments within 15 minutes. If adjustments are not made within 15 minutes, the establishment shall suspend the treatment and shall not process carcasses until appropriate adjustments are made. If a second

antimicrobial treatment is in place and functioning properly, the use of the nonconforming antimicrobial treatment may be discontinued and processing of carcasses may continue. Product not treated in conformance with approved parameters shall be retained for disposition by the Inspector in Charge.

(c) *Exemptions for exported product.* Product designated for export only to a country which will not accept product exposed to the antimicrobial treatment installed in the establishment will be exempted by the inspection program from the requirement for antimicrobial treatment if the product is properly identified, segregated, and labeled.

Subpart K—Post Mortem Inspection: Disposition of Carcasses and Parts

21. In § 381.76, Table 1—Definitions of Nonconformances, would be amended in paragraph A–1 by removing the word ''feces'', by amending paragraph A–2 to remove the end note regarding feces, and by removing paragraph A–8, ''Feces ≥⅛'', and renumbering paragraphs A–9 through A–20 as A–8 through A–19.

22. Section 381.79 would be amended by revising the heading, redesignating the existing text as paragraph (a), and adding a new paragraph (b) to read as follows:

§ 381.79 Passing of carcasses; microbial testing.

(a) * * *

(b) *Microbial Testing*—(1) *General.*

(i) *Incidental sampling.* In the event of an outbreak of foodborne disease or other evidence of a threat to public health attributable to a poultry or poultry food product, the Administrator will conduct a sampling and testing program as may be required. Poultry at official establishments may be included in such a sampling and testing program. Procedures and protocols will vary, depending on the pathogen of concern and other circumstances.

(ii) *Routine sampling.*

(A) All establishments that have slaughter operations or produce raw, ground poultry are required to collect a minimum of one sample for testing each day from each slaughter class and/or species of ground poultry. The sample will be tested for *Salmonella* species. The results of the analysis will be provided to FSIS, as well as to the establishment. The results of the analysis will be entered by the establishment in a moving sum verification chart or table for review by Program employees.

(B) FSIS will require producers to evaluate and improve their process controls when their performance, as indicated by the number of positive samples over a specified time, exceeds established Acceptable Limits.

(C) Establishments that have adopted a Hazard Analysis and Critical Control Point system documenting that product being produced meets or exceeds the established targets for pathogen reduction may, upon approval by the Administrator, continue their current operating procedure in lieu of the proposed testing verification program, set forth in paragraph (b)(1)(ii)(C) of this section.

(2) *Sample collection.* (i) Each establishment will prepare written procedures outlining specimen collection. Procedures will address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure will be made available to Program employees for verification that it is being followed.

(ii) The establishment will designate an employee or agent to collect the specimen, as follows:

(A) Whole birds will be collected at the end of the chilling process, after the drip line, and rinsed in an amount of buffer appropriate for the type of bird sampled.

(B) Samples from raw ground poultry will be taken prior to packaging. Samples will be 1/2 pound (0.4 kg).

(3) *Analysis.* (i) An establishment may test the specimens in its own laboratory or in a commercial/contract laboratory. However, the laboratory which is selected must demonstrate experience in testing poultry for *Salmonella* spp. Either an internal or external quality assurance/quality control (QA/QC) program with check sample analysis is required. QA/QC records must be available to FSIS employees and FSIS reserves the right to send official check samples to the laboratory to verify laboratory capabilities.

(ii) The method used for analyzing a sample for *Salmonella* must be one of the following:

(A) The method published by FSIS in the current edition of the Microbiology Laboratory Guidebook. A copy of this method may be obtained from the Microbiology Division, Science and Technology, Food Safety and Inspection Service, Washington, DC 20250.

(B) Any method for *Salmonella* species recognized by the Association of Official Analytical Chemists or other recognized scientific body that may be approved by the Administrator for this purpose. The analytic method used must be accepted by this third party authority as being at least as sensitive as the method used by FSIS for official samples.

(4) *Reports and recordkeeping.* (i) The designated laboratory or establishment employee will record the test results and supply them on a daily basis to the establishment. The establishment will provide the results, at least weekly, to Program employees. The results may be electronically transmitted.

(ii) The establishment will be responsible for entering the results into a moving sum verification chart or table. The verification chart or table will be maintained by the establishment for each type of production (slaughter class and/or species of comminuted product). This chart or table will consist of a moving sum of results (i.e., a moving count of positives) that is updated with each new result. The moving sum procedure is determined by width of window (n) in terms of number of days' results to include, and maximum acceptable number of positives during that time frame.

(A) An example of a moving sum process control chart with the corresponding decision about process acceptability is given below. In the example, the window is 8 days (n=8), and the maximum number of positives permitted in that window is 3 (AL=3):

Day No.	Test result	Moving sum	Comparison to AL	Days included
1	0	0	Meets	1.
2	0	0	Meets	1, 2.
3	0	0	Meets	1 to 3.
4	1	1	Meets	1 to 4.
5	0	1	Meets	1 to 5.
6	0	1	Meets	1 to 6.
7	1	2	Meets	1 to 7.
8	0	2	Meets	1 to 8.
9	0	2	Meets	2 to 9.

Day No.	Test result	Moving sum	Comparison to AL	Days included
10	0	2	Meets	3 to 10.
11	0	2	Meets	4 to 11.
12	0	1	Meets	5 to 12.
13	0	1	Meets	6 to 13.
14	0	1	Meets	7 to 14.
15	0	0	Meets	8 to 15.

Note: Thus, the moving sum value for day 10 is the sum of the results in the 8 day window ending that day; it can be calculated simply by counting the number of 1's in the daily result column on days 3 through 10.

(B) The following chart specifies the initial values of width of windows (n) and Acceptable Limits (AL) for each product class:

Commodity	Moving sum rules		
	Target (percent positive for *Salmonella*)	Window size (n) in days	Acceptable limit (AL)
Broilers	25	16	5
Turkeys	15	15	3
Raw Ground Poultry	.....	.....	.....

(5) *Corrective action.* (i) Establishments not meeting Acceptable Limits will be presumed to have process control deficiencies. In such instances, a complete review by the establishment of the production process is required. A written report of the evaluation, including the reason for process failure and proposed corrective actions, will be submitted to the Inspector in Charge within 14 days from the day the process exceeded the limits. This report shall be updated on a weekly basis until the moving sum procedure indicates the process is in control.

(ii) During the time the results fail to meet the Acceptable Limits, sampling should be conducted at a rate of two specimens or more. The sampling rate will return to normal when the establishment meets Acceptable Limits, indicating the process is in control.

Subpart Q—Records, Registration, and Reports

23. Section 381.175 would be amended by adding new paragraphs (b)(6), (7), (8) and (9) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(6) Written Sanitation Standard Operating Procedures, and daily records, as prescribed in § 381.45 of this part.

(7) Temperature control plans and records, as required by § 381.66 of this subpart.

(8) Written protocol for sampling raw product for pathogen testing, as required by § 381.79 of this subpart.

(9) HACCP plans and records, as required by subpart Z of this part.

24. Section 381.177 would be amended by adding new paragraphs (c), (d) and (e) to read as follows:

§ 381.177 Record retention period.

* * * * *

(c) Standard Operating Procedures (SOP) for sanitation shall be retained as required in § 381.45 of this subchapter.

(d) Temperature monitoring plan and records shall be retained as required in § 381.66 of this subchapter.

(e) Records of HACCP plans and systems, as required by subpart Z of this part, shall be retained as required in § 381.606(d).

25. Section 381.180 would be amended by revising paragraph (a) to read as follows:

§ 381.180 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, antimicrobial treatments, mandatory microbiological testing, and other aspects of the operations of the establishment, and the conduct of inspection thereat as may be required by the Administrator in special cases.

* * * * *

Subpart S—Transportation; Exportation; Sale of Poultry or Poultry Products

26. Subpart S would be amended by adding a new § 381.188 to read as follows:

§ 381.188 Shipment of raw poultry and poultry products.

(a) Poultry carcasses and poultry products, as defined in § 381.66 of this part, shall have an internal temperature of 40°F or below when loaded on vehicles for shipping. Such products that are shipped from an official establishment to another official establishment shall arrive at the receiving establishment at an internal temperature of 40°F or below.

(b) The date and time of shipment of carcasses and raw poultry products from an official establishment to another official establishment shall be recorded on the waybill, running slip, conductor's card, shipper's certificate, or any other such papers accompanying a shipment.

Subpart T—Imported Poultry Products

27. Section 381.196 would be amended by redesignating paragraph (a)(2)(ii)(*h*) as paragraph (a)(2)(ii)(*i*) and by adding a new paragraph (a)(2)(ii)(*h*) to read as follows:

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a) * * *

(b) * * *

(ii) * * *

(*h*) Development and maintenance of a Hazard Analysis and Critical Control Point (HACCP) system pursuant to subpart Z of this part in each certified establishment; and

* * * * *

Subpart W—Rules of Practice Governing Proceedings Under the Poultry Products Inspection Act

28. Subpart W would be amended by adding a new undesignated center heading and a new § 381.237 to read as follows:

Rules Applicable to the Suspension of Inspection for Failure To Have a Validated HACCP Plan

§ 381.237 Refusal or suspension of inspection service under the PPIA for failure to comply with HACCP requirements.

(a) In any situation in which the Administrator determines that an establishment which is applying for inspection or receives inspection under the Poultry Products Inspection Act does not have a valid HACCP plan as required by § 381.607, he shall refuse to render inspection at the establishment.

The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal and the reasons therefor, and the action which the Administrator deems necessary to have valid HACCP plan. In the event of oral notification, written confirmation shall be given, as promptly as circumstances permit, to the applicant or operator of the establishment in the manner prescribed in § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any applicant or operator of an establishment so notified fails to take the necessary action to have a valid HACCP plan within the period specified in the notice, the Administrator may issue a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service shall be refused or withdrawn from such establishment pending final determination in the proceeding.

30. A new subpart Z would be added to read as follows:

Subpart Z—Hazard Analysis and Critical Control Points (HACCP) System

Sec.

381.601 Definitions.
381.602 Development of HACCP plan.
381.603 HACCP principles.
381.604 Implementation of the HACCP plan.
381.605 Operation of HACCP system.
381.606 Record review and maintenance.
381.607 Enforcement.

§ 381.601 Definitions.

For purposes of this subpart, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Criterion. A requirement on which a judgment or decision can be based.

Critical control point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical control point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.

Deviation. Failure to meet a critical limit.

HACCP. A hazard analysis and critical control point (HACCP) system that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

HACCP system. The result of the implementation of the HACCP plan.

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.

Hazard Analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's are identical, except that optional operations or CCP's, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, poultry, poultry byproduct, or poultry food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees which satisfies the following: consists of at least 3 days, 1 day devoted to understanding the seven principles of HACCP, 1 day devoted to applying these concepts to this and other regulatory requirements of FSIS, and 1 day devoted to development of a HACCP plan for a specified process.

Responsible establishment official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of safe and wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.

§ 381.602 Development of HACCP plan.

(a) Every official establishment shall develop, implement, and operate a HACCP plan, as set forth in paragraph (c) of this section, for each process listed below conducted by the establishment.

Categories of Processes for HACCP:

01 Raw-Ground
02 Raw Other—Inclusive
03 Thermally Processed/Commercially Sterile
04 All Other Shelf Stable, Not Heat Treated
05 Fully Cooked—Not Shelf Stable
06 All Other Shelf Stable, Heat Treated
07 All Non-Shelf Stable, Heat Treated, Not Fully Cooked
08 Non-Shelf Stable, w/Secondary Inhibitors
09 Slaughter—All Poultry Kind

(b) At a minimum, the HACCP plan(s) shall be developed with the assistance of a HACCP-trained individual employed by the establishment, whose name and resume is on file at the establishment, and who is knowledgeable of each process conducted by the establishment. The person(s) developing the plan shall be knowledgeable of HACCP and the associated recordkeeping procedures, and shall be capable of: identifying the hazards of the establishment's process and of understanding the source of such hazards; establishing relevant CCP's throughout the process; and developing appropriate critical limits, monitoring procedures, corrective action procedures, verification procedures and their frequency, and operating procedures to implement the HACCP plan.

(c) Prior to the initiation of the Hazard Analysis phase of HACCP plan development, each establishment shall have on file a copy of its procedures for maintaining adherence to recommended Standard Operating Procedures for sanitation as set forth in § 381.45.

(d) The development of the HACCP plan shall consist of two stages: a Hazard Analysis, as provided under Principle 1 in § 381.603(a); and the development of the remainder of the HACCP plan for each specific process as defined in § 381.602(a), including activities to ensure that the HACCP plan, as developed, is valid. These steps shall be completed over a period not to

exceed 6 months prior to the phase-in date of the process category, as prescribed in § 381.607, or upon application for the grant of inspection, or when a new process is intended for implementation.

(1) The HACCP plan should be in a format that is similar to the National Advisory Committee on Microbiological Criteria for Foods and FSIS generic models to ensure that both the establishment and program employees can readily identify the requirements in §§ 381.602(c) and 381.603.

(2) Each HACCP principle, as prescribed in § 381.603 must be included in the HACCP plan.

§ 381.603 HACCP principles.

The following principles and associated components shall be included in each HACCP plan:

(a) *Principle No. 1.* A hazard analysis shall be conducted to identify biological (including microbiological), chemical, and/or physical properties of raw materials and processing steps that may cause a product or products to be unsafe for consumption. A list of steps in the process where potentially significant hazards may occur and the preventive measures to be taken shall be prepared. Hazard analysis should take into consideration factors such as: ingredients; physical characteristics and composition; processing procedures; microbial content of the product or products; facility and equipment design; packaging; sanitation; conditions of storage between packaging and the end user; intended use; and intended consumer. All identified hazards associated with each step in the process must be listed and its significant risk and severity evaluated. The preventive measures to control identified hazards must be listed. The steps in application of this principle shall, at a minimum, include:

(1) A flow chart describing the steps of each process and product flow in the establishment; and

(2) Identification of the intended use and consumers of the product based upon normal use by the general public or a particular segment of the population.

(b) *Principle No. 2.* Identify the CCP's in the process using a decision tree and the information derived from § 381.603(a). CCP's shall be identified for purposes of product safety only. They must include physical, chemical, and biological (including microbiological and residue) hazards; must encompass the health and safety process control points required by FSIS regulations, or their equivalents; and must be specified for each identified hazard.

(c) *Principle No. 3.* Establish specific critical limits for preventive measures associated with each identified CCP. Critical limits which are a part of other portions of relevant regulations must be included.

(1) All critical limits shall meet or exceed any requirement set forth in this part pertaining to a specific process and which are currently a part of FSIS regulations or other FSIS requirements.

(2) The responsible establishment official shall ensure that the critical limits are sufficient to control the identified hazards through a validation process consisting of verification and monitoring activities.

(d) *Principle No. 4.* Establish CCP monitoring requirements. Establish specific procedures for using the results of CCP monitoring to adjust and maintain process control.

(1) The responsible establishment official shall ensure that establishment employees are assigned to monitor each CCP effectively, as determined by Hazard Analysis.

(2) When monitoring is not possible on a continuous basis, the monitoring interval established shall reliably indicate that the hazard can be controlled as demonstrated by process validation performed during the Hazard Analysis and plan development.

(3) All records and documents associated with CCP monitoring shall be dated and signed or initialed by the person(s) conducting the monitoring.

(e) *Principle No. 5.* Establish corrective action(s) to be taken when monitoring indicates that there is a deviation from an established critical limit.

(1) The corrective actions shall describe the step(s) taken to identify and correct the cause of noncompliance to assure that the CCP is under control, ensure that no safety hazards exist after these actions, and define measures to prevent recurrence.

(2) Corrective actions shall include a determination of the effect of the deviation(s) on product safety; how noncompliant product will be handled, including segregation and holding procedures; a definition of lot size; whether the deviation indicates a modification or revision of the HACCP plan is required; and time frames for modification or revision of the HACCP plan.

(f) *Principle No. 6.* Establish effective recordkeeping and systematic review procedures that document the HACCP system. The required records are specified in § 381.606.

(g) *Principle No. 7.* Establish procedures for verification by a HACCP-trained individual that the HACCP system is functioning effectively to ensure product safety and process control. This is the plan validation process and therefore includes methods, procedures, or tests in addition to those used for monitoring. Such validation shall ensure:

(1) The adequacy of the critical limits at each CCP;

(2) The continuing effectiveness of the establishment's HACCP plan and system, including taking into account changes in production volumes, procedures, personnel, and product use;

(3) The accuracy of the HACCP plan through the completion of all seven principles and their associated actions including revalidation whenever significant product, process, deviations, or packaging changes require modification of the plan; and

(4) The evaluation of product safety in situations where the establishment identifies deviations from critical limits, all steps taken in response to a deviation, and the adequacy of the corrective response.

§ 381.604 Implementation of the HACCP plan.

(a) Upon completion of the Hazard Analysis and development of the HACCP plan, a responsible establishment official shall review and approve the written plan by signing it.

(b) Upon completion of the Hazard Analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended, ensuring the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions. During this initial HACCP plan validation period, the establishment shall conduct repeated verifications and meet frequently with Program employees to assure the HACCP system is functioning as intended, which shall include a review of the records generated by the HACCP system.

(c) When an ingredient change, product reformulation, manufacturing process or procedure modification, equipment change, or any other such change requires modifications to the establishment's HACCP plan, the responsible establishment official, in consultation with a HACCP-trained individual employed by the establishment, shall ensure that the HACCP plan is modified to reflect such changes. The development of the modified HACCP plan shall be

conducted in accordance with §§ 381.602 and 381.603.

§ 381.605 Operation of HACCP system.

(a) The establishment's HACCP system, as set forth in the establishment's HACCP plan, shall be operated with the advice and guidance of a HACCP-trained individual as defined in § 381.601(i).

(b) The responsible establishment official shall be held responsible for the operation of the HACCP system to ensure compliance with the Act and regulations thereunder. In all respects, however, the Administrator shall continue to provide the Federal inspection necessary to carry out the provisions of the Act.

§ 381.606 Record review and maintenance.

(a) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the time recorded, and the record shall be signed or initialed by the establishment employee making the entry. Prior to shipping product produced under each process, the establishment shall review, on a defined, systematic basis, all processing and production records associated with the HACCP plan to ensure completeness, to determine whether all critical limits were met and, if appropriate, corrective action(s) were taken, including proper disposition of product. This review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by the HACCP-trained individual, or the responsible establishment official.

(b) The following records supporting the establishment's HACCP plan shall be maintained:

(1) The written HACCP plan including all portions of the Hazard Analysis as prescribed in this subpart;

(2) Records associated with the monitoring of CCP's, which include the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s) identity, or slaughter production lot; and date the record was made; and

(3) Records associated with supporting documentation for the Hazard Analysis, development of the selected CCP's, critical limits, frequency of monitoring and verification procedures, and corrective actions taken.

(c) All such records shall be made available to any Program employee upon request. Documents associated with a deviation from a critical limit shall be brought to the attention of the appropriate Program employee promptly.

(d) All records shall be retained at the establishment at all times, except that records for monitoring CCP's, corrective actions, and verification procedures shall be retained at the establishment for no less than 1 year, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees.

§ 381.607 Enforcement.

(a) *Implementation.* (1) The following establishments shall meet the requirements of this subpart by the date prescribed:

(i) Establishments that conduct the following categories of processes shall comply by [insert date 12 months after publication of final rule]: Raw, Ground (including mechanically separated poultry); Thermally Processed/ Commercially Sterile; and All Other, Shelf Stable, Heat Treated.

(ii) Establishments that conduct the following categories of processes shall comply by [insert date 18 months after publication of final rule]: Non-Shelf Stable, Heat Treated, Not Fully Cooked; and Shelf Stable, Not Heat Treated.

(iii) Establishments that conduct the following categories of processes shall comply by [insert date 24 months after publication of final rule]: Fully Cooked, Non-Shelf Stable; and Non-Shelf Stable with Secondary Inhibitors.

(iv) Establishments that have the following categories of processes shall meet the requirements of this part by [insert date 30 months after publication of final rule]: Raw, Other; and Slaughter, All Poultry Kind.

(v) Small entities that generate less than $2.5 million dollars of product per year shall comply by [insert date 36 months after publication of final rule].

(2) Any establishment that obtains Federal inspection on or after the effective date(s) for the process category(ies) to be conducted shall conduct a Hazard Analysis, and shall develop and validate its HACCP plan(s), as set forth in § 381.602(d) of this subpart, concurrent with the grant of inspection. Process analysis, as set forth in § 381.604(c), shall commence after obtaining Federal inspection to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(3) Any establishment that institutes a new process requiring development of a HACCP plan on or after the applicable effective date(s) of this regulation shall conduct all activities required for hazard analysis, development, and validation of its HACCP plan(s) for the process category(ies), as set forth in § 381.602(d) of this subpart, before commencing production and shall conduct process analyses, as set forth in § 381.604(b), to assure compliance with the critical limits of the HACCP plan and that the HACCP system is functioning as intended.

(4) Commencing with the applicable effective date(s), the Program shall refuse new inspection services requested for, or, using the procedures in § 381.237, suspend inspection services from establishments or specific processes within establishments not having HACCP plans.

(b) *Verification.* The Program shall verify that HACCP plan(s) are effective and validated, and otherwise in compliance with this regulation. Such verification and process validation may include:

(1) Reviewing the HACCP plan,

(2) Reviewing the CCP records,

(3) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs,

(4) Conducting verification activities to determine whether CCP's are under control,

(5) Reviewing the critical limits,

(6) Reviewing other records pertaining to the HACCP plan or system,

(7) Random sample collection and analysis to determine the safety of the product, and/or

(8) On-site observations and records review for revalidation of HACCP plans.

(c) *Suspension, correction of invalid plans.* (1) If the Program finds a HACCP plan to be invalid, inspection service for the process covered by the HACCP plan will be suspended using the procedures in § 381.237. The processing facilities identified shall not be used for production of poultry product pending completion of the specified corrective action(s), as prescribed in paragraph (c)(3) of this section, and written acknowledgement thereof by the designated Program official. Product produced by that process prior to the suspension suspected of being adulterated shall be retained at the establishment pending disposition by the Program, and if such product has been shipped, it shall be subject to voluntary recall as necessary to protect public health.

(2) A HACCP plan may be found invalid if:

(i) The HACCP plan does not meet the requirements of this subpart,

(ii) HACCP records are not being maintained as required to validate the

plan or verify process control under the plan, or

(iii) A processing failure results in production of adulterated product.

(3) Invalid HACCP plans must be corrected by:

(i) Submission to the designated program official of a written, detailed verification by a HACCP-trained individual that a modified HACCP plan has been developed in consultation with that individual and that as modified the plan corrects the deficiencies found, and

(ii) In the case of a processing deficiency resulting in production of adulterated product, submission to the designated Program official of and adherence to a written plan for finished product produced under the modified HACCP plan to be tested by an external laboratory for chemical or microbial characteristics, at the establishment's expense, as appropriate to demonstrate that the process under the modified HACCP plan corrects the identified problem.

(4) If the establishment fails to adhere to the modified HACCP plan and, if applicable, the testing plan, resulting in a subsequent suspension of the same process for the same or a related deficiency, the designated Program official will, upon receipt and before acknowledgement of any subsequent modified plan(s) under paragraph (c)(3) of this section, also review the establishment's performance under the inspection regulations generally and make a written recommendation to the Administrator as to whether any additional inspection or enforcement measures may be required.

(5) If the Administrator finds deliberate falsification of HACCP records, the Administrator will issue a complaint for withdrawal of inspection services from the establishment and will refer the case to the Department of Justice for criminal prosecution.

Done at Washington, DC, on January 25, 1995.

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Acting Under Secretary for Food Safety.

Note: The following Appendix will not appear in the Code of Federal Regulations.

Appendix—Generic HACCP for Raw Beef

National Advisory Committee on Microbiological Criteria for Foods

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I. Introduction

The following generic Hazard Analysis Critical Control Point (HACCP) plan for beef slaughter and processing focuses on the slaughter and processing portions of the total ''farm to consumption'' scope of a complete HACCP program. The Committee realizes that animal production practices can play a significant role in controlling microorganisms of food safety concern. An overview of key attributes of live animal management that significantly impact introduction or control of foodborne pathogens in relation to the ultimate microbiological safety of raw beef products is included in Section V.A. Likewise, specific practices and procedures are required to ensure the microbiological integrity of beef products while they are in distribution networks and during retailing. Improper handling of products during processing, distribution, in food service establishments or in the home, can result in the introduction, survival, or growth of pathogenic microorganisms. A lack of adequate controls throughout the complex food chain will increase the risk of foodborne disease. This portion of the total HACCP program is introduced in Section V.C, and will be additionally discussed in a more general document that will be developed to identify critical factors that must be controlled to ensure the safe distribution and marketing of meat and poultry products.

The generic HACCP plan reviews the processing steps of slaughter operations. The goal of HACCP for slaughter operations is to prevent, eliminate, or reduce both the incidence and levels of microorganisms pathogenic for humans. While beef slaughter operations do not include a lethal treatment (e.g., thermal process) that ensures elimination of pathogenic microorganisms, a number of the processing steps can be controlled to minimize microbiological hazards. The overall objective of the HACCP program is to ensure that processing is conducted in a manner that enhances the microbiological safety of the product. This is achieved through the effective management of key operations that can be used to realistically prevent or control the introduction or growth of pathogens.

Integral to HACCP systems is adherence to the general practices common to all well controlled food production facilities such as adequate sanitation, good manufacturing practices (GMPs), effective equipment/facility design, and maintenance (ICMSF, 1988; Druce, 1988). A knowledgeable, well trained workforce is essential in carrying out these practices. Important GMPs related to beef slaughter operations are outlined in ATTACHMENT A.

Several new technologies for beef slaughtering are in various stages of development, testing, and implementation. New technologies that are likely to become operational in the near future are included in the generic HACCP plan. A summary that discusses each of the new technologies and the anticipated benefits of implementation is included (Section VII). Areas where additional research is required are also discussed (Section VIII). Academic, government, and industry researchers should be encouraged to address these and related areas that provide new knowledge and technologies for enhancing the microbiological safety of beef products.

The generic plan provides general guidance for developing plant-specific plans. Such individualized HACCP plans for specific products and facilities should be developed and implemented by manufacturers as the optimal means for food safety management (NACMCF, 1992). HACCP is also recommended for use as a tool for inspection operations. The food processor has the responsibility for developing and implementing well-defined HACCP plans. The role of the regulatory agency is to verify that the processor's HACCP plans are effective and being followed. The USDA inspector should use the HACCP plan for monitoring and conducting verification as necessary. A discussion of the role of regulatory agencies and industry is included in Section VI.

In addition, a generic document which outlines the specific roles of the regulatory agencies and industry in HACCP has been prepared by a separate Working Group of the Committee.

The Committee recommends the adoption of HACCP principles to reduce

the risk of contamination by pathogenic microorganisms. In accordance with the NACMCF focus on safety (NACMCF, 1992), the current plan specifically addresses microbiological safety. However, it is worth noting that the increased process/product control achieved through the adoption of HACCP is also likely to enhance the microbiological quality of raw beef products. Full implementation is critical for HACCP plans to be successful. Management's commitment to the HACCP concept is imperative for successful implementation. The Committee recommends that HACCP plans include consideration of specific mechanisms for facilitating communication among all levels of plant operations and management.

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II. Epidemiology of Foodborne Illness Associated With Raw Beef

A. Introduction

Foodborne disease is an important cause of morbidity in the United States and throughout the world (Archer and Kvenberg, 1985; Cliver, 1987). Surveillance of foodborne diseases and prospective studies have identified foods of animal origin as important vehicles for microorganisms causing human illness (Todd, 1983, 1989; Bean and Griffin, 1990). The live animal is exposed to a variety of potential sources of microorganisms (e.g., soil, water, feeds, air, other animals, etc.), and often acquires pathogenic microorganisms initially as a result of exposure ''on the farm'' or during transport (Galton, et al., 1954; Ayers, 1955; Linton, et al., 1974; Martin and Smith, 1984; Clegg, et al., 1986; Grau, 1987; Linton and Hinton, 1987). In healthy animals, microorganisms are confined primarily to the gastrointestinal tract and exterior surfaces (hooves, hide, hair). During slaughtering and dressing, the surface of the carcass and subsequent cuts of meat may become contaminated with these microorganisms (Ayers, 1955; Mackey and Derrick, 1979; Smeltzer, 1984; Chandran, et al., 1986; Grau, 1987; Dixon, et al. 1991). Foods of animal origin may also be contaminated by microorganisms persisting in the processing environment, or as a result of contact with food handling personnel or equipment during processing, distribution, retailing, and use (Empey and Scott, 1939; Ingram, 1949; DeWit and Kampelmacher, 1981, 1982; Smeltzer, 1984; Smulders and Woolthuis, 1983; Druce, 1988; Ligugnana and Fung, 1990; Restaino and Wind, 1990). The extent of this contamination will depend, to a large degree, on the sanitary control exerted during slaughtering and dressing (Ayers, 1955; Empey and Scott, 1949; Ingram, 1949; Smulders and Woolthuis, 1983; Chandran, et al., 1986; Dixon, et al., 1991). This section focuses on the microorganisms that are the primary cause of morbidity and mortality associated with raw beef products.

B. Sources and Limitations of Data

In the United States, foodborne disease data are derived from outbreak investigations, prospective studies, and outbreak and sporadic disease surveillance conducted and reported by public health organizations such as the U.S. Centers for Disease Control and Prevention (CDC). The majority of the data is acquired through passive outbreak surveillance programs. It is assumed that the incidence data represent only a fraction of the total number of cases due to significant under reporting (Bean and Griffin, 1990; Buchanan and DeRoever, 1993). Such programs do not effectively record the incidence of sporadic disease. Assessing the impact of raw beef products on foodborne disease is complicated by the potential for such foods to serve as an indirect source of pathogens. Further, most available outbreak data are for cooked beef products. Identification of any relationship between an outbreak and the presence of pathogenic microorganisms in raw beef must be determined through adequate investigations that pinpoint food handling, processing, and preparation errors. Typically, microbial foodborne disease outbreaks involve errors associated with mishandling or inadequate processing of the raw beef, failure to control time and temperature after cooking, or post-processing contamination.

C. Outbreak Data

In the United States between 1973 and 1987, beef products accounted for 9% of reported outbreaks and 10% of the cases in which a food vehicle was implicated (Bean and Griffin, 1990). Similar results were reported for Canada (Todd, 1989). Raw beef has been reported to serve as a vehicle for a variety of disease causing organisms (i.e., viruses, protozoa, parasites, etc.); however, bacterial pathogens accounted for 92% (159 of 172) of beef-associated outbreaks in which an etiologic agent was identified (Bean and Griffin, 1990). The primary bacterial etiologic agents for beef-related outbreaks were *Salmonella* spp. (48%), *Clostridium perfringens* (32%), and *Staphylococcus aureuas* (14%). Recently, *Escherichia coli* 0157:H7 has played an increasingly important role as a cause of raw beef associated foodborne illness. Contamination of the raw beef combined with improper food handling practices is an important factor in a substantial portion of the *Salmonella* cases (Silliker, 1982; Bryan, 1979). *Clostridium perfringens* outbreaks are generally associated with cooked products that are held at inadequate holding temperatures in institutional and food service settings (Bryan, 1980). Spices and other dry ingredients can also be a source of *C. perfringens*, enterotoxigenic *Bacillus cereus*, *S. aureus*, and *Salmonella* (NRC, 1985). Food handling personnel are the primary source of *S. aureus*, and outbreaks are generally associated with temperature abuse after contamination of the cooked products (Bryan, 1980).

D. Sporadic Cases

Foodborne diseases that are predominately associated with sporadic cases are under-represented by outbreak data. A pertinent recent example associated with beef is *E. coli* 0157:H7, a major agent of hemorrhagic colitis (Belongia, et al., 1991; Doyle, 1991; Griffin, et al., 1988; Riley, 1987; Wells, et al., 1991). A prospective study of diarrheal disease in the State of Washington identified this organism as the third most frequently isolated cause of bacterial diarrheal disease (MacDonald, et al., 1988). Of particular concern is this organism's association with hemolytic uremic syndrome (HUS), a sequela of hemorrhagic colitis. This life-threatening, chronic kidney disease occurs in 2–7% of patients with shiga-like toxin *E. coli*-associated disease (Griffin and Tauxe, 1991). HUS has a 6% rate of mortality, with children being the most susceptible.

Listeria monocytogenes is another pathogen where a substantial portion of the cases caused by this microorganism are sporadic. While foodborne transmission appears to account for most human listeriosis cases, no epidemiological link to beef products

has been established (Schuchat, et al., 1991, 1992; Farber and Peterkin, 1991; Ryser and Marth, 1991).

E. Mechanisms of Transmission and Risk Factors

Since beef products may be eaten after cooking procedures that are insufficient to assure elimination of bacterial pathogens, intrinsic contamination of the raw product represents a potential risk. This is particularly true for ground beef where contamination that would normally be limited to the exterior of meat is spread throughout the product during grinding (ICMSF, 1980). This problem has also occurred when roast beef that was internally contaminated by restructuring or injection was inadequately cooked (Bryan and McKinley, 1979).

Food handling errors often contribute to foodborne disease outbreaks (Todd, 1983, 1989). These include such factors as improper holding temperatures, inadequate cooking, contaminated equipment, and food handler hygiene. Inadequate cooking and improper holding temperatures are particularly pertinent for beef products. A number of these factors have been addressed successfully. For example, undercooking in commercial plants has been addressed through the standardization of thermal processing requirements, such as the guidelines for roast beef (USDA, 1983 NACMCF, 1989). However, similar levels of control have not been achieved in the home or in all food service establishments.

Other factors that appear to influence the incidence of foodborne disease are the source, primary purpose, and health of the animals. At least for *E. coli* 0157:H7, there is a strong correlation with meat from dairy cattle, but not ''fed'' cattle (Wells, et al., 1991; Doyle, 1991; Griffin and Tauxe, 1991). The incidence was highest in young animals. Higher incidences of *Salmonella* contamination of raw beef products also appears to be correlated with calf slaughter operations (Hogue, et al., 1993).

The beef industry is made up of two major segments. Animals for the fed-cattle market come through feedlots to the slaughter plants. These are largely animals raised for higher quality meat, and are processed into wholesale cuts for boxed beef. The trimmings go into manufacturing ground beef or sausage. The majority of fed-cattle are slaughtered by a small number of large operators. Cow meat is produced from culled dairy cattle or beef cows advanced in age. The primary use of cow meat is ground beef and processed meats. This segment of the industry is characterized by a large number of small operators. A recent survey of the beef slaughter industry indicated that the overall microbiological quality of raw beef was inversely correlated to slaughter volume; however, no such association was observed for *Salmonella* contamination (Hogue, et al., 1993). *Salmonella* contamination was more closely related to the health of animals brought to slaughter. It is important to note that surveys of this type only provide broad statistical trends. Further work is needed to determine the operational differences both within and between large and small volume operations that could account for the observed trends.

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III. Microbiological Profile of Raw Beef

A. General Microbiological Parameters Associated with Beef

Beef muscle is a nutrient-rich substrate that can support the growth of a wide range of microorganisms. It is generally assumed that the interior of intact muscle is free of microorganisms. However, localized presence of bacteria can occur in lymph nodes or the area adjacent to bone joints, particularly if they are inflamed. Microorganisms are introduced into the interior of meats as a result of the translocation of bacteria from the surface of the carcass. The initial microflora is diverse at the time of slaughter; however, subsequent refrigerated storage selects for a limited group of aerobic psychrotrophic species, particularly those of the *Pseudomonas-Moraxella-Acinetobacter* group (Johnston and Tompkin, 1992). The specific genera encountered is dependent on the storage temperature, oxygen availability, pH, and moisture content (von Holy and Holzapfel, 1988).

1. Temperature

Microbial growth in beef is strongly dependent on environmental temperature. As storage temperatures are lowered toward freezing there is a significant decrease in the rate of microbial growth as well as a reduction in the diversity of the microflora.

2. Moisture Content

Fresh meat has a water activity (a_w) of ≥0.99 which supports the growth of a wide variety of bacteria, yeast, and molds. At high a_w values (a_w >0.97), the rapid growth rates characteristic of bacteria allow them to predominate. However, as meat surfaces dry, the differential in growth rates becomes less important. Below a_w values of 0.94, fungal species play an increasingly important role as the dominant type of microorganism.

3. pH

The pH of fresh beef is dependent on a number of factors including feeding and handling practices at the time of slaughter, and range from 5.3–6.5. Under normal conditions, the pH of beef after slaughter and chilling is ≤5.8. Both the rate of microbial growth and the diversity of the microflora will be restricted at the lower end of the pH range (Grau, 1981).

4. Oxygen Availability

Unpackaged fresh beef actually represents two microbiological environments in relation to oxygen availability. The surface is aerobic; an environment that permits the rapid growth of aerobic psychrotrophs such as *Pseudomonas*. However, the poising capacity of meat tissue is high, and an anaerobic environment predominates within 2 mm of the surface. This selects for anaerobes, microaerophiles, and facultative anaerobes. Restricting oxygen availability through the use of physical barriers can substantially alter microbial growth at the surface of meats. Fresh beef is an actively respiring system and even a partial restriction of oxygen permeability across a plastic wrap results in a depletion of oxygen and an accompanying increase in carbon dioxide. This produces a shift from aerobic species (e.g., pseudomonads) to microaerophiles and facultative anaerobes such as *Lactobacillus, Pediococcus, Leuconostoc, Streptococcus, Carnobacterium*, and *Brochothrix*. Grinding raw beef increases the surface area exposed to oxygen, at the same time distributing any contamination present on the surface throughout the meat. However, the increased surface area also increases the amount of actively respiring muscle tissue, leading to rapid oxygen depletion within packaging material that restricts oxygen availability.

There has been speculation that vacuum packaging or modified atmosphere packaging (VP/MAP) could lead to a situation where if a product

was temperature abused, the normal aerobic spoilage microflora could be suppressed, but pathogenic facultative anaerobes would grow unabated (Genigeorgis, 1985; Hintlian and Hotchkiss, 1986; Gill and DeLacy, 1991). At present, there is little epidemiological or other data available indicating that there are any problems with VP/MAP of raw beef. However, the potential must be considered when evaluating the hazards associated with beef.

B. Potential for Foodborne Pathogens

Low levels of pathogenic bacteria can be isolated from a varying percentage of raw beef products. A number of studies have examined raw beef products for *L. monocytogenes* worldwide, with reported incidence rates ranging from 0 to >50% (Ryser and Marth, 1991). The incidence rates for *Salmonella* on raw beef are generally low (<5%); however, higher rates have been reported (Felsenfeld, et al., 1950; Weissman and Carpenter, 1969; Goo, et al., 1973; Nazer and Osborne, 1976; Stolle, 1981). The incidence of *E. coli* 0157:H7 in raw beef appears to be low, and associated with dairy cattle (Doyle and Schoeni, 1987; Belongia, et al., 1991; Wells, et al., 1991).

The sources of pathogenic microorganisms vary. For example, *S. aureus* is generally associated with food handlers or mastitic cows. *Salmonella, E. coli*, and other enteric pathogens are typically associated with fecal material and can be commonly isolated from the hooves and hides of cattle (Stolle, 1981). There appear to be several means by which enteric pathogens become attached to raw beef, though there does appear to be a preferential binding to connective tissue (Benedict, et al., 1991). Recent research has indicated that the preferential binding of *Salmonella* to connective tissue involves a genetically encoded cell surface binding site (Sanderson, et al., 1991). *L. monocytogenes* can be endemic in cattle; however, recent European studies (Ryser and Marth, 1991) suggest that the food processing environment can be an important source of this pathogen. The presence of low levels of pathogenic bacteria on beef may be unavoidable; however, care must be exercised to ensure that this level is minimal. Further, beef products should be handled in a manner that assures that pathogens of significance have little or no opportunity to proliferate (Gill and DeLacy, 1991).

A variety of mesophilic foodborne pathogens are potentially capable of growing in the microbiological environment associated with both the surface or the interior if the meat is held above 8–10°C (Mackey, et al., 1980; Grau, 1981; Gibson and Roberts, 1986; Smith, 1987). The microflora of raw beef may contain members that competitively inhibit the growth of enteric pathogens such as *Salmonella* under certain conditions (Gilliland and Speck, 1977; Gill and Newton, 1980). However, a number of studies have concluded that the microflora of raw beef cannot be relied on to prevent the growth of mesophilic pathogens in temperature-abused beef (Mackey, et al., 1980; Smith, 1985, 1987; Mackey and Kerridge, 1988). Further, vacuum and modified atmosphere packaged raw beef that is temperature abused at ≥12°C and ≥15°C may support significant growth of *Salmonella* before overt spoilage is detected (Gill and DeLacy, 1991). Initial studies on the growth characteristics of *E. coli* 0157:H7 (Buchanan and Klawitter, 1992c; Glass, et al., 1992) indicate that it is likely to behave in a manner similar to other serotypes of *E. coli* and *Salmonella* (Smith, 1985, 1987; Hughes and McDermott, 1989).

Psychrotrophic pathogenic species, including *L. monocytogenes*, *Yersinia enterocolitica*, *Aeromonas hydrophila*, and some strains of *Bacillus cereus*, represent a special concern because they are capable of growth at refrigeration temperatures. While both *Y. enterocolitica* and *B. cereus* have been epidemiologically linked to products of animal origin, typically they are not associated with raw beef products. *Aeromonas hydrophila* can be frequently isolated from refrigerated raw beef; however, the role of this organism in disease outbreaks involving non-immunocompromised individuals is still poorly understood (Palumbo, et al., 1991).

While there have been no outbreaks of listeriosis attributed to raw beef products, *L. monocytogenes*' growth characteristics, increased thermal resistance compared to enteric pathogens, and incidence in raw and cooked meat products (Ryser and Marth, 1991) has prompted investigations of its behavior in raw beef. *Listeria monocytogenes* is capable of growth in temperature-abused raw beef (Buchanan and Klawitter, 1992a); however, there are conflicting reports concerning the ability of the organism to grow in raw beef at ≥5°C (Kahn, et al., 1972; 1973: Johnson, et al., 1988a, b; Grau and Vanderlinde, 1988; Buchanan, et al., 1989; Gill and Reichel, 1989; Glass and Doyle, 1989; Shelef, 1989; Dickson, 1990; Buchanan and Klawitter, 1991; Kaya and Schmidt, 1989, 1991). The observed differences may be attributable to either the pH (Gill and Reichel, 1989; Kaya and Schmidt, 1991) or the physical form (cuts versus ground) (Buchanan and Klawitter, 1991) of the meat. The effects of individual microorganisms of meat microflora on the growth of *L. monocytogenes* include none, inhibitory, and even stimulatory, depending on the specific species or strain (Ingram, et al., 1990; Tran, et al., 1990; Mattila-Sandholm and Skytta, 1991). A number of raw meat isolates of lactic acid bacteria, particularly *Carnobacterium* and *Lactobacillus* species, have been reported to produce bacteriocins against *L. monocytogenes* (Schillinger and Lucke, 1989; Ahn and Stiles, 1990a, b; Mortvedt and Nes, 1990; Lewus, et al., 1991; Buchanan and Klawitter, 1992a, b). While there are potential applications for controlling foodborne pathogens through the use of a competitive microflora (Buchanan and Klawitter, 1992b), the current state of knowledge does not allow this to be relied on as a primary means of control. The primary means for controlling psychrotrophic pathogen growth remains the maintenance of storage temperatures as low as possible (≤2°C) and a normal low pH (<5.8).

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IV. Hazard Analysis

Epidemiological data (section II. A–E) indicate that three microorganisms have accounted for 94% of the outbreaks in which beef has been implicated. Raw beef has been a major source for salmonellae in the outbreaks. Raw beef has been one of many potential sources

for *C. perfringens*. Raw beef can be a source of *S. aureus*. This is a concern in the manufacture of fermented and dried meats. Raw beef is a source for sporadic cases and, occasionally, outbreaks of illness due to *E. coli* 0157:H7.

The hazard analysis leads to the conclusion that raw beef can be an important vehicle in the transmission of two important foodborne pathogens: salmonellae and *E. coli* 0157:H7. These pathogens are similar in a number of respects, such as:

a. Sensitivity to heat and cold,

b. Sensitivity to chemicals,

c. The ability to multiply asymptomatically in the bovine intestinal tract, and

d. Potential for low infectious doses.

E. coli 0157:H7 and certain *Salmonella* serovars may cause secondary infections and chronic sequelae. Also, both pathogens may cause death, particularly with *E. coli* 0157:H7.

The primary microbiological hazards encountered during the beef slaughtering process are salmonellae and *E. coli* 0157:H7. The following generic HACCP plan will be directed primarily at control of these pathogens. Efforts to improve slaughter hygiene will reduce the presence of other pathogens (*C. perfringens, S. aureus, L. monocytogenes*) on carcass meat.

V. Generic HACCP

The factors that impact the microbiological safety of raw beef products during its ''farm to consumer'' lifetime can be subdivided into four segments: (1) live animal practices, (2) slaughter and processing operations, (3) distribution and retailing operations, and (4) consumer food handling practices. Key factors associated with live animal practices are introduced and discussed in Section V.A. The individual steps involved in slaughter and processing operations are detailed as a generic HACCP plan in Section V.B. The primary thrust of the first two sections is the control of enteric bacteria, the class of pathogenic microorganisms associated with and amenable to control during these phases of raw beef production and processing. The factors associated with distribution, retailing, and consumer practices that impact the safety of raw beef products are introduced in Section V.C.

A. Farm Management Practices

Raw beef originates from several sources of cattle. These can be classified into two major categories, fed beef and mature beef. Fed beef typically comes from animals that have been raised to desired market weight, usually less than two years of age. Mature beef comes from dairy or beef animals that have been marketed after being used for milk or calf production. Fed beef serves as the major source of whole beef products and some ground beef products. Mature dairy and beef animals are a primary source of ground meat and patties to consumers, including food service establishments.

The husbandry practices under which fed beef cattle and mature dairy and beef cattle are managed are quite different. However, potential for microbial contamination of the final product exists in both and they share many of the same risks. There are major aspects in the production phase that can influence incidence, control, and prevention of potential human pathogens in cattle.

1. Transportation

The production cycle, especially of fed beef, typically involves time spent on two or more premises prior to movement to processing facilities. Transportation is often necessary but contributes to an increased incidence of contamination due to both the stress placed upon animals and the increased risk of exposure of cattle to potential human pathogens (Cole, et al., 1988; Hutcheson and Cole, 1986). Dairy animals handled in a similar manner would experience similar risk.

Transport time should be such that the animals reach other production facilities and processing establishments in an expedient manner, with stress kept to a minimum. Transport vehicles should be free of injurious structural defects. Vehicles should be clean at the time animals are loaded, and cleaned and sanitized following unloading at the slaughter facility.

2. Marketing

Marketing is accomplished through a number of outlets that introduce varying degrees of risk. Cattle frequently are sold or moved through either auction markets, direct selling from producer to backgrounder or feedlot, video auctions, or collection points. Animals from multiple sources are commonly commingled at one or more points during production, resulting in transfer of potential pathogens between animals.

Inspectors at slaughter plants must maintain high standards regarding diseased and otherwise inferior animals, including continued close communication with cattle producers to provide information to improve quality and safety standards in slaughter animals.

3. Animal Husbandry

Numerous management practices are influenced by environmental conditions. For example, excessive moisture conditions generally result in higher levels of hide contamination with mud, feces, and other extraneous matter. Management systems that minimize the impact of adverse environmental conditions would be expected to decrease microbial contamination. This may involve basic changes in animal husbandry (Smith and House, 1992). Controlling exposure and contamination is especially important immediately prior to shipment to slaughter.

4. Role of Stress

Stressed animals have lowered disease resistance, making them more susceptible to pathogens and at increased risk of shedding potential human pathogens (Breazile, 1988). For example, animals which are exposed to salmonellae can become intermittent shedders of this organism. Various forms of stress can result in increased shedding and clinical disease, causing increased exposure to pennates, increasing the risk also to humans through contaminated meat.

Management systems addressing increased animal welfare and better husbandry decrease levels of stress, and would be expected to decrease the incidence of pathogens. For example, improvements in cattle handling systems reduce stress-related immune suppression associated with animal processing procedures (Grandin, 1984, 1987). A number of other factors, such as animal density, frequency of feedlot pen use, and commingling of sick animals, can affect stress levels and thus risk of human pathogen exposure. *Salmonella* is capable of surviving variable, prolonged periods of time in animal facilities (Rings, 1985).

5. Feed and Water Contamination

Feed and water are potential sources of microbial contamination to cattle (Robinson, et al., 1991). Feedstuffs should be documented free of *Salmonella* and other enteric pathogens (Mitchel and McChesney, 1991). This is especially critical for feeds containing rendered byproducts. Water must be from clean, non-fecally contaminated sources.

6. Antimicrobial Use

Therapeutic and subtherapeutic use of antimicrobials has long been a practice in the cattle industry. Recent emphasis on regulations and resulting industry response, such as quality assurance programs, has resulted in more

responsible use of antibiotics in cattle. Therapeutic use of antibiotics is used to reduce effects of clinical diseases in cattle, including potential human pathogens such as salmonellae. Additional information is needed regarding advisability of some currently accepted practices, especially when considering human health risks (Rings, 1985; Kennedy and Hibbs, 1993).

7. Animal Identification

The beef and dairy industries, along with state and federal agencies, must continue to develop adequate means to identify animals from the initial production unit through the slaughter process. Permanent animal identification is essential so producers can assume further responsibility for the beef they market by being able to track animals through the entire production, slaughter, wholesale, and retail processes. Currently, mature animals are identified by backtags as part of the Brucellosis eradication program. Retention of this portion of the program is suggested until better means of identification are implemented. Permanent identification is a critical issue for improving the safety of raw beef at the producer level.

Projected Needs: Current and future strategies that may be useful in decreasing the risk of microbial contamination at production levels include assessments of the prevalence of human pathogens in cattle, permanent identification of animals using advanced technology (USAHA, 1992; Maher 1991; Nelson, 1991), use of new and improved vaccines, use of improved management methods in reducing microbial contamination risk, and incorporation of biotechnological advances in cattle production as they are proven to be beneficial in minimizing or preventing microbial contamination.

Producers should be encouraged to carefully review production methods and HACCP guidelines to decrease risks associated with pathogenic microbial contamination (Smith and House, 1992). Utilization of quality management principals is recommended since these concepts will result in improved quality assurance and pre-harvest food safety programs (Schmitz, 1993; FAPMC, 1992; AVMA, 1992). Implementation of production practices suggested by these programs are critical at all phases of cattle production regardless of unit size or type.

B. Slaughter Operations

Unit operations associated with the slaughter and dressing of beef are summarized in Figure 1. A more detailed examination of each of the steps is provided in ATTACHMENT D.

A CCP within a Hazard Analysis and Critical Control Point (HACCP) program is defined as any point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels (NACMCF, 1992).

Seven specific CCP process steps have been designated in the processing of raw beef (Figure 1 and Table 1). These include (1) skinning, (2) post-skinning wash/bactericidal rinse, (3) evisceration, (4) final wash/bactericidal rinse, (5) chill, (6) refrigerated storage, and (7) labeling.

For each of these CCP steps critical limits are defined for proper control. These CCPs must be monitored at a frequency sufficient to ensure process control. Corrective actions to be taken when CCPs do not meet critical limits should be specified clearly in the HACCP plan. This should include the priorities of actions to be taken and the individuals to be notified of the deviation. The HACCP system should be verified according to HACCP principle #7 (NACMCF, 1992).

The seven CCPs with procedures associated with the processing step are shown in the following outline.

Implementation and Management of HACCP Critical Control Points

CCP 1: Skinning

The hide is the first major source of microbial contamination on fresh beef carcasses. Cattle leaving the farm, feed lot, or sales barn for delivery to the slaughter plant, carry with them microbial populations indicative of what occurred during the care and handling of the live animal. *Salmonella* and other types of bacteria can be spread during the skinning process through contact with hide, hands and various pieces of equipment (Empey and Scott, 1939; Newton, et al., 1978; Stolle, 1981; Grau, 1987). Current skinning technology does not provide a means for destroying enteric pathogens that reside on the hide of animals coming to slaughter. There also is no available means to remove all soil from the hide of animals prior to slaughter; however, preslaughter washing does have a positive effect (Empey and Scott, 1939; Dixon, et al., 1991). Skinning, therefore, should be done in a manner that will minimize cross-contamination from the hide to the carcass. This contamination can be minimized by pulling the hide down and out from the carcass as opposed to upward and away. In addition, equipment and carcass contact surfaces must be properly cleaned and sanitized. The operator performing the skinning process must be trained to minimize contamination. Management must reinforce the proper techniques through adequate supervision.

The effectiveness of the CCPs outlined in this document are based on the concept of additive impact. Wash and bactericidal rinse steps will significantly reduce the level of microbial contamination resulting from the skinning or evisceration steps; however, the efficacy of these processes are dependent on control of skinning and evisceration. The procedures and corrective actions outlined for CCP 1 and CCP 3 minimize the level of contaminating material that must be removed by the wash and rinse steps.

If critical limits for CCP 1 are exceeded, corrective actions must be taken prior to the carcasses being subjected to the post-skinning wash and bactericidal rinse. Corrections of CCP 1 deviations can be achieved by adding additional operators to the skinning procedure, reducing the chain speed in the skinning area, and/or conducting carcass trimming prior to the post-skinning wash and bactericidal rinse.

CCP 2: Post-Skinning Wash and Bactericidal Rinse

During the skinning process, newly exposed carcass surfaces can become contaminated with dressing defects, i.e., fecal material, hide and/or dirt, that may introduce bacterial pathogens. A post-skinning wash and bactericidal rinse is an effective means of reducing this contamination. Any pathologic conditions, i.e., abscesses, septic bruises, etc., should be removed prior to CCP 2.

Maximum benefit of post-skinning wash and bactericidal rinse can be achieved if the amount of contaminating material is minimized, emphasizing the importance of CCP 1 (skinning). Proper skinning procedures must be achieved for effective post-skinning wash and bactericidal rinse.

Post-skinning wash and bactericidal rinse should occur as soon after skinning as possible to limit irreversible attachment of pathogens to the carcass. An in-line, post-skinning, potable water wash at 90–100°F and a pressure of 345–2070 kPa (50–300 psi) removes much of the visible surface contamination (hair, specks) and reduces microbial contamination to some extent (DeZuniga, et al., 1991). The water wash should be followed immediately by a bactericidal rinse to provide an effective reduction of surface bacteria. The bactericidal rinse should be an approved antimicrobial agent such

as chlorine (50 mg/L) or an organic acid (1–2% acetic, lactic, or citric acids) at a temperature of 120–140°F and a pressure of 70–275 kPa (10–40 psi) (Prasai, et al., 1991). Monitoring of this CCP should be conducted by continuous confirmation of concentration, temperature, pressure, and chain speed.

Validation of CCP 2 should be accomplished by microbiological testing of carcasses before and after CCP 2. A reasonable level of testing should be performed at the initiation of a HACCP program to establish baselines for total aerobic, mesophilic bacteria and/or *Enterobacteriaceae*. These microbiological indices are useful indicators of process control and overall sanitation, but are not effective as indicators of enteric pathogens. All testing should be performed using standard methods (Vanderzant and Splittstoesser, 1992). After establishment of the baseline, verification of CCP 2 can be achieved by periodic sampling of carcasses for the two microbiological indicators, using the same methods employed in establishing the baseline. These data should be reviewed using trend analysis and statistically significant increases should prompt a review of CCP 2 operations. Literature indicates a functioning wash and bactericidal rinse step in conjunction with acceptable adherence to CCP 1 should deliver an approximate 90% reduction in microbial levels. Specific bactericidal agent concentrations, temperatures, and pressures to be used should be based on appropriate available literature and in-plant testing to obtain optimal bacterial reductions (Patterson, 1968, 1969; Kotula, et al., 1974; Emswiler, et al., 1976; Quartey-Papafio, et al., 1980; Osthold, et al., 1984; Woolthuis and Smulders, 1985; Acuff, et al., 1987; Prasai, et al., 1991; and Dickson and Anderson 1992).

CCP 3: Evisceration

The intestinal tract is the second major source of enteric pathogens during the slaughtering process. Although the animals may be asymptomatic, they can still harbor large populations of enteric pathogens in their intestinal tract. The bunging and evisceration operators must be properly trained in removing the intestinal tract intact to successfully adhere to the control parameters of CCP 3. It is essential that the viscera not be accidentally cut and the contents contaminate the carcass, the operator, or equipment (Empey and Scott, 1939; Mackey and Derrick, 1979; Eustace, 1981; Smeltzer and Thomas, 1981; Grau, 1987). When the intestines are accidentally cut and contamination occurs, immediate sanitizing of equipment and knives should be performed with 180°F water, and involved personnel should utilize hand washing and sanitizing facilities to avoid contamination of subsequent carcasses. The most effective means of control lies in adequate training of the operator in the correct procedures, including providing the rationale on the importance of maintaining the viscera intact, coupled with positive reinforcement through appropriate supervision. Accordingly, monitoring this CCP entails periodic observation of the evisceration operations including visual inspection of eviscerated carcasses. This can correlate to potential carcass contamination.

CCP 4: Carcass Final Wash

Additional microbial contamination of the carcass surface is likely to occur as a result of evisceration, viscera handling, and carcass splitting. An in-line, potable water wash at 90–100°F and a pressure of 345–2070 kPa (50–300 psi) will help reduce microbial levels, including enteric pathogens (DeZuniga, et al., 1991). This final water wash should be followed by a bactericidal rinse containing an approved antimicrobial agent such as chlorine (50 mg/L) or an organic acid (e.g., 1–2% acetic, lactic, or citric acids) at a temperature of 120–140°F and a pressure of 70–275 kPa (10–40 psi) (Prasai, et al., 1991).

This combination of a final wash and bactericidal rinse will help minimize carriage of pathogens through the remaining beef fabrication and packaging processes. Monitoring of this CCP should be through continuous confirmation of antimicrobial concentration, temperature, pressure, and chain speed. Verification can be achieved by conducting microbiological testing as described in CCP 2 to confirm that CCP 4 is providing the anticipated level of control of microbial levels. Maximum effectiveness of CCP 4 can only be realized if the critical limits for CCP 1–3 are maintained. Any deviations associated with the earlier CCPs must be corrected before the product is subjected to the final wash. Specific bactericidal agent concentrations, temperatures, and pressures to be used should be based on appropriate available literature and in-plant testing to obtain optimal bacterial reductions (Patterson, 1968, 1969; Kotula, et al., 1974; Emswiler, et al., 1976; Quartey-Papafio, et al., 1980; Osthold, et al., 1984; Snijders, et al., 1985; Woolthuis and Smulders, 1985; Smulders, et al., 1986; Acuff, et al., 1987; Prasai, et al., 1991; and Dickson and Anderson 1992; Siragusa and Dickson, 1992; Dickson, 1992).

CCP 5: Chill

The bacterial flora including any enteric pathogens found on the sides of fresh beef could multiply if the meat is not properly chilled. Cooling rates must be sufficient to limit the growth of enteric pathogens. Temperature guidelines would include a deep muscle (6 in.) temperature of ≤ 45°F within 36 hours, with a temperature of ≤ 50°F reached within the first 24 hours (Reuter, 1990). Overnight rapid chilling of properly spaced beef sides is a proven system to control the multiplication of enteric pathogens (Grau, 1987; Mackey, et al., 1980). The CCP can be monitored through the continuous confirmation of physical factors affecting cooling rates such as environmental temperatures and air circulation rates. Verification can be achieved through the periodic recording of deep muscle cooling rates for selected carcasses, using appropriately calibrated temperature recording devices (e.g. thermocouple).

CCP 6: Refrigerated Storage

After chilling, the carcasses and resulting raw products must be maintained under adequate refrigeration during all subsequent handling and processing until the final product is ultimately consumed. This highly diffuse CCP requires that manufacturers, distributors, retailers, food service operators, and consumers each take responsibility for assuring that raw beef products are kept under adequate refrigeration. Maintaining products in a refrigerated state (product temperature ≤45°F), along with appropriate cleaning and sanitizing of equipment and food contact surfaces, will control the multiplication or accumulation of non-psychrotrophic pathogens. Further, maintaining storage temperatures as close to freezing as practical will enhance control of psychrotrophic pathogens.

CCP 7: Labeling

Adequate product identification (e.g., code dates, lot identification) is necessary for product control in the event that product must be traced or retrieved. To facilitate the responsibilities of distributors, retailers, food service operators and consumers, all raw and partially cooked beef products should be labeled to indicate that the product must be refrigerated, handled, and cooked properly to ensure safety. Methods of cooking and sanitary handling should reflect the needs of the specific product. Labels should be appropriate for either retail and

institutional consumers. A universal logo should be designed to identify raw beef products for consumers. The logo should include space for instructional information specific for the product. An example of a potential logo is depicted in Figure 2.

The seven CCPs are summarized in Table 1.

C. Distribution, Retailing, and Preparation

An effective HACCP plan for the production, slaughtering, and initial processing of raw beef will greatly increase control of pathogenic microorganisms; however, even under the best operating conditions low numbers of pathogens may remain on the carcass. Further, care must be exercised to prevent re-introduction of pathogens, such as *Salmonella* and *S. aureus*, that are epidemiologically linked to beef products.

After slaughter, dressing and processing, raw beef goes through a complex system of distribution and marketing (including wholesalers, distributors, retail stores and food service establishments) before ultimately reaching the end users who consume the products. Throughout distribution and preparation of raw meats, there is a significant potential for product mishandling leading to the introduction of additional pathogenic microorganisms, or the spread of any pathogens remaining on raw beef to other foods. Improper handling and storage practices, including improper holding temperatures, inadequate cooking, contaminated equipment and food worker hygiene, have all contributed to beef associated foodborne outbreaks (Bryan, 1988). The microbiological hazards associated with raw beef can be controlled by extending HACCP principles to product handling activities in retail stores, food service establishments, institutional feeding facilities, and homes.

The goal of the HACCP system in food distribution and preparation is to minimize microbial contamination, reduce the opportunities for pathogens that may be present to multiply, assure the destruction of pathogenic microorganisms through proper cooking procedures, and prevent the cross-contamination of pathogens from raw to cooked foods.

HACCP properly applied to all segments of distribution and preparation has the potential for:

1. Reducing the opportunities for pathogen growth, thereby reducing the risk of foodborne disease;

2. Assuring the destruction of enteric and other non-spore forming pathogens through proper cooking procedures;

3. Preventing the reintroduction of pathogens to the cooked product and cross-contamination of other foods; and

4. Controlling the growth of spore forming pathogens (e.g., *C. perfringens*) by use of proper time/temperature relations for storage, holding, and serving.

An effective HACCP system in food distribution and preparation depends on a general understanding of and adherence to the principles of sanitation, good manufacturing and food preparation practices as well as proper facility layout and equipment design and maintenance (See Attachment A). The education and training of all personnel is critical to the process and effectiveness of any HACCP program.

HACCP plans for handling and processing raw beef should be developed and implemented by food retailers and food service establishments as the optimal system for food safety assurance. In institutional feeding operations such as hospitals, nursing homes, day care centers, and prisons where the populations may be more vulnerable to foodborne disease, special care must be taken in the preparation of all foods, including raw beef products . The Committee recommends that HACCP systems be implemented immediately by food service establishments and institutions preparing foods for these special groups with increased susceptibility. General guidelines for the safe handling of raw beef in retail food stores and food service establishments are provided in Attachment B.

Several national surveys (Weimer and Jones, 1977; Williamson, et al., 1992) have shown that the public has a limited understanding of the basic principles of food microbiology and safe home food handling and preparation practices. In households, the successful use of HACCP principles is dependent on the interest, knowledge and skills of the food preparer. General guidelines for the safe handling of raw beef by consumers are provided in Attachment C.

D. HACCP Records and Verification

The acquisition and maintenance of records are an integral and critical principle of HACCP (NACMCF, 1992). Records of CCP performance along with documentation of related verification activities and process deviations are the primary tool by which a HACCP operation is managed and decisions are reached concerning the efficacy of process. The records of designated objective and subjective observations that should be maintained must be specified in the HACCP plan and maintained at the processing location. All records should be reviewed and integrated on a specified, routine basis. This should include subjecting the data to trend analysis to identify and correct problems before they result in CCPs exceeding critical limits. It is recommended strongly that this review be integrated, and the results communicated to both employees and supervisory personnel. The mechanism and duration of records maintenance is the responsibility of plant management, and should be specified in the HACCP plan. However, any system established must take into account the primary role that records review plays in verifications by regulatory agencies.

Establishing procedures for verification that the HACCP system is working correctly is an integral element in developing an effective HACCP plan and system. The verification procedures should:

1. Verify that the critical limits for CCPs are satisfactory,

2. Ensure that the facility's HACCP plan is functioning effectively,

3. Consist of documented revalidations, audits, or other verification procedures to ensure the accuracy of the HACCP plan, and

4. Provide regulatory verification that the HACCP system is functioning satisfactorily.

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TABLE 1.—GENERIC HACCP PLAN CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION

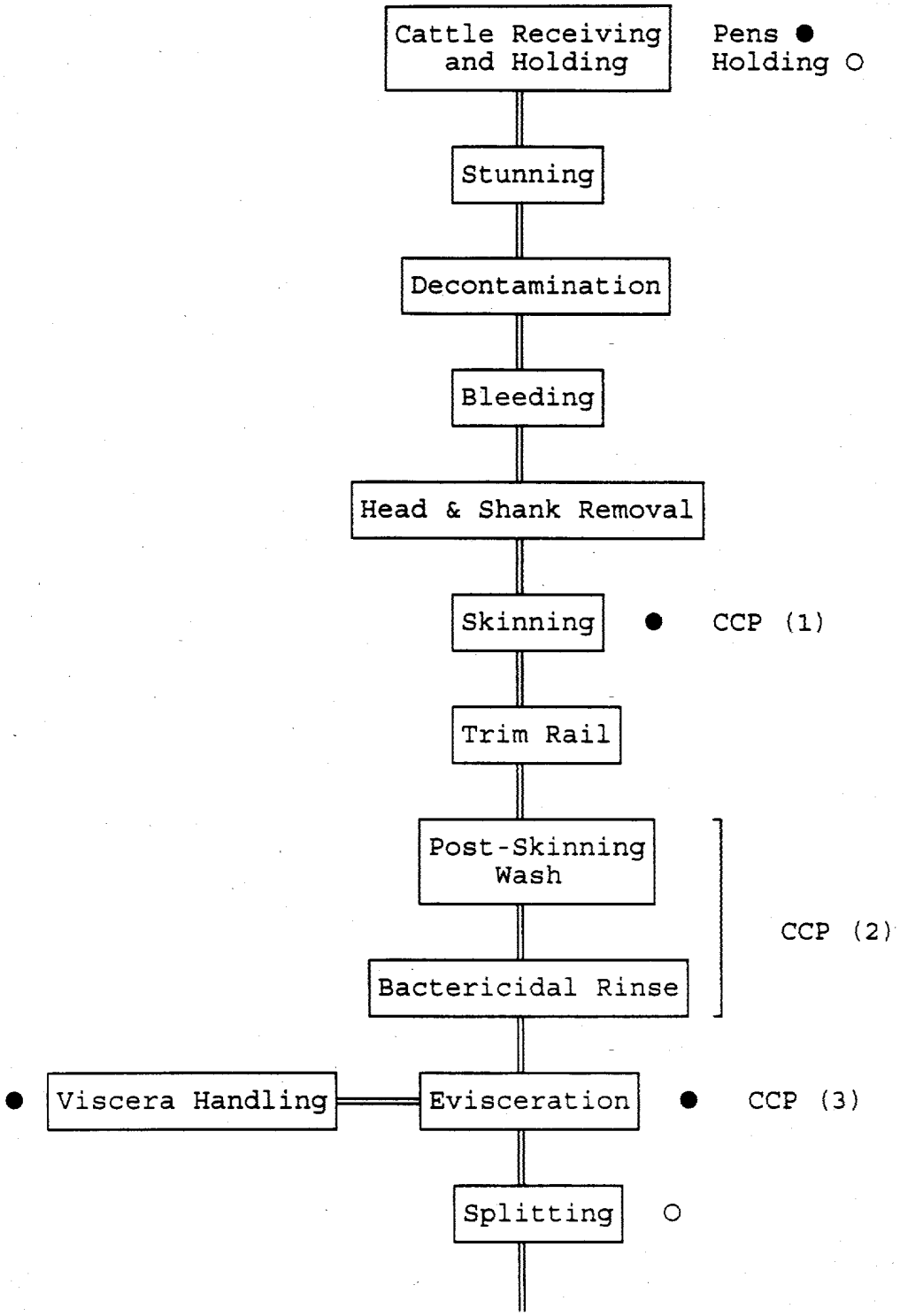
Process/step	CCP	Critical limits	Monitoring procedure/frequency	Corrective action	Records	Verification
Skinning	CCP(1) ...	≤20% of carcasses with dressing defects.	Operator observes effectiveness of skinning process for each carcass. Visual analysis should be conducted under adequate lighting per USDA requirements.	Add operators ... Reduce chain speed. Conduct carcass trimming.	Random post-skinning carcass examination log.	Examination of random carcasses after skinning is complete using sampling plan sufficient to assure process control. Supervisory review of records. Initially, conduct microbiological analyses for aerobic mesophiles and/or *Enterobacteriaceae* to establish baseline data on expected bacterial numbers. Periodic follow-up analyses and trend analysis to verify process control. Review control charts to confirm that sampling frequency is sufficient to detect 20% defect criteria.
Post-skinning Spray Wash and Bactericidal Spray.	CCP(2) ...	Washing: 1. 90–100°F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: 1–2%. 115–130°F. 2. Chlorine: 50 ppm. Ambient temperature. 3. 70–275 kPa (10–40 psi) 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration..	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration Examine and repair equipment as needed.	Post-skinning wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological analyses for aerobic mesophiles and/or Enterobacteriaceae coupled with trend analysis to confirm adequacy of process in comparison to data collected at CCP(1). Periodic testing of equipment to ensure it is operating according to design specifications.
Evisceration	CCP(3) ...	0% occurrence of the following defects for a single carcass: Fecal material, ingesta, urine or abscesses.	Employee observes contamination and routes contaminated carcass for immediate trimming.	1. Trained employee immediately trims defect area on carcass. 2. Add operators. 3. Reduce chain speed. 4.4. Sanitize soiled evisceration tools with 180°F water. 5. Sanitize soiled clothing 120°F water or appropriate sanitizer.	Random post-evisceration carcass examination log.	Supervisory review of records and operations. Random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.

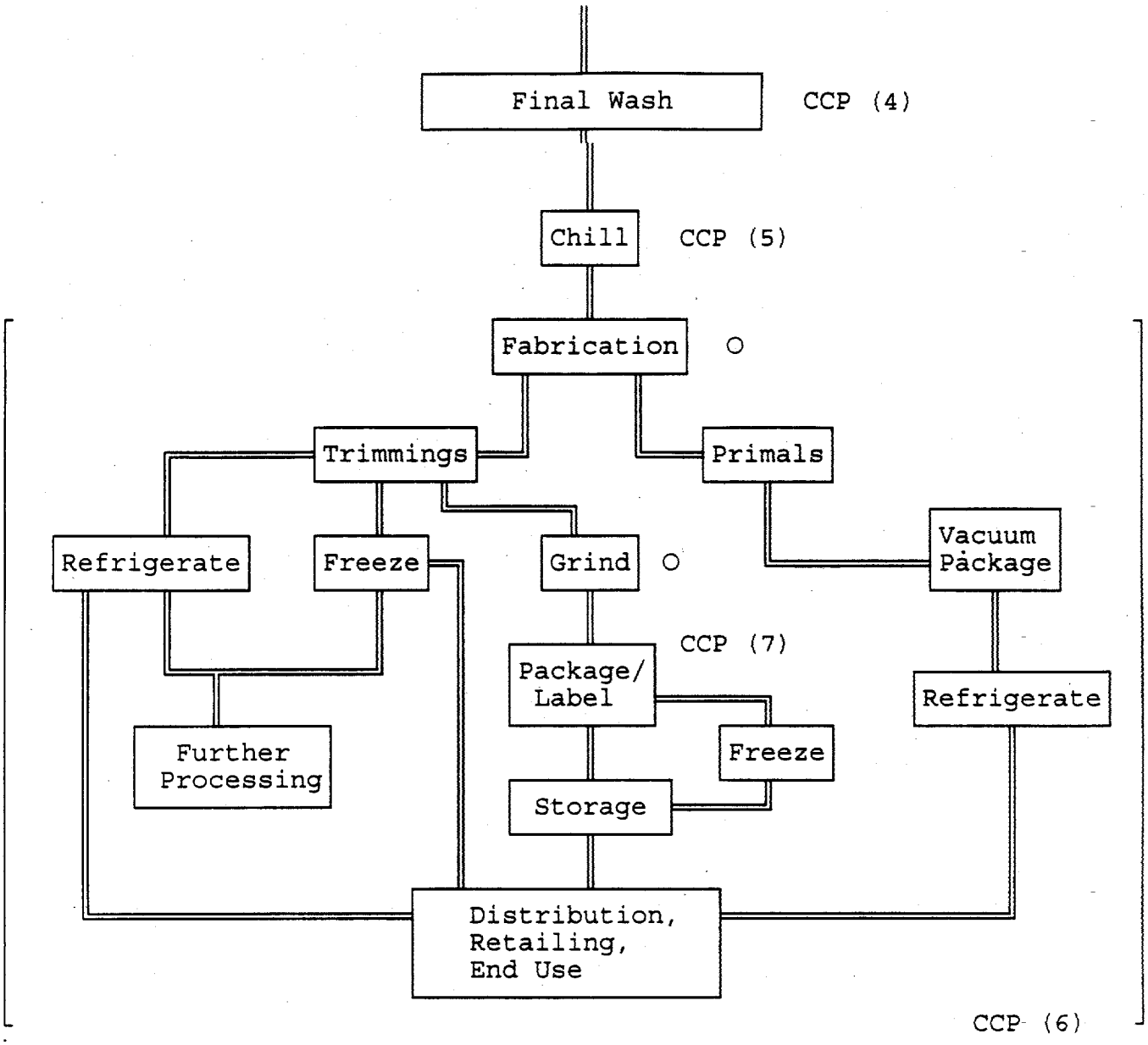
TABLE 1.—GENERIC HACCP PLAN CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION—Continued

Process/step	CCP	Critical limits	Monitoring procedure/frequency	Corrective action	Records	Verification
Final Wash Spray and Bactericidal Spray.	CCP(4) ...	Washing: 1. 90–100°F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: 1–2%. 115–130°F. 2. Chlorine: 50 ppm. Ambient temperature. 3. 70–275 kPa (10–40 psi). 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration.	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration. Examine and repair equipment as needed.	Final wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological assays for aerobic mesophiles and/or Enterobacteriaceae to confirm an adequate reduction in bacterial numbers compared to baseline data collected at CCP(1) and CCP(3). An effective organic acid decontamination system is indicated by a ≤90% reduction in bacterial numbers from CCP(1) to CCP(4). Periodic testing of equipment to ensure operation in accordance to design specifications.
Chill	CCP(5) ...	Deep muscle (6 in.) temperature of ≤45°F within 36 hours, reaching ≤50°F after the first 24 hours. Carcasses spaced a minimum of 1–2 inches apart.	Continual confirmation of environmental conditions (e.g., room temperature, air velocity, humidity, etc.) that influence cooling rates. Monitor carcass spacing upon arrival to chill coolers. Conduct random temperature monitoring of carcasses after appropriate chill time.	Adjust carcass spacing. Adjust chill cooler temperature, air velocities, etc. Alert maintenance if cooler unit is not functioning properly. Continue chilling carcass until internal temperature reaches ≤45°F.	Chill log	Supervisory review of records. Review thermometer calibration log and spacing control charts. Periodic monitoring of cooling rates of deep muscle tissue through the use of temperature recording devices.
Refrigerated Storage.	CCP(6) ...	Product temperature of ≤45°F).	Check product temperature. Continuous monitoring of temperatures of storage facility.	Adjust temperature of storage facility. Place product on hold (i.e., retain), investigate, and take appropriate action.	Temperature records.	Supervisor record review.
Labeling	CCP(7) ...	Instructional labels and logo. Product date	Visual checks of each lot. Inspection of product to ensure use of correct instructional label and/or logo.	Assure correct label and relabel if incorrect.	Labeling records	Supervisory review of records.

FIGURE 1. BEEF SLAUGHTER, FABRICATION, AND PACKAGING

○ Potential site of minor contamination
● Potential site of major contamination




Final Wash
CCP (4)
Chill
CCP (5)
Fabrication
O
Trimmings
Primals
Refrigerate
Freeze
Grind
O
Vacuum Package
CCP (7)
Package/ Label
Refrigerate
Further Processing
Freeze
Storage
Distribution, Retailing, End Use
CCP (6)

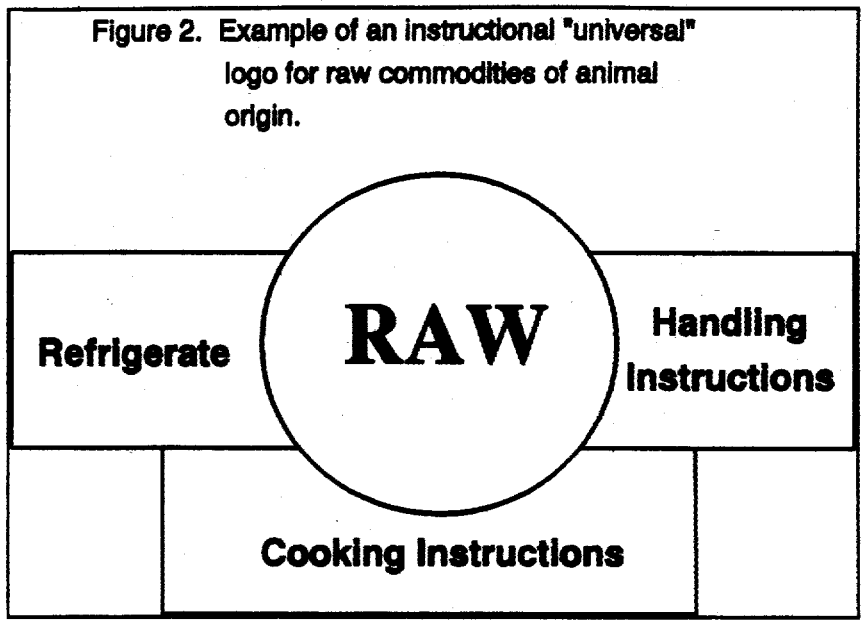


Figure 2. Example of an instructional "universal" logo for raw commodities of animal origin.

BILLING CODE 3410–DM–C

VI. Role of Regulators and Industry in HACCP-based Beef Processing

The processor has primary responsibility for development and implementation of HACCP plans for beef slaughter, fabrication, packaging and distribution. These plans, however, must consider the entire food system from production to consumption. The major role of the regulatory agency(s) is to verify that the processor's HACCP system is effective and working as intended. In general, this includes assurance that following the HACCP plan fulfills the intended purpose of providing a product that is safe when properly handled and prepared for consumption.

The role of regulatory agency(s) in inspection of beef processing operations should be based on the recommendations of the HACCP Subcommittee on ''The Role of Regulatory Agencies and Industry in HACCP''. The regulatory agency(s) in cooperation with industry and other experts in HACCP shall be actively involved in promoting the HACCP principles and their application to assure uniformity and common understanding. Regulations and guidelines that are promulgated by the regulatory agency(s) should be consistent with these principles.

The focus of the regulatory agency(s) should be on those activities associated with verification of critical control points. The processor must make HACCP records available to the regulatory agency(s). These records would include the processor's HACCP plan, CCPs, critical limits, monitoring, deviations, product disposition, and corrective actions. The HACCP plan and associated processor records must be considered proprietary information that must not be made available outside the regulatory agency(s).

Specific verification procedures may include: Establishing verification inspection schedules based on risk; review of the HACCP plan; review of CCP records; review of deviations and corrective actions; visual inspection of operations, random sampling of final products; review of critical limits; review of the processors verification records; review of revalidation of the HACCP plan; and review of HACCP plan modifications. The regulatory agency(s) should establish the manner and frequency of verification, format for verification reports, and other activities based on the HACCP Subcommittee recommendations (NACMCF, 1992).

Industry's responsibility is to develop, implement and maintain an effective HACCP system. The system should be based on the NACMCF recommendations on HACCP principles and application (NACMCF, 1992). Each facility should develop an HACCP team and provide for proper training in HACCP principles. It is the processor's responsibility to provide HACCP records to the regulatory agency(s). The processor must assure that the records are complete, accurate and up to date. Records for review must include pertinent information for verification and revalidation of the HACCP plan. When necessary, amendments to the HACCP plan will be made in response to the regulatory inspection.

It is recommended that the beef processors and associated regulatory agency(s) adopt the principles for implementation of HACCP as outlined by the HACCP Subcommittee on the Role of Regulatory Agencies in HACCP. These recommendations include uniformity in adopting HACCP principles, the characteristics of a HACCP-based inspection program, and procedures to facilitate the adoption and implementation of HACCP.

Reference

1. NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 1992. Hazard analysis and critical control point system. Int. J. Food Microbiol. 16:1–23.

VII. New Technologies and Procedures

New technologies and procedures for improved microbial control during the slaughtering process fall into two activities: preventing contamination and decontamination. Both will be considered. In addition to microbial control, improvements in carcass identification and product coding can be beneficial for determining the source of microbial pathogens.

A. Reducing the Potential for Contamination

This section includes those new technologies or improvements in existing procedures which can be used during slaughtering to reduce contamination from current levels to lower levels. Operators of slaughter facilities should be encouraged to

develop procedures which reduce or control the spread of pathogens from manure, internal organs, hair, water, etc. to the carcass or the processing environment. Such systems might include improved methods for hide removal; dehairing before removing the hide; washing and/or sanitizing saws, knives or other equipment during slaughtering operations; or other new techniques.

The trim rail, for example, should be moved to an area as far forward in the slaughter process as possible, preferably before the pre-evisceration wash. Such a move would facilitate preventing carcass contamination. This trim area should also be used to trim bruises, lesions, and grubs before spraying the carcass with water or other approved solutions.

The method of cutting around and handling the bung (e.g. tying off, covering, etc.) is another example. The preferred method has been debated for a number of years. There is general agreement, although there is little or no published data, that this step can be a significant source of contamination to the carcass. It is recommended that this step be reviewed and one or more methods be specified which will minimize carcass contamination.

B. Decontamination

There are two basic approaches to decontamination. The first approach usually consists of spraying carcasses during slaughtering and/or chilling. These procedures can reduce but will not destroy all the enteric pathogens. The second approach consists of irradiating packaged meat. Irradiation doses currently approved for use with poultry (Cross, 1992) would be sufficient to destroy the levels of enteric pathogens that would normally be present on freshly packaged meat.

Both approaches require that the slaughtering process be controlled to minimize contamination. The number of enteric pathogens on the carcasses should be as low as possible before either method of decontamination is applied. In addition, the method of decontamination and the organoleptic quality of the decontaminated meat must still be acceptable to consumers.

1. Organic Acid Sprays, etc.

Research and commercial experience has demonstrated that microbial contaminants on the surface of carcasses can be reduced through the use of organic acid sprays, hot water, steam and various combinations of these and other approved bactericidal materials. There may be more than one combination of treatments at one or more steps during slaughtering and/or chilling. The Committee encourages the development and implementation of such bactericidal systems to reduce the number and incidence of enteric pathogens on carcasses and fresh meat. As systems are developed and approved, FSIS should consider requiring the use of systems that have been proven to actively reduce enteric pathogens. The minimum efficacy required for such systems should be a specified reduction of Enterobacteriaceae (e.g. a 10-fold reduction) using standardized protocols recognized by the regulatory agency with input from other interested parties (e.g., academia, industry, USDA–ARS, NACMCF, and professional organizations). The conditions (e.g., time, temperature, pH, acid concentration, etc.) for effective operation of the decontamination system should be specified in the HACCP plan of the slaughter establishment.

In addition to its use as an in-line system for decontamination, this technology can be applied to unique situations. For example, under current inspection procedures for cattle, the following occurs in the event that during evisceration a break in viscera contaminates the body cavity:

Carcass siderailed;

Carcass trimmed by peeling out fascia in body cavity;

Exposed bone is trimmed; and

Visual reinspection.

An alternate approach to the above may be the following:

Carcass siderailed.

Decontamination of the body cavity by:

Extensive body cavity and carcass wash with potable water.

Decontamination of the body cavity by an approved procedure (e.g., organic acid, alkaline solution, hot water, steam, etc.)

2. Irradiation

Irradiation is an effective technology for destroying enteric pathogens in fresh meats. The irradiation of poultry for pathogen control has been approved in the United States and ten other countries (e.g., France, United Kingdom, and The Netherlands) (ICGFI, 1992). Irradiation of raw beef should, likewise, be approved. Used appropriately, irradiation can be an effective method for assuring the safety of raw meats, particularly raw ground beef.

C. Carcass Identification, Product Coding

Procedures should be developed so that carcasses can be identified as to source and can be traced back to the farm. In addition, minimum requirements for the coding of raw beef products should be developed so that information can be obtained relative to processing establishment(s), sources of raw materials and time of production.

References

1. Cross, H.R. 1992. Irradiation of poultry products. 9 CFR Part 381. Federal Register 57:43588–43600.
2. ICGFI. 1992. Ninth Meeting of the International Consultative Group on Food Irradiation. Inventory of product clearances. International Consultative Group on Food Irradiation, Joint FAO/IAEA Division, International Atomic Energy Agency, Vienna.

VIII. Research Needs

1. Recent research has indicated that the attachment of enteric pathogens involves a specific, genetically-controlled interaction between the bacterial cell surface and connective tissue. Further research is needed to confirm these observations and elucidate the underlying biochemistry of attachment. Potentially, this information could be used to develop enhanced methods for preventing contamination and/or enhancing the removal of enteric pathogens from raw beef.

2. One of the long standing questions with raw meat and poultry products has been the epidemiological significance of low numbers of infectious bacteria such as *Salmonella*, *Listeria*, and *E. coli* O157:H7. Recent biotechnological advances allow for the first time the active tracing of such foodborne pathogens from the farm, through the processing operations, and to ultimate isolation in a clinical setting. An active surveillance study should be undertaken to establish unequivocally the role of raw meat and poultry in transmission of human enteric diseases.

This research should be designed and conducted to identify the major points of introduction and/or dissemination of *Salmonella* and *E. coli* O157:H7. This information is needed to perform accurate hazard analyses and risk assessments to develop preventive measures on the basis of sound information.

The study should be conducted in a manner that permits acquisition of quantitative information of the levels of pathogens related to overt disease. While the establishment of an absolute Minimum Infectious Dose for individuals is not a reasonable

objective, there is a need to know on a population basis the incidence of active infections that are likely to occur as a function of levels enteric pathogens ingested. This information is needed to make realistic, cost-effective decisions concerning microbiological criteria. For example, if the infection rate at 10,000 cfu/g is 90% whereas at 100 cfu/g it is 0.01%, one could estimate risk factors versus the cost of achieving a significant improvement in public health. Using the cited example, it is unlikely that there would be much practical significance in mandating a minimum level of less than 1 cfu/g if there was not further reduction in infection rate.

3. Determine how techniques in microbial risk assessment can be applied to the transmission of bacterial pathogens via raw beef products. This includes quantifying the relative importance of both the different potential sources of pathogenic bacteria and the critical control points that control the microbiological hazards associated with beef slaughter operations.

4. Establish baseline data for the types and extent (level) of microbial contamination that can be expected on raw beef products produced under good manufacturing conditions. These data will serve as the basis for assessing the efficacy of alternate intervention approaches. This should include an examination of large and small volume slaughter operations for fed-cattle and dairy cattle to determine factors that effect incidence of foodborne pathogens in these segments of the beef industry.

These surveys should be accompanied with an evaluation of the relationship between the results of traditional organoleptic inspections and assessments of both the incidence and extent of contamination with specific human pathogens. Particular emphasis should be directed to assessing the relationship between animal health at the time of slaughter and the overall degree of contamination of the meat.

5. Surveys of the adequacy of refrigeration in distribution channels, retail markets, food service establishments, and the home have indicated that there is a significant potential that raw beef products will be temperature abused before consumption. There is a need to establish quantitative data on the impact of transitory or marginal temperature abuse on the growth of pathogens on raw beef products. Data on time/temperature relationships would provide a scientific basis for courses of action that should be followed when there is a loss of temperature control.

6. Establish how refrigerated raw beef should be stored to maximize microbiological safety, with particular reference to control of psychrotrophic pathogens.

7. Identify microbiological inhibitors that could be used in raw meat and poultry, particularly ground beef.

8. Evaluate decontamination procedures to determine if they could be employed as an alternate means to trimming for effectively eliminating fecal contamination from carcasses.

9. The continued development of improved methods for the identification of foodborne pathogens in meat and poultry products should be encouraged. This includes rapid methods that can be used both to identify animals that harbor enteric pathogens prior to slaughter and to periodically verify the effectiveness of HACCP operations. Studies of improved means for sampling to decrease lower limits of detection, enhance accuracy, and decrease number of samples required for statistical validity should also be encouraged.

10. It is often assumed that enteric pathogens are limited to the surface of beef carcasses. However, evidence indicates that lymph nodes can harbor enteric pathogens (e.g., salmonellae). This suggests that the processing procedures described in this document would be less effective than anticipated. The relative significance of beef carcass lymph nodes as a potential source of *Salmonella* and *E. coli* O157:H7 is unknown. Studies should be undertaken to determine the incidence of these pathogens in bovine lymph nodes.

Attachment A—General Sanitation Controls for Beef Slaughter and Fabrication Operations

Successful implementation of HACCP within a beef slaughter or fabrication facility requires the following basic plant support programs. Good manufacturing practices (GMPs) must be stressed throughout the facility. These practices include programs that cover employee personal hygiene, effective sanitation, pest management, equipment selection and maintenance, plant environmental management, potable water sources, operational practices, and proper storage of packaging materials and supplies. Effective adherence to GMPs requires orientation and follow-up training for all employees.

A. Hygiene Practices

All personnel should be trained in the importance of personal hygiene.

Hair nets, beard covers, knives, steels, lockers, aprons, smocks, boots, etc., should be handled and maintained in a clean and sanitary manner. Disposable personal items should be changed as required to assure cleanliness.

Hot water sanitizing stations should be kept at 180°F with frequent changes of water. After knives are dipped they should be sanitized by approved sanitizers for an appropriate time interval before reuse. This may require multiple knives to allow adequate time in the sanitizer to assure proper microbial kill.

Knives and all personal equipment should be cleaned, sanitized, and dried prior to storage. Special attention should be given to boots and footwear. Storage lockers should be kept clean and free of dirty clothes, rags, etc.

Shrouds, aprons, gloves, and cotton items should be placed in a marked plastic container after use. These items should be given a proper wash with a chlorine rinse and dried thoroughly before being returned to the processing plant.

B. Equipment

Acquisition of USDA approved equipment should include consideration of ease of cleaning, sanitation, and maintenance.

All equipment should be cleaned and sanitized daily. Pre-operative inspections should be conducted prior to start-up.

All equipment must be maintained in good repair. As materials age, deterioration occurs and care must be taken to monitor the equipment. Preventive maintenance helps ensure equipment works properly and facilitates proper cleaning and sanitizing.

Plastic or metal pallets are preferable, however, if unavailable, wooden pallets may be used provided they are kept dry and clean.

All plastic belts and other food conveyance surface should be inspected frequently, and replaced or resurfaced as soon as there is evidence of cracking, pitting, or other defects that would hamper effective cleaning and sanitizing.

A major equipment concern is controlling material buildup, i.e., bone dust and meat particle accumulation in areas that increase in temperature during processing. Such problems can be minimized by regular cleaning and appropriate documentation of all actions.

C. Movement of Personnel and Equipment

Movement of personnel and equipment between areas, particularly between slaughter and fabrication or

processing zones can be a source of cross contamination.

Fork lifts can be a continuing source of cross-contamination. Movement must be excluded from areas where product is exposed.

Movement of personnel between zones should be controlled and minimized. Sinks, boot washes, and clean outer garment exchange should be used at zone entrances, particularly if individuals are moving from a ''dirty'' zone to a ''clean'' area (e.g., movement from abattoir to fabrication room).

D. Packaging

A basis for selection of approved food packaging material should be effectiveness for protecting the product and preventing contamination. Packaging integrity must be maintained to avoid recontamination, i.e., proper seals, clips, covers, vacuum levels, etc. All packaging materials and supplies should be received and stored in manner that ensures their integrity.

E. Pest Control

An active program for control of insects, rodents, wild birds, and other pests should be maintained, including periodic examination of facilities for evidence of infestations.

F. Plant Environment Management

The processing environment should be maintained to meet GMP requirements. This includes daily operative checks to ensure compliance.

G. Water

Water for processing should be obtained from a potable source or where permitted, recycled according to approved guidelines. Periodic analysis of the water should be conducted to ensure that the source meets the recognized microbiological criteria for potable water.

General Guidelines for the Handling of Raw Beef Products in Retail Food Stores and Food Service Establishments

A. Food Receiving and Storage

Raw beef products should be received in good condition and at a temperature of 40°F or less. A visual inspection should be conducted to assure the condition of raw beef products.

B. Refrigerated Storage

Storage temperatures of less than 40°F will minimize microbial growth of *Salmonella.* Proper stock rotation should be practiced and:

A first-in, first-out stock rotation system should be utilized. All foods should be kept covered, wrapped, dated, labelled and rotated. Older products should be used before newly received foods.

Raw products should be stored separately from cooked, ready-to-eat products to prevent cross-contamination.

The cooler should be regularly inspected for good sanitary conditions and maintained at the proper temperature (<40°F) and humidity. Products should be stored to assure sufficient air circulation.

C. Food Preparation

Delicatessen employees and food service workers should be aware of and practice good personal hygiene at all times, especially when preparing and handling foods.

Employees should not work when ill and should wash hands frequently, especially after handling raw foods and after using the restroom.

Clean clothing and appropriate hair cover should be worn by all personnel involved in food preparation.

Raw foods should be kept separate from cooked, ready-to-eat foods. Equipment and utensils used in the preparation of raw beef products should be properly cleaned and thoroughly sanitized before use with other foods.

Intact cuts of beef (roasts, chops, etc.) should be cooked to a minimum internal temperature of 140°F. The temperature should be checked with a good quality thermometer in the thickest part of the meat.

Hamburgers and other ground or restructured beef products should be cooked to a minimum internal temperature of 155°F. At this temperature, the meat is well done and has no pink color.

Beef products that are cooked and held for hot display should be kept at a temperature of at least 140°F.

Leftover meat products should be refrigerated immediately in shallow containers so quick cooling can be achieved and microbial growth can be prevented.

Reheat leftover meats and other precooked beef products to a minimum internal temperature of 165°F.

General Guidelines for the Handling of Raw Beef Products by Consumers

A. Food Purchasing

Buy perishable foods last, after all other grocery items have been selected. Insist that grocery baggers place all raw food of animal origin (red meat, poultry, seafood, eggs, etc.) in a separate plastic bag for transport. Never allow raw meat to contact a package of food that will not be cooked before consumption. Cold foods should be placed together in a paper bag to help prevent excessive warming during transport.

Take purchases home immediately and place items to be kept refrigerated or frozen in proper storage as soon as possible.

B. Kitchen Appliances and Utensils

Use a thermometer to assure refrigerator temperature is 40°F or below and that freezer temperature is below 0°F.

Keep refrigerator and freezer shelves clean and sanitize periodically.

Separate raw from cooked foods in the refrigerator or freezer. Raw foods should never be stacked on top of cooked foods.

Use an oven thermometer to verify that the oven temperature is approximately the same as the temperature dial selector. Most oven owner's manuals will have instructions for adjusting the temperature selector for accuracy.

Counter tops, sinks, and cutting surfaces should be cleaned and sanitized after contacting any raw food. Clean surfaces with hot soapy water and rinse thoroughly. Sanitize the surface with a chlorine solution (one cap of bleach in one gallon of cold water; a new solution prepared weekly).

If washing utensils by hand, knives and cutting boards used with raw meats should be washed with hot, soapy water, followed by a hot water rinse and sanitation with a chlorine solution after each use. Washing in a dishwasher having a hot water rinse will sufficiently sanitize utensils (the temperature of the rinse should be at least 120°F).

C. Food Preparation

Cross-contamination occurs when utensils, plates, or hands used in preparing raw foods are not thoroughly washed and sanitized before using with cooked foods or foods that will not be cooked (e.g., salads). Never use the same plate to transport raw and cooked beef unless thoroughly washed and sanitized between uses.

Frozen products should be thawed in the refrigerator or under cold running water.

Cook intact beef cuts (roasts, chops, etc.) to a minimum internal temperature of 140°F. Always check temperatures with a meat thermometer at the thickest part of the meat.

Hamburgers and other ground or restructured beef products should be cooked until the meat is well-done (no pink color, juices run clear). The temperature at the coolest portion of the meat should reach 155°F.

Cold beef should be stored and served at 40°F or less.

Leftovers should be refrigerated immediately in shallow containers to

prevent bacterial growth. Allowing a cooked food to ''cool down'' at room temperature before refrigerating may allow bacterial growth.

Reheat leftovers and other precooked beef products to an internal temperature of 165°F.

ATTACHMENT D: CONTROL POINTS AND CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION

○ Potential site of minor contamination.
• Potential site of major contamination.

Process/step	○, •, CCP	Criteria or critical limits	Monitoring procedure/frequency	Corrective/preventive action	Records	Verification
Cattle receiving:						
Pens	○	Pens dry and clean.	Visual check each shift.	Reclean. Remove standing water.	Receiving/holding log.	Supervisory review of records.
Cattle holding.	○	Holding <24 h ...	Check holding records each shift.	Coordinate holding and slaughter speed.	Receiving/holding log.	Supervisory review of records.
Stunning:						
Bleeding	.....	Sanitize knife (180 °F water) between sticks.	Visual checks and water temperature checks each shift.	Correct procedures and temperature.	None	Supervisory review.
Head/shank removal:						
Skinning	CCP(1) •	≤20% of carcasses with dressing defects.	Operator observes effectiveness of skinning process for each carcass. Visual analysis should be conducted under adequate lighting per USDA requirements..	Add operators. Reduce chain speed. Conduct carcass trimming.	Random post-skinning carcass examination log.	Examination of random carcasses after skinning is complete using sampling plan sufficient to assure process control. Supervisory review of records. Initially, conduct microbiological analyses for aerobic mesophiles and/or *Enterobacteriaceae* to establish baseline data on expected bacterial numbers. Periodic follow-up analyses and trend analysis to verify process control. Review control charts to confirm that sampling frequency is sufficient to detect 20% defect criteria.
Post-skinning spray wash and bactericidal spray.	CCP(2) ...	Washing: 1. 90–100 °F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: . 1–2% 115–130°F. 2. Chlorine: x 50 ppm. ..... Ambient temperature ..... 3. 70–275 kPa (10–40 psi) .... 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration.	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration. Examine and repair equipment as needed	Post-skinning wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological analyses for aerobic mesophiles and/or *Enterobacteriaceae* coupled with trend analysis to confirm adequacy of process in comparison to data collected at CCP(1). Periodic testing of equipment to ensure it is operating according to design specifications.

ATTACHMENT D: CONTROL POINTS AND CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION—Continued

○ Potential site of minor contamination.
• Potential site of major contamination.

Process/step	○, •, CCP	Criteria or critical limits	Monitoring procedure/frequency	Corrective/preventive action	Records	Verification
Evisceration	CCP(3) •	0% occurrence of the following defects for a single carcass: Fecal material, ingesta, urine or abscesses.	Employee observes contamination and routes contaminated carcass for immediate trimming.	1. Trained employee immediately trims defect area on carcass. 2. Add operators 3. Reduce chain speed. 4. Sanitize soiled evisceration tools with 180°F water. 5. Sanitize soiled clothing with 120°F water or appropriate sanitizer	Random post-evisceration carcass examination log.	Supervisory review of records and operations. Random examination of carcasses after evisceration using a sampling plan sufficient to assure process control.
Viscera handling.	•	No viscera contamination of carcasses.	Visual checks	Correct defects ..	None	Supervisory review of operations.
Splitting	○	Clean saw and sanitize in 180 °F water.	Visual checks	Reclean saw	None	Supervisory review of operations.
Final wash spray and bactericidal spray.	CCP(4) ...	Washing: 1. 90–100 °F. 2. 345–2070 kPa (50–300 psi). Bactericidal Spray: 1. Organic acid: . 1–2%. 115–130°F. 2. Chlorine: 50 ppm. Ambient temperature 3. 70–275 kPa (10–40 psi). 4. Other applications per USDA–FSIS guidelines.	Continuous monitoring of temperature, pressure and bactericidal rinse concentration.	Washing: adjust temperature or pressure. Bactericidal spray: adjust temperature, pressure or concentration. Examine and repair equipment as needed.	Final wash spray and bactericidal spray log. Log of preventative maintenance.	Supervisory review of records. Periodic microbiological assays for aerobic mesophiles and/or *Enterobacteriaceae* to confirm an adequate reduction in bacterial numbers compared to baseline data collected at CCP(1) and CCP(3). An effective organic acid decontamination system is indicated by a >90% reduction in bacterial numbers from CCP(1) to CCP(4). Periodic testing of equipment to ensure operation in accordance to design specifications.

ATTACHMENT D: CONTROL POINTS AND CRITICAL CONTROL POINTS FOR BEEF SLAUGHTER AND FABRICATION—Continued

○ Potential site of minor contamination.
• Potential site of major contamination.

Process/step	○, •, CCP	Criteria or critical limits	Monitoring procedure/frequency	Corrective/preventive action	Records	Verification
Chill	CCP(5) ...	1. Deep muscle (6 in.) temperature of ≤45 °F within 36 hours, reaching ≤50 °F after the first 24 hours. 2. Carcasses spaced a minimum of 1–2 inches apart.	Continual confirmation of environmental conditions (e.g., room temperature, air velocity, humidity, etc.) that influence cooling rates. Monitor carcass spacing upon arrival to chill coolers. Conduct random temperature monitoring of carcasses after appropriate chill time sufficient to maintain process control.	Adjust carcass spacing. Adjust chill cooler temperature, air velocities, etc. Alert maintenance if cooler unit is not functioning properly. Continue chilling carcass until internal temperature reaches ≤45 °F. Product should not be moved to the next step in processing until temperature is reached.	Chill log	Supervisory review of records. Review thermometer calibration log and spacing control charts. Periodic monitoring of cooling rates of deep muscle tissue through the use of temperature recording devices.
Fabrication (cut up).	○	1. Product temperature of ≤45°F. 2. Product transported through fabrication procedures and into storage within 1 hour..	Checks of product temperature. Continuous monitoring of room temperatures. Check speed of product movement through fabrication.	Adjust room temperature. Adjust speed of incoming product to accommodate 1 hour fabrication room limit.	Temperature and product speed records.	Supervisory review of records.

Note: The following Supplement will not appear in the Code of Federal Regulations.

Supplement—Preliminary Regulatory Impact Assessment for Docket No. 93–016P, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems''

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I. HACCP Produces Net Benefit to Society

Food Safety and Inspection Service (FSIS) is proposing, in docket no. 93–016P, above, to require all federally inspected meat and poultry plants to adopt a Hazard Analysis and Critical Control Points (HACCP) processing control system for each of its processes within 3 years of publication of the final rule. The proposed regulations also mandate some near-term pathogen reduction interventions prior to HACCP plan implementation. In the same document, FSIS provides advance notice of plans to establish interim targets, guidelines, and standards to establish public health goals for pathogens.

The objective of these regulations is to initially reduce and eventually minimize the risk of foodborne illness from four human pathogens in meat and poultry in the manufacturing sector under current production technologies. These pathogens are:

1. *Campylobacter jejuni/coli;*
2. *Escherichia coli 0157:H7;*
3. *Listeria monocytogenes; and*
4. *Salmonella.*

These regulations also require appropriate controls to minimize or prevent other biological, chemical and physical safety hazards. To a certain extent HACCP can improve quality aspects of products and production efficiency. However, the benefits assessed here are based only upon pathogen reduction and control for safety.

FSIS has selected mandatory HACCP as the centerpiece for this new regulatory program because scientists and industry leaders agree that it provides the most effective food processing controls available to reduce and control meat and poultry pathogens and accomplish other food safety objectives such as chemical residue control.

The function of this regulatory impact assessment is to evaluate the costs and benefits of a mandatory HACCP-based regulatory program for all meat and poultry establishments under inspection. The HACCP ''program'' includes all the interventions in this proposal. Because contamination can occur any place in the production process, no one intervention can minimize the risk; indeed, the value of the HACCP system is that it provides a framework for systematically using interventions to minimize risk. For this reason benefits have been estimated only for the entire HACCP program. Costs are provided for each individual intervention. (A Supplement on Costs is available from Diane Moore, Docket Clerk, Room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.)

Because there are no scientific data that can be used to relate intermediate pathogen reductions to reductions in foodborne illness, benefits have been based on the Agency's intention to minimize the risk of foodborne illness in the manufacturing sector. Risk minimization means the elimination of almost all the foodborne illness caused by the contamination of meat and poultry products with the four pathogens listed above in inspected plants. The amount of reduction in pathogens needed to do this is unknown and would vary for individual pathogens and products. The testing requirement will enable the Agency to learn more about what pathogen reduction standards would be appropriate to minimize risk.

The conclusion of the cost-benefit analysis is that mandating HACCP-based processing control systems will result in net benefits that far exceed implementation and operation costs. Table 1 provides a summary of these costs and benefits. The proposed regulation will redistribute costs in a fashion more acceptable to societal values which have always given priority to minimizing the occurrence of controllable diseases.

TABLE 1.—COST-BENEFIT COMPARISON HACCP/PATHOGEN REDUCTION PROPOSAL

(Millions of $—discounted 20 years)*

	Costs		Benefits**
Total	$2,298.9	Total	$6,422–23,935
Near-Term:		Foodborne illness avoided:.	
Micro testing	131.9	Campylobacter jejuni/coli	2,919–4,670
Sanitation SOP	86.6	E. coli 0157:H7	1,168–2,419
Time/Temperature Requirements	45.5	Listeria monocytogenes	584–1,168
Antimicrobial Treatments	51.7	Salmonella	1,751–15,178
Subtotal	315.7		
HACCP Implementation:			
Plan development	35.7		
Micro testing	1,262.5		
Record keeping	456.4		
HACCP Training	24.2		
Aseptic Training	1.9		
Fed. TQC Overtime	20.9		
Agency Training	0.4		
SOP under HACCP	181.2		
Subtotal	1,983.2		

Source: Economic Research Service, Centers for Disease Control and Prevention, and Food Safety and Inspection Service.

*These costs have been discounted using the OMB suggested rate of 7%.

**Benefits from elimination of *Salmonella, E. coli 0157:H7, Campylobacter jejuni/coli* and *Listeria monocytogenes* are estimated at 90% of the total meat- and poultry-related medical costs and productivity losses associated with each pathogen as depicted in Table 4. Total benefits start 5 years after publication of final rule.

It is not known exactly what percentage of contamination takes place in the manufacturing sector in contrast to that which occurs afterwards during distribution and preparation. It is clear that most contamination takes place during manufacturing since it derives from processing animals and cross contamination during further processing. Agency microbiologists have estimated that about 90 percent of pathogen contamination occurs within

the manufacturing sector, and accordingly, only 90 percent of the benefits from the reduction of foodborne illness costs have been included as benefits in the analysis.

FSIS expects it to take about five years from the publication of the final rule for the proposed interventions and HACCP to reach the risk minimization goal. By that time, all establishments will have implemented effective pathogen reduction interventions and will have been systematically controlling their processes for from 2 to 4 years. Although there is reason to believe that during the first five years, significant benefits will be generated by the interventions and controls in place, there are no data to estimate these benefits.

Sensitivity Analysis for Table 1

The calculation of benefits in table 1 assumes benefits are zero for years 1 to 4 and the maximum possible (i.e., 100 percent of the 90 percent attributable to contamination in the inspected plants) for years 5 to 20. Given achievement of the estimated benefits in years 5 through 20, actual benefits to society would likely exceed these benefit estimates for several reasons. These reasons include the conservative valuation of a human life, no consideration of consumers' willingness to pay for avoidance of illness, and the assumption of zero benefits from near-term interventions and early implementation of HACCP. The achievement of maximum benefits is also subject to uncertainty.

In order to account for the possibility of positive benefits in years 1 through 4 and the uncertainty of benefits in years 5 through 20, an analysis was performed to examine the sensitivity of the cost-benefit analysis to changes in the estimated stream of benefits. The results of this analysis are presented in table 1A, and a discussion of the assumptions used in this analysis follows.

First, the assumption of zero benefits until year 5 is replaced by the assumption that benefits grow linearly starting from zero and reach the undiscounted maximum of $0.99–$3.7 billion in year 5. Thus, the low and high end estimates of undiscounted benefits in the first year are $0.198–$0.74 billion. Benefits increase in year 2 to $0.396–$1.48 billion and increase at the same rate until year 5. The discounted value of benefits for years 1 to 4 is $1.733 to $6.478 billion. The discounted value of benefits over 20 years becomes $8.155–$30.413 billion.

SENSITIVITY ANALYSIS OF ALTERNATIVE BENEFIT LEVELS

	Added benefits, years 1–4[1]		Baseline benefits[2]		Reduced benefits, years 5–20[3]	
	Low	High	Low	High	Low	High
Year	Billion dollars, discounted at 7 percent					
1	0.20	0.74	0	0	0	0
2	0.37	1.38	0	0	0	0
3	0.52	1.94	0	0	0	0
4	0.65	2.41	0	0	0	0
5	0.76	2.82	0	0	0	0
Sum of benefits, years 1–4	1.73	6.48	0	0	0	0
Sum of benefits, years 5–20	6.42	23.94	6.42	23.94	5.78	21.54
Total benefits, years 1–20	8.16	30.41	6.42	23.94	5.78	21.54
Benefit-cost ratio[4]	3.5	13.2	2.8	10.4	2.5	9.4

[1] Assumes benefits start at 0 and increase linearly to base level benefits in year 5.
[2] Base level of benefits are those presented in table 1.
[3] Assumes 90 percent of base level of benefits.
[4] Assumes costs presented in table 1.

Alternative assumptions regarding the size of benefits are possible. The linear assumption is arbitrary; the purpose is to demonstrate that any benefits in years 1 to 4 will increase the 20-year total discounted value of benefits.

Second, the assumption of zero benefits until year 5 is retained but the realized benefit in year 5 and later is reduced by 10 percent, making the annual undiscounted benefits $0.89–$3.32 billion. The discounted value of benefits over 20 years becomes $5.780–$21.542 billion. The uncertainty involved in estimating the annual cost of foodborne illness is already accounted for in the range reported in table 4. The 10 percent reduction is an arbitrary assumption to demonstrate the sensitivity of the cost-benefit analysis.

In neither case are costs affected. All estimates of discounted benefits are far larger than the discounted costs for each set of assumptions. The benefit-cost ratio ranges from 2.5:1 to 13.2:1.

Costs

Costs to meat and poultry processors across the Nation will vary according to how much improvement in process control each plant needs. Plants that now have good processing controls will have relatively few implementation costs, while plants that have little or no process control will need to spend more for implementation. A detailed analysis of industry's costs to develop, implement, and operate HACCP systems appears in Section V.

Costs to the Government would be for training FSIS employees. Existing resources would be used. No additional funding is anticipated.

Program Goals

The quantifiable benefits to society from the proposed regulation range from $6.4 to $23.9 billion as 20 years of foodborne illness and attendant costs to society are avoided. (The wide range of benefits is attributable to uncertainties in the data used to estimate the incidence of foodborne illness.)

The predictability of foodborne illness reductions from a reduction of pathogens in meat and poultry is made difficult by the fact that little quantitative data on the relationship between these two variables exists because many of the risk assessments necessary to establish this relationship have not been undertaken. Therefore, it is not known how much pathogens need to be reduced to minimize the risk of foodborne disease from meat and poultry. One component of the proposal is the testing of product to generate data on pathogen incidence which will help to elucidate the relationship between pathogen contamination and foodborne

disease, and the Agency also intends to undertake additional risk assessments to generate dose/response curves for specific pathogens. The Agency will use the new information from this research to adjust targets, if necessary, to meet its goal of risk minimization.

The Agency believes that it is reasonable to set a goal of risk minimization assuming the implementation of the requirements in this proposal. Current technologies can and frequently do produce product of minimal risk. Contamination occurs from poor practices (errors) and lack of systematic preventive controls throughout the production process. For the first time, in this proposal the Agency is focusing on reducing pathogens. It is mandating interventions that a large part of the industry already uses to correct errors that cause pathogen contamination, and it is proposing the use of a system of controls that prevents pathogens which is the most effective way of reducing them. Empirical evidence of how effective these interventions and HACCP process controls are where they are currently used and the Agency's knowledge that many establishments do not currently use them leads the Agency to believe that the risk of pathogens in the manufacturing sector can be minimized by the implementation and enforcement of these requirements for all inspected establishments.

Further, the Agency is mandating product testing for pathogens which will enable it to set targets that can establish a standard of pathogen control throughout the industry that will minimize the risk of foodborne illness.

II. Market Failure Justifies Regulation of Pathogens to Protect Public Health

Consumers make choices about the food they purchase based upon factors such as price, appearance, convenience, texture, smell, and perceived quality. In an ideal world, people would be able to make these decisions with full information about product attributes and choose those foods which maximize their satisfaction. In the real world, however, information deficits about food safety complicate consumer buying decisions.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food unavoidably entails some risk of pathogen exposure and foodborne illness to consumers. However, the presence and level of this risk cannot be determined by a consumer, since pathogens are not visible to the naked eye. Although they may detect unwholesomeness from obvious indications such as unpleasant odor or discoloration caused by spoilage microorganisms, consumers cannot assume products are safe in the absence of spoilage. They simply have no clear-cut way to determine whether the food they buy is safe to handle and eat.

When foodborne illness does occur, consumers often cannot correlate the symptoms they experience with a specific food because some pathogens do not cause illness until several days after exposure. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen and other hazard controls. The widespread lack of information about pathogen sources means that businesses at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product. An additional complication is that raw product is often fungible at early stages of the marketing chain. For example, beef from several slaughterhouses may be combined in a batch of hamburger delivered to a fast food chain. Painstaking investigation by public health officials in cases of widespread disease often fails to identify foodborne illness causes; in half the outbreaks the etiology is unknown.

Most markets in industrialized economies operate without close regulation of production processes in spite of consumers having limited technical or scientific knowledge about goods in commerce. Branded products and producer reputations often substitute for technical or scientific information and result in repeat purchases. Thus brand names and product reputations become valuable capital for producers.

In the U.S. food industry, nationally recognized brand names have historically provided significant motivation for manufacturers to ensure safe products. In recent years, more and more meat and poultry have come to be marketed under brand names.

Yet in the case of meat and poultry contaminated with pathogenic microorganisms, even brand name protection has not provided enough motivation for processors to produce the safest product they can make.

The failure of meat and poultry industry manufacturers to produce products with the lowest risk of pathogens and other hazards cannot be attributed to a lack of knowledge or appropriate technologies. The science and technology required to significantly reduce meat and poultry pathogens and other hazards is well established, readily available and commercially practical.

There are three main explanations for why a large portion of the meat and poultry industry has not taken full advantage of available science and technology to effectively control manufacturing processes.

1. Meat and poultry processing businesses are relatively easy to enter; there are no training or certification requirements for plant operators. Consequently, the level of scientific and technical knowledge of management in many plants is minimal.

2. The industry is very competitive and largely composed of small and medium-sized firms that have limited capital and small profits.

3. Management in many of these plants has little incentive to make capital improvements for product safety because they are not distinguishable by customers and therefore yield no income.

In spite of these barriers, many industry establishments do produce meat or poultry products using process controls that assure the lowest practical risk of pathogens and other hazards. But a significant part, particularly those producing raw products for consumers for further processing, do not.

FSIS has concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention to protect public health.

Regulating Pathogens

The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry

pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS judges to be unacceptable. A Federal regulatory program that reaches every level of meat and poultry production, processing, distribution and marketing is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP program is the only means of achieving this goal. Alternatives cannot achieve the reduction in pathogens necessary to assure the maximum reduction in food illness. To the extent that reductions in pathogen levels in meat and poultry can be achieved with current technology and without causing significant economic or social distortions, FSIS as a public health agency can support no alternative to HACCP.

The economic argument supporting HACCP is that its benefits to society outweigh the costs imposed by this proposal. Table 1 shows that in terms of the costs and benefits that can be quantified, HACCP implementation would generate considerable net benefits to society.

In addition, HACCP is supported by redistribution arguments that are based on widely accepted social values. Public health legislation itself clearly implies society's preference for having costs manifest themselves as regulatory or production costs rather than as costs associated with illness.

Even with demonstrated net benefits to society, it is important to keep the HACCP costs to industry down as much as possible to avoid unintended economic effects of HACCP implementation such as higher food prices or putting firms out of business. The use of systematic process control as reflected in the HACCP system would not require any establishment to change its production process, and the costs of monitoring a HACCP system are relatively small.

Thus, costs should have a minimal effect on the industry as a whole. Table 2 shows the increased cost per pound of product based on the estimated HACCP costs.

TABLE 2.—EFFECTS ON THE COST PER POUND OF MEAT AND POULTRY

Inspection program	1993 poundage* (billion)	Four-year estimated poundage (billion)	Near-term and HACCP implementation total costs (million)	Cost per pound
Total State and Federal	77.7	310.9	$733.5	$0.00236

*Poundage data is slaughter carcass weight for Federal and State establishments with 26 of 27 states reporting slaughter data.

A reduction in the incidence of foodborne illness is the principal performance goal for both USDA and industry. Mandatory HACCP implementation is projected to produce a direct reduction in foodborne illness with public health benefits estimated at $6.4–24.0 billion for 20 years (see Table 1). The Agency believes that these benefits clearly outweigh industry discounted costs of $2.3 billion associated with implementing and maintaining HACCP controls for 20 years.

III. Alternatives

A. Process Control Regulatory Strategy

FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination and control other hazards in food products and lower the risk of subsequent foodborne illness. Accordingly, a regulatory strategy has been formulated to mandate process control improvements to achieve immediate reductions and an eventual minimization of the risk of meat and poultry pathogens in the Nation's food supply. Chemical and physical hazards will also be prevented. This strategy is supported by consumers, scientists, and the majority of meat and poultry industry processors who already recognize the benefits of good process control.

Process control is a proactive strategy that all segments of industry can undertake to anticipate manufacturing problems in advance and prevent unsafe foods from ever being produced. In practice, process control is a systematic means to:

- identify and control production hazards;
- determine control points in the processing system;
- establish standard measures for each control point;
- set procedures for plant workers to monitor requirements;
- provide clear instructions for appropriate corrective actions when a control point goes out of control;
- establish record-keeping to document control point measurements; and
- provide procedures for product verification tests to ensure system continues to operate as planned.

The process control strategy summarized in this paper is founded on three principles:

1. USDA regulatory policy should be focused on providing a solution to meat and poultry biological, chemical and physical hazards that present the highest public health risks;

2. Pathogenic microorganisms—which present the greatest foodborne risk to human health—are now present in significant percentages of raw meat and poultry products; and

3. These pathogens and resulting risks of foodborne illness can be largely avoided by uniform meat and poultry industry efforts to attain and maintain more effective methods of control during the manufacturing process.

The focus of this strategy is explicitly on prevention; it is designed to prevent the production of defective product as opposed to more costly and less effective detect-and-condemn methods.

Process control is not a substitute for inspection any more than inspection could be a substitute for process control. This distinction is important because Federal inspection was never intended to be—and cannot be—the front-line control for food safety in meat and poultry processing plants. Safety controls must be built into the manufacturing process and be administered continuously by industry. The objective of inspection in a process control environment is to assure that those controls are present, adequate and are being used properly.

The primary benefits of a process control regulatory strategy are that it will: (1) Provide industry the tools and incentive to reduce meat and poultry pathogens as a means to improve food safety and (2) help reorient Federal inspection to better address product,

process and plant risks. A regulatory program that imposes better manufacturing process control methods as a means to reduce pathogen contamination and control other hazards emphasizes the fact that industry is primarily responsible for product safety while the Government's role is oversight.

B. Factors Considered in Evaluating A Process Control Strategy

The process control regulatory strategy was evaluated using five factors for effectiveness. A processing control program is effective if it:

1. Controls production safety hazards;
2. Reduces foodborne illness;
3. Makes inspection more effective;
4. Increases consumer confidence; and
5. Provides the opportunity for increased productivity.

The following sections discuss these five effectiveness factors that have been applied to evaluate process control alternatives.

Controls Production Safety Hazards

Process control is a system for identifying food hazards and reducing or eliminating the risks they present. In operation, control points are established in a food production line where potential health hazards exist; management of these points has proven to be effective in reducing the probability that unsafe product will be produced. Ongoing records of each process control will enable plant managers and quality control personnel to spot trends that could lead to problems and devise a strategy that prevents them before they occur.

Detection by end product testing is not a viable alternative to process control because it only sorts good product from bad and does not address the root cause of unacceptable foods.

Additionally, keeping ''bad'' foods out of commerce through sorting end product is possible only when tests and standards for sampling are well established and it is practical only where the ''test'' is not expensive because sorting requires a huge number of samples for reliability.

Reduces Foodborne Illness

As industry improves its control over the safety aspects of meat and poultry production, foodborne illness will begin to decline. This is the principal non-negotiable goal for both USDA and industry.

The precise occurrence of human health problems attributed to pathogenic microorganisms or other potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants is not known. Foodborne illness is nevertheless recognized by scientists around the world as a significant public health problem and there is wide agreement that pathogenic microorganisms are the major cause of food-related disease. The cost of foodborne illness related to meat and poultry products alone is between $4.5–7.5 billion annually.

Makes Inspection More Effective

Currently, FSIS inspectors in meat and poultry plants perform random inspection tasks that generate independent data about a plant's production processes and environment. This activity produces ''snapshots'' of plant operations at that moment. In contrast, process control generates records of plant performance over time. These records and periodic verification inspections will enable FSIS inspectors to see how a plant operates at all times, i.e., whether and where processing problems have occurred, and if so, how they were addressed.

The availability of more and better processing data will establish trends that set benchmarks from which deviations can be more quickly and accurately assessed. USDA inspectors will be trained to spot these deviations and take action when needed to ensure plants bring a faulty process back into control. This type of Federal oversight is substantially more effective than a regulatory program that merely detects and condemns faulty end products. In the words of the National Advisory Committee on Microbiological Criteria for Foods, ''Controlling, monitoring, and verifying processing systems are more effective than relying upon end-product testing to assure a safe product.''

Increases Consumer Confidence

The number of foodborne illness outbreaks and incidents attributable to pathogens in meat or poultry raise questions about whether federal inspection is as effective as it should be. Highly visible public controversies about meat and poultry inspection indicate an erosion of public confidence in the safety of meat and poultry products. There are growing demands that USDA improve its regulation of pathogens. The process control regulatory strategy described in this paper is USDA's response to those demands.

Many outbreaks of foodborne illness have been determined to be caused by mishandling of meat and poultry products after federally-inspected processing. USDA believes that additional efforts to reduce pathogens during manufacturing will reduce these risks as well. This, coupled with the improved retail regulatory controls from state adoption and enforcement of the Food and Drug Administration's Food Code should reduce this cause of illness.

A significant portion of the meat and poultry industry does not take advantage of readily available methods to control its manufacturing processes. This is due in large part to the fact that meat and poultry processing industries are relatively easy to enter and are composed largely of small and medium-sized firms. Managers in these firms are frequently not as knowledgeable about safe production practices as they should be.

The Department has concluded that further regulation will bring industry standards up to what can practically be achieved in the manufacture of meat and poultry products through current scientific knowledge and available process control techniques. Raising the safety floor through regulations that mandate better process controls will demonstrate to the public that USDA and industry are making a concerted effort to reduce the risk of foodborne illness from meat and poultry.

The economic benefits of increased consumer confidence can be conceptually realized in the amount consumers would be willing to pay for safer food. This overall 'willingness to pay' is made up of several components. It reflects consumer desires to avoid foodborne illness and the expected medical and other costs associated with pathogens. In theory the total benefit associated with processing control regulations could be decomposed into two parts: first, the reduction in medical and other costs associated with pathogen-related illnesses (as discussed in a previous section), and the additional benefits which accrue to consumers not made ill but who may place a value on reduced risk of exposure to pathogens. At this time, the data are not available to make quantitative estimates of the consumer's willingness to pay.

Provides the Opportunity for Increased Productivity

Better process control is a sound and rational investment in the future of our nation's meat and poultry industry. USDA's process control strategy will educate industry management about the need and methodology for development of a consistent, preventive, problem-solving approach to safety hazards, which can be expanded to other business objectives such as product

quality and production efficiency. There is much evidence of how process control has improved worldwide industrial productivity in the past 40 years. This proposal will extend process control principles to parts of the meat and poultry industry that have not formerly used them.

Some important non-safety benefits that will accrue from industry use of better process control methods are:

- First, better production controls will result in more efficient processing operations overall with fewer product defects. Fewer defects mean less reworking, waste and give-away, resulting in increased yields and more profit opportunities.
- Second, better controls will significantly reduce the risk to processors that product with food safety defects will slip into commerce. Expensive and embarrassing product recalls can be entirely avoided with proper process controls.
- Third, better control of pathogens will impact all microorganisms, including those responsible for decomposition, resulting in quality improvements and longer shelf life for products.
- Fourth, better production controls improve plant employee productivity which improves profit opportunities.

C. Evaluation of Mandatory HACCP to Provide Process Control

Considering the five effectiveness factors of process control, the most effective means for ensuring that all industry uses adequate process control systems is a mandatory HACCP regulatory program. This alternative clearly meets all five criteria described above. In fact, a mandatory HACCP program was judged to be the only option that will effect adequate processing improvements in all establishments throughout the industry. Only through mandatory HACCP can pathogen risks be minimized to the fullest extent possible; thereby reducing foodborne illness to the maximum, improving effectiveness of inspection, increasing consumer confidence, and ensuring a more viable industry. No other alternative accomplishes as much in these five areas as mandatory HACCP.

In summary, FSIS has determined that:

- HACCP is a processing control strategy that has been scientifically proven effective in food manufacturing plants; and, therefore
- Mandating HACCP systems in all plants under USDA jurisdiction will protect the public from unreasonable risks due to meat and poultry consumption.

HACCP is widely recognized by scientific authorities such as the National Academy of Sciences and international organizations such as the Codex Alimentarius. It is used today by a number of plants in the food industry to produce consistently safe products. This approach has been supported for years by numerous groups that have studied USDA meat and poultry regulatory activities.

In 1983 FSIS asked the National Academy of Sciences to evaluate the scientific basis of its inspection system and recommend a modernization agenda. The resulting report, issued in 1985, was the first comprehensive evaluation of a scientific basis for inspection. The 1985 NAS report provided a blueprint for change: it recommended that FSIS focus on pathogenic microorganisms and require that *all* official establishments operate under a HACCP system to control pathogens and other safety hazards.

After urging the intensification of ''current efforts to control and eliminate contamination with micro-organisms that cause disease in humans,'' NAS encouraged USDA to ''move as vigorously as possible in the application of the HACCP concept to each and every step in plant operations of all types of enterprises involved in the production, processing, and storage of meat and poultry products.''

The General Accounting Office (GAO) has also identified needed improvements in USDA's present inspection system. In its reports and congressional testimony, and in numerous publications, GAO has endorsed HACCP as the most scientific system available to protect consumers from foodborne illness. This sentiment is most clearly expressed in a May 1994 report, ''Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry,'' in which GAO recommended development of a mandatory HACCP program that includes microbial testing guidelines. GAO urged USDA to assist meat and poultry plants in the development of their microbial testing programs by, among other things, disseminating information on the programs already in operation.

A third major proponent of HACCP is the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established in 1988 by the Secretary of Agriculture to advise and provide recommendations to the Secretaries of Agriculture and of Health and Human Services on developing microbiological criteria to assess food safety and wholesomeness. Since 1989 NACMCF has prepared a series of reports on the development and implementation of HACCP. As one of its first tasks, the Committee developed ''HACCP Principles for Food Production'' in November 1989. In this report, the Committee endorsed HACCP as a rational approach to ensure food safety and set forth principles to standardize the technique. In 1992, the Committee issued an updated guide, ''Hazard Analysis and Critical Control Point System.''

In 1993 NACMCF defined the roles of regulatory agencies and industry in implementing HACCP. ''The Role of Regulatory Agencies and Industry in HACCP'' proposed responsibilities for FDA, USDA, and other agencies and industry during various phases of HACCP implementation. Similar suggestions for program change have been voiced by consumers, industry, state and local government representatives, as well as other constituent groups. For example, consumers at recent public hearings and the HACCP Round Table supported implementation of mandatory HACCP throughout the meat and poultry industry.

The meat and poultry industry has itself provided broad support for HACCP as a means to control pathogens, emphasizing that HACCP-based food production, distribution, and preparation can do more to protect public health than any Federal inspection program. They have recommended that HACCP be used to anticipate microbiological hazards in food systems and to identify risks in new and traditional products. State departments of health and agriculture have also endorsed the HACCP approach.

D. Evaluation of Other Alternatives

FSIS examined six other approaches before determining that mandatory HACCP was the most effective means for industry to eliminate pathogens in meat and poultry:

1. Status quo;
2. Intensify present inspection;
3. Voluntary HACCP regulatory program;
4. Mandatory HACCP regulation with exemption for very small establishments;
5. Mandatory HACCP regulation only for ready-to-eat products; and
6. Modified HACCP—recording deviations and responses only.

These alternatives were assessed using the five effectiveness factors presented in the previous section. Since

FSIS's goal is to achieve the maximum pathogen reduction possible, and none is judged to be as effective as mandatory HACCP, the costs of these alternatives are not relevant. The following six sections summarize the appraisal of each alternative.

Status Quo

This option would essentially continue plant processing controls and Federal inspection as they are now. Good plants with adequate methods for managing process lines would probably remain under control. The Agency, under its present authority, cannot shift resources out of good plants so the situation of poor performing plants is unlikely to change. This situation raises immediate questions about the first factor—controls production safety hazards—being met. Experience has proven that Federal inspection cannot substitute for management in establishments which have difficulty producing safe product consistently. Also, inspection cannot be as effective in the current plant environment as in a process control plant environment.

Status quo does not target industry and inspection resources at preventing hazards in areas of highest risk which leads to the greatest reduction in foodborne illness (factor two). In addition, food safety experts, consumers, and other observers have told USDA they are not satisfied with pathogen control by organoleptic methods as practiced in the present plant program. Doing nothing new would perpetuate consumer doubts about the ability of Federal inspection to regulate pathogens which is counter to factor four. Consequently, the Department has concluded that business as usual is not an acceptable response to proven problems with pathogens associated with meat and poultry products. Agency public health responsibilities alone require that more positive actions be taken.

Intensify Present Inspection

As one alternative to the proposed mandatory HACCP regulation, FSIS could intensify its present inspection system i.e., focus new resources on suspected areas of risk in each plant. This approach would assign to FSIS responsibility for designing, testing and mandating by specific regulation, process control systems for all meat and poultry products with potential safety hazards. A major flaw with this approach is the burden of ensuring a safe product would be placed largely on FSIS instead of plant managers where it belongs. Plant management would have little motivation to become knowledgeable about process control or to implement process control systems.

Agency experience with mandating specific requirements has sometimes succeeded, where HACCP-like regulations have been successful in correcting food safety problems in certain ready-to-eat products. However, these controls largely consisted of lethal heat treatments applied during final product processing. This approach is obviously inappropriate for product that is marketed raw which is most frequently associated with meat and poultry foodborne illness.

Thus, intensified regular inspection fails to meet the primary criterion for process control, i.e., control production safety hazards at all stages of meat and poultry slaughter and processing. Related to this failing, inspection would be ineffective without all plants maintaining process control systems (factor three.) This option would require significant resource increases and results in more of the same type of Federal oversight which would be more costly to taxpayers without the payback of significant reductions in foodborne illness (factor two). With the burden of control and monitoring on USDA's inspection force rather than plant managers, industry performance would be unlikely to improve. Industry growth would be less certain which is counter to meeting factor five.

Voluntary HACCP Regulatory Program

A voluntary HACCP program would not provide reduction of pathogens uniformly across the processing spectrum (i.e., many in industry would choose not to participate) and therefore would not be sufficient to attain the necessary reduction in foodborne illness (factor two).

Voluntary HACCP would be implemented most frequently in plants with good processing controls already, while plants with unsophisticated controls would be less likely to participate. The explanation for this flaw is to be found in simple economics and, to a large degree, the attitudes of plant management. Plants with good processing controls now are most likely to adopt HACCP voluntarily because their management understands the linkage between how a product is handled during preparation and its finished quality and safety.

Conversely, plants without good processing controls today are much less likely to participate in a voluntary HACCP program. These plants are more often operated by management that lacks the knowledge or motivation to institute better processing controls. Nevertheless, it is precisely this group of low performing plants that FSIS must reach to attain its public health goal. Nothing short of a mandatory HACCP regulatory program will be effective in bringing processing improvements to these marginal performers.

The Agency's regulation permitting the use of voluntary Total Quality Control (TQC) Systems provides a useful analogy to how effective a voluntary HACCP program would be. TQC focuses on establishment responsibility for meeting or exceeding the standards set by FSIS for all operations that are conducted in a plant, including incoming raw materials, processing procedures, critical limits for product standards, and action limits for establishment quality control personnel. These systems operate under Agency oversight with an emphasis on timely and accurate record-keeping and the necessity for appropriate action to be taken by an establishment when a limit set forth in an approved system is met or exceeded. However, over the last 10 years the number of plants with active TQC Systems has declined from a high of around 500 (approximately 8% of all plants) to the present 351 participating plants (approximately 5% of all plants). USDA experience has shown that a voluntary approach to HACCP would provide little assurance that a major portion of meat and poultry products had been produced under controls designed to minimize food safety hazards.

Mandatory HACCP Regulation With Exemption for Small Establishments

Under this alternative, FSIS would mandate HACCP; but, provide an exemption for small establishments as was done with nutrition labeling. However, since major goals in implementing HACCP are to improve processing controls and plant performance across all of industry (factor one) as a means to achieve foodborne illness reductions (factor two), this option is inherently flawed by exemption of plants that perform the least process control. USDA inspection experience shows that some of the small establishments which would be exempted under this option have particular difficulties maintaining control over their processing system.

While it is true that small establishments produce a minimal amount of the total meat and poultry supply, they do produce a full range of products, including those most frequently associated with foodborne illness from the meat and poultry supply.

This option also fails on factor three—provide more effective inspection. Two

different inspection systems would be needed: one risk-based system to inspect HACCP plants with good processing controls; the other to provide resource intensive coverage for plants that largely do not. If the number of small plants continues to increase, more inspection resources would be required.

Mandatory HACCP Regulation Only for Ready-to-Eat Products

This option would mandate HACCP only for establishments that prepare ready-to-eat meat and poultry products, but not for plants that produce raw products. However, this decision would leave the public without adequate protection from pathogenic microorganisms clearly associated with product marketed in raw form. Very little reduction in the most frequent causes of foodborne illness (factor two) could be anticipated from this approach.

Government inspection costs would continue to increase to provide traditional resource-intensive inspection for slaughtering and allied processing plants that would not be subject to mandatory HACCP. Since most of the unsolved problems with pathogenic microorganisms are associated with raw products, not on those which would be the subject of this HACCP option, this is an especially inappropriate regulatory approach.

Modified HACCP—Only Recording Deviations and Responses

A final alternative considered would be to mandate HACCP, modified to eliminate the recordkeeping burden to the inspected industry, especially small establishments. Specifically, this option would modify the HACCP record-keeping principle so that instead of demanding continuous records at critical control points, companies would need to record only deviations from critical limits and the response to them. This would mean that HACCP-controlled operations would not generate continuous monitoring data to reflect the operation at critical control points, but would only record data when deviations occurred. This arrangement eliminates the continuous picture of plant operations which is the underpinning of factor three—make inspection more effective.

Such an approach would substantially reduce the paperwork burdens associated with mandatory HACCP as recommended by NACMCF and recognized by CODEX. However, it would also seriously compromise the usefulness of HACCP as a means to make inspection more effective and avoid program cost increases. Regulatory officials need to have a system which can be reviewed in its entirety, so that a comprehensive picture of the process is available, not just the truncated version which grows out of recording deviations.

IV. HACCP Benefits—Foodborne Illness

A. Incidence of Foodborne Illness in the United States

The safety of the meat and poultry supply has been widely discussed during the past few years. Precise data on the incidence of illness associated with meat and poultry or other food products are lacking. There is no mandatory reporting system for such illnesses and there is no complete national database on the occurrence of human health problems that might be attributed to pathogenic microorganisms or potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants. Foodborne illness is nevertheless recognized by scientists as a significant public health problem in the United States, and there is wide agreement among scientists that pathogenic microorganisms are the primary cause of foodborne illness. The following discussion focuses on pathogenic microorganisms.

Foodborne illness can strike individuals of all ages, sexes, nationalities and socioeconomic levels. People have been getting sick from foods throughout the ages; the reasons change but the problem persists. The most common types of foodborne illness typically appear as acute gastroenteritis with sudden onset of vomiting or diarrhea, or both, with accompanying abdominal pain. Some episodes include fever, prostration, shock, or neurological symptoms. The incubation period, i.e., the time between eating and onset of first symptom, as well as the type and duration of symptoms can vary from a few hours to several days, depending on the etiological agent, the infected individual's genetic predisposition and physical condition. In a percentage of the population—especially among children, the elderly, and immuno-compromised individuals—foodborne illness can be life-threatening.

Researchers estimate that between 6 and 33 million people, (between 3 and 14 percent of the population) become ill each year from pathogenic microorganisms in their food. An estimated 6,000 to 9,000 of these illnesses annually result in death. Other data show at least 18 million cases of diarrheal disease of foodborne origin occur in the United States annually; another several million persons may be affected by secondary person-to-person spread of infectious agents from cases caused by consumption of pathogen-contaminated food.

Foods contaminated with pathogenic microorganisms can lead to infection and illness in two major ways. The first is by direct consumption of the contaminated food under conditions that allow the survival of the pathogen or its toxin, such as when a meat or poultry product is consumed raw or undercooked. The second way contaminated product can lead to illness is through cross-contamination in the processing plant (e.g. cooked product), kitchen or other food-handling area, such as when the *Salmonella*-contaminated exterior of raw chicken contaminates a cutting board, countertop, or kitchen utensil, which then comes into contact with cooked product or foods consumed raw, such as salad. For some pathogens, such as *Salmonella,* more cases of illness result from cross-contamination than from direct consumption of undercooked product. Poor hygiene by infected food handlers, plant employees, etc, can also introduce pathogens which later cause illness.

Foodborne illness appears to have remained steady or increased slightly during the last decade. Possible increases in foodborne illness are variously attributed to changes in animal production procedures, automated processing, increased reliance on fast foods, greater use of prepackaged foods and microwave ovens, extended shelf-lives, more complex distribution systems, urbanization, public naivete about food manufacturing methods, and lack of knowledge about the hygienic precautions required at all stages of food handling, including preparation and serving. Other factors contributing to reported increases may include better surveillance, improved reporting, more sensitive diagnostic tests, emerging pathogens, and improved methods of detecting pathogens and chemical residues.

Data for evaluating trends and the most common causes of foodborne illness are compiled by the Centers for Disease Control and Prevention (CDC), based on reported ''outbreaks'' of illness, discussed below.

Estimates of the current foodborne disease burden in the United States are based on estimates of the annual incidence of disease. Incidence estimates are the annual estimates of the new cases of foodborne disease which occur each year. CDC compiles reports from State and local health authorities of foodborne illness outbreaks where

two or more persons have become ill from a common source. These reported cases are only a fraction of the actual annual incidence of foodborne disease cases for many reasons:

- Symptoms typical of several forms of foodborne illness include diarrhea, vomiting, abdominal pain, and physical weakness. These symptoms are also common to a wide variety of bacterial and viral infections not generally associated with food consumption. Consequently, many treated cases of foodborne illness are generically diagnosed as non-specific gastroenteritis or ''the flu'' and not identified as being caused by a specific foodborne pathogen.
- Most foodborne illness is transitory and self-limiting. People often become sick within a few hours after consumption of contaminated food, suffer acute symptoms, and recover spontaneously. These people are unlikely to seek medical attention, and will not become part of the reporting database.
- While some foodborne pathogens cause illness within a few hours of food consumption (*Staphylococcus aureus* and *Salmonella*), many common pathogens cause illness after a lag of several days (*E. coli* O157:H7 and *Campylobacter*) or weeks (*Listeria monocytogenes*). The longer the lag between consumption and illness, the less likely the connection to food will be made.
- Individual cases of foodborne illness are excluded from the CDC reporting system, except for botulism, toxic fish, mushrooms, and certain chemical poisonings where one case constitutes an outbreak.
- Around half of CDC's reported outbreaks and cases are never identified with a causative pathogen.
- CDC primarily relies upon voluntary reporting from State and local health agencies which, in turn, rely on hospitals, clinics, and individual health care professionals for information. All these institutions have resource limitations and different disease reporting requirements. For example, 12 States have no surveillance staff assigned to monitor foodborne diseases.

For the 4 foodborne pathogens of greatest concern, the case and severity estimates presented here are the ''best estimates'' of the actual incidence of foodborne disease associated with specific pathogens, rather than the fraction of cases actually reported to CDC. Many of the ''best estimates'' were developed by the landmark CDC study by Bennett, Holmberg, Rogers, and Solomon, published in 1987, which used CDC surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence and case-fatality ratio for all infectious and parasitic diseases, and identified 17 as foodborne pathogens. All the estimates of bacterial foodborne disease cases in Table 3 are based on CDC data to estimate actual cases of foodborne disease caused by each pathogen. (The estimated cases for the parasitic disease, congenital toxoplasmosis, are based on various reports in the medical literature.)

TABLE 3.—REFERENCE SOURCES OF DATA FOR SELECTED HUMAN PATHOGENS, 1993

Pathogen	Foodborne illness cases (#)	Source(s) for case estimates
Bacteria:		
Campylobacter jejuni or coli	1,375,000–1,750,000	Tauxe; Tauxe et al.
Clostridium perfringens	10,000	Bennett et al.
Escherichia coli O157:H7	8,000–16,000	AGA Conference.
Listeria monocytogenes	1,616–1,674	Roberts and Pinner; Schuchat.
Salmonella	732,000–3,660,000	Helmick et al.; Bennett et al.; Tauxe & Blake.
Staphylococcus aureus	1,513,000	Bennett et al.
Parasite:		
Toxoplasma gondii	2056	Roberts, Murrell, and Marks.

Sources: American Gastroenterological Association Consensus Conference on *E. coli* O157:H7, Washington, DC, July 11–13, 1994.

Bennett, J.V., S.D. Holmberg, M.F. Rogers, and S.L. Solomon. 1987. ''Infectious and Parasitic Diseases,'' In R.W. Amler and H.B. Dull (Eds.) *Closing the Gap: The Burden of Unnecessary Illness.* Oxford University Press, New York.

Helmick, C.G., P.M. Griffin, D.G. Addiss, R.V. Tauxe, and D.D. Juranek. 1994. ''Infectious Diarrheas.'' In: Everheart, JE, ed. *Digestive Diseases in the United States: Epidemiology and Impact.*

USDHHS, NIH, NIDDKD, NIH Pub. No. 94–1447, pp. 85–123, Wash, DC: USGPO.

Roberts, T., K.D. Murrell, and S. Marks. 1944. ''Economic Losses Caused by Foodborne Parasitic Diseases,'' *Parasitology Today.* vol. 10, no. 11: 419–423.

Roberts, T. and R. Pinner. ''Economic Impact of Disease Caused by *Listeria monocytogenes*'' in *Foodborne Listeriosis* ed. by A.J. Miller, J.L. Smith, and G.A. Somkuti. Elsevier Science: Amsterdam, The Netherlands, 1990, pp. 137–149.

Schuchat, Anne, CDC, personal communication with T. Roberts at the FDA Science Forum on Regulatory Sciences, Washington, DC, September 29, 1994.

Tauxe, R.V., ''Epidemiology of *Campylobacter jejuni* infections in the United States and other Industrialized Nations.'' In Nachamkin, Blaser, Tompkins, ed. *Campylobacter jejuni: Current Status and Future Trends,* 1994, chapter 2, pages 9–19.

Tauxe, R.V. and P.A. Blake, Salmonellosis. Chap. 12. In: Public Health & Preventive Medicine. 13th ed. (Eds: Last JM; Wallace RB; Barrett-Conner E) Appleton & Lange, Norwalk, Connecticut, 266–268.

Tauxe, R.V., N. Hargrett-Bean, C.M. Patton, and I.K. Wachsmuth, 1988, ''Campylobacter Isolates in the United States, 1982–1986,'' *Morbidity and Mortality Weekly Report,* vol. 31, no. 88–2.

Data collected by CDC also show food source for foodborne illness. Food products of all types, including beef, pork, turkey, chicken, bakery products, dairy products, eggs, finfish, shellfish, ice cream, mushrooms, fruits and vegetables, are associated with foodborne illness. Among foodborne illness outbreaks reported to CDC, the majority of those which can be identified are traced to pathogenic bacteria. The six target pathogens account for nearly all meat and poultry foodborne illness outbreaks and about 75% of total reported outbreaks caused by a bacterial agent.

B. Costs of Foodborne Illness

Table 4 shows the estimated cost of all foodborne illness to be approximately $5.6–9.4 billion in 1993.

Meat and poultry products are associated with approximately $4.5–7.5 billion and the remaining $1.1–1.9 billion is associated with non-meat and poultry sources.

TABLE 4.—Foodborne Illness Costs and HACCP Benefits, 1993

Food source	Foodborne illness	
	Costs billions)	Benefits (billions)
All Foods	$5.6–9.4	
Non-meat and Poultry	$1.1–1.9	
Meat and Poultry Only	$4.5–7.5	
Meat and Poultry Parasitic Pathogens	$2.7	
Meat and Poultry Bacterial Pathogens	$1.8–4.8	
USDA Target Bacterial Pathogens	$1.1–4.1	
Campylobacter jejuni/coli—.5–.8		
E. coli 0157:H7—.2–.5		
Listeria monocytogenes—.1–.2		
Salmonella—.3–2.6		
Reduction of USDA target pathogens attributed to HACCP (90%)	.....	.99–3.7

Source: Economic Research Service and Centers for Disease Control and Prevention.

The proposed HACCP system is designed to control all of the public health hazards identified in each meat and poultry establishment. FSIS regulation currently and under HACCP will address all public health hazards. Table 5 shows the bacterial pathogens largely responsible for meat and poultry illnesses.

The proposed near-term requirements and significant parts of HACCP will target pathogen reduction on carcasses and raw product, currently the least systematically controlled hazard. This is the most effective overall approach for reducing pathogen contamination. The benefits are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli 0157:H7, Salmonella* and one environmental pathogen Listeria monocytogenes. The reduction of these pathogens to as near to zero as possible in meat and poultry during slaughter and processing would produce an estimated 90% reduction in the foodborne illness attributed to these microbial pathogens. The remaining 10% are due to causes not affected by the proposed regulations because contamination also occurs after product leaves the inspected plant. (The estimated reduction is based on the expert judgement of FSIS microbiologists.) This would result in a $.99–3.69 billion saving annually, as shown in Table 4.

Two other pathogens—*Clostridium perfringens* and *Staphylococcus aureus*—primarily enter meat and poultry foods in restaurants, other commercial kitchens and in homes. Consequently, the proposed regulatory program, which focuses on federally inspected processing, will not significantly affect the incidence of disease caused by these organisms. It is expected, however, that the FDA's Food Code will dramatically reduce the cause of illness attributable to retail practices upon its adoption and implementation. Our continued consumer education activities coupled with safe handling labels should significantly impact practices in the home.

The costs described in this section for foodborne illness costs are borne not only by those who become ill, but by their families, and employers; the food industries; and taxpayers. Costs to stricken individuals include medical bills, time lost from work, pain, and inconvenience. Food industry costs include product recalls, loss of plant production due to closings for cleanup, and higher premiums for product liability insurance. Perhaps most costly to industry in the long-term is loss of product reputation and reduced demand when an outbreak is traced back and publicized. These and other ''defensive'' industry costs of foodborne disease run in the millions of dollars annually and are, for the most part, entirely avoidable. Taxpayer costs include medical treatment for those who cannot afford it, including higher health insurance premiums and costs of public assistance to disabled individuals and their dependents.

Table 5.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993

Pathogen	Foodborne illness cases (#)	Foodborne* costs (bil. $)	Percent from meat/poultry (%)	Total costs* meat/poultry (bil. $)
Bacteria:				
Campylobacter jejuni or coli	1,375,000–1,750,000	0.6–1.0	75	0.5–0.8
Clostridium perfringens**	10,000	0.1	50	0.1
Escherichia coli O157:H7	8,000–16,000	0.2–0.6	75	0.2–0.5
Listeria monocytogenes	1,616–1,674	0.2–0.3	50	0.1–0.2
Salmonella	732,000–3,660,000	0.6–3.5	50–75	0.3–2.6
Staphylococcus aureus**	1,513,000	1.2	50	0.6
Subtotal	3,639,616–6,950,674	2.9–6.7	N/A	1.8–4.8
Parasite:				
Toxoplasma gondii	2,056	2.7	100	2.7

Table 5.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED HUMAN PATHOGENS, 1993—Continued

Pathogen	Foodborne illness cases (#)	Foodborne* costs (bil. $)	Percent from meat/ poultry (%)	Total costs* meat/poultry (bil. $)
Total	3,641,672–6,952,730	5.6–9.4	N/A	4.5–7.5

Source: Economic Research Service and Centers for Disease Control and Prevention, 1993.
*Column rounded to one decimal place.
**Roberts' rough approximation of costs in ''Human Illness Costs of Foodborne Bacteria'', *Amer. J. of Agricultural Economics,* vol. 71, no. 2 (May 1989) pp. 468–474 were updated to 1993 dollars using the Consumer Price Index (all items, annual average). Cost estimates for other pathogens are more detailed, see the following for a discussion of the methodology: listeriosis—Roberts, Tanya and Robert Pinner, ''Economic Impact of Disease Caused by *Listeria monocytogenes*'' in *Foodborne Listeriosis* ed. by A.J. Miller, J.L. Smith, and G.A. Somkuti. Elsevier Science: Amsterdam, The Netherlands, 1990, pp. 137–149, *E. coli* O157:H7—Roberts, T. and Marks, S., ''*E. coli* O157:H7 Ranks as the Fourth Most Costly Foodborne Disease,'' *FoodReview,* USDA/ERS, Sept-Dec 1993, pp. 51–59, salmonellosis—Roberts, Tanya, ''Salmonellosis Control: Estimated Economic Costs,'' *Poultry Science.* Vol. 67 (June 1988) pp. 936–943, campylobacteriosis—Morrison, Rosanna Mentzer, Tanya Roberts, and Lawrence Witucki, ''Irradiation of U.S. Poultry—Benefits, Costs, and Export Potential, *FoodReview,* Vol. 15, No. 3, October-December 1992, pp. 16–21, congenital toxoplasmosis—Roberts, T., K.D. Murrell, and S. Marks. 1944. ''Economic Losses Caused by Foodborne Parasitic Diseases,'' *Parasitology Today.* vol. 10, no. 11: 419–423; and Roberts, Tanya and J.K. Frenkel, ''Estimating Income Losses and Other Preventable Costs Caused by Congenital Toxoplasmosis in People in the United States,'' *J. of the Amer. Veterinary Medical Assoc.,* vol. 196, no. 2 (January 15, 1990) pages 249–256.
N/A indicates item is not-applicable.

Other taxpayer costs include public health sector expenses to operate a disease surveillance system and to investigate and eliminate disease outbreaks. Approximately $300 million is spent for this annually by the Federal public health sector. Government costs in the United States, Canada, and other countries, average about $200,000 per foodborne illness outbreak.

Cost Computation Methodology

The costs of foodborne disease associated with meat and poultry pathogens were estimated using a traditional ''cost of illness'' method which includes medical costs, productivity losses, and special educational or residential care associated with some chronic conditions. Disease frequencies reflect CDC's ''best estimate'' of the actual number of foodborne illness cases each year.

The present value of lifetime medical costs for those becoming ill in 1993 was estimated using nationwide databases, such as published Medicare reimbursement rates and per-capita expenditures on physicians' services from the Health Care Financing Administration, the National Center for Health Statistics' National Hospital Discharge Survey, the American Hospital Association's Hospital Statistics, or Blue Cross/Blue Shield charges. The average cost to community hospital per patient was used to compute hospitalization costs.

Productivity losses occur because workers are ill and miss work. These have been approximated by the Average Weekly Earnings for non supervisory production workers in private nonagricultural jobs, published by the Bureau of Labor Statistics (BLS) of the U.S. Department of Labor, plus estimated fringe benefits. For illness in subsequent years, a present value of the reduced stream of earnings is calculated. For deaths, Landefeld and Seskin's human capital/willingness to pay method was used. It combines elements of both methods to generate the present value of expected lifetime after-tax income and housekeeping services at a 3-percent real rate of return, adjusted for an annual 1-percent increase in labor productivity and a risk-aversion premium that increases the estimates by 60 percent.

These cost estimates are based on the annual incidence of disease, rather than the prevalence, to help us estimate *preventable* illness. Incidence estimates are the annual increase in cases and associated disease costs. Interventions today which prevent future costs will eliminate all the medical, productivity, and special care costs of prevented cases, and so represents one component of the overall economic benefit of disease prevention.

C. The Relationship Between Foodborne Illness and Consumer Knowledge and Behavior

The National Academy of Science's *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C)* (1990) repeated the theme of numerous other studies, stating ''. . . the public expects the government to ensure zero risk of meat-borne disease through inspection. The [NAS] committee heard little evidence that the public is aware that some bacterial contamination of raw meat is inevitable and no mention of the crucial role of food handling, preparation, and serving methods in limiting foodborne diseases.'' The disturbing but real fact that consumers fail to make a connection between their food handling behavior and safe food recurs throughout the literature on the subject.

Behavioral research shows that food habits are the most difficult of all forms of human behavior to change. This finding is supported by research of consumer knowledge and practices, which indicate that a large portion of the U.S. population lacks basic food safety information and skills and engages in food handling and preparation practices that epidemiological studies have linked with a significant number of foodborne illness outbreaks. Moreover, little correlation exists between consumers' food safety knowledge and their food handling and preparation practices. Even people who characterize themselves as ''knowledgeable'' do not necessarily follow good food safety procedures. The CDC estimates that 20–30 percent of foodborne illness is due in part to consumer mishandling of food.

Available evidence concerning consumer behavior related to safe food handling and preparation supports the need for a comprehensive pathogen reduction effort. Food safety can best be assured by establishing a ''chain of responsibility,'' with each participant in the food system, from the producer all the way through to the consumer—understanding, accepting, and acting on its responsibility for food safety. While FSIS will pursue and support all possible means of consumer education and outreach, the Agency realizes that consumer education alone will not control pathogen-related foodborne illness. This is even more true today than ever before, as more people in our society are assuming responsibility for food handling and preparation in the home and elsewhere, without

experience in food preparation and knowledge of safe food handling and storage methods. These people include:

- Food service workers, many of whom receive inadequate training, are part-time and teenagers, who experience high-turnover;
- Men and women in the workplace, who have minimal time for food preparation and often little experience or interest in food preparation;
- Children, who are increasingly expected to shop and prepare their own meals;
- Immigrants, who might not be able to read food handling instructions, or whose cultural practices include eating raw or very rare meat and poultry products. Other vulnerable sectors of the population, more severely affected by foodborne illness, are also increasing in size;
- Immunocompromised persons (i.e., persons with diabetes, cancer, chronic intestinal diseases, organ transplants, and AIDS);
- Persons 65 years and older—a growing proportion of the population—who, due to the normal decline in immune response, are at increased risk.

In 1993, to increase awareness about pathogens, FSIS promulgated a regulation requiring safe handling labels on most raw meat and poultry products. The Agency's Meat and Poultry Hotline provides consumers with immediate responses to questions about food handling and safety. These steps are important but they are not a substitute for building into the food production and regulatory system measures to reduce to the maximum extent possible the presence of microbial pathogens in meat and poultry products purchased by U.S. consumers.

V. Costs Associated With HACCP

This section details the costs to the meat and poultry industry of the proposed measures to control pathogenic microorganisms and other biological, physical and chemical hazards. Unless otherwise stated, the figures used are three-year undiscounted costs. They have been estimated for:

- Four near-term initiatives that could be implemented shortly after promulgation of a final rule. These include the creation of Standard Operating Procedures (SOPs) for sanitation and three pathogen reduction and control interventions: antimicrobial treatment of carcasses, microbiological testing, and time and temperature requirements for all raw product received, held, and shipped by inspected establishments.
- The longer-term Hazard Analysis and Critical Control Point (HACCP) systems developed by establishments would be phased in over an approximate three-year period after the final rule is promulgated.

Total cost of the near-term initiatives and the three-year HACCP implementation is estimated at $733.5 million. This includes $552.8 million for federally inspected establishments and $180.7 million for State establishments. The costs for small establishments, which make up about a third of the total establishments, are estimated at $330.6 million, or just under 45 percent of the total. The Agency recognizes the problem these costs could present to small firms and has requested in the proposal public comments that will help it make appropriate adjustments to modify this burden.

A. Cost Analysis Procedures

In estimating the costs of the proposed rule, FSIS used data generated by various Agency operational and research components such as Total Quality Control (TQC), Partial Quality Control (PQC), and the various Baseline Microbiological Surveys. An especially important source was the cost information from the HACCP Pilot Program conducted from 1991 to 1993. The cost analysis also relied heavily on four of the Agency's main databases.

New databases were created by merging selected variables from the four FSIS databases and enhancing them with additional economic and financial data. The Enhanced Economic Analysis Database contains information on each of the slaughter and processing establishments active as of August 1994.

Described below as a prelude to the sections containing the estimated near-term and long-term costs are the assumptions, criteria, and other factors underlying or used in this cost analysis. Details of cost methodology and estimations are available in an appendix.

1. Number of Establishments

There are 6,186 Federal slaughter, processing, and combination (performing both slaughter and processing operations) establishments. An additional 2,893 establishments fall under State inspection. For some cost analysis purposes, combination establishments (performing both slaughter and processing) were counted as two separate plants.

2. Establishment Size

For its cost analysis, FSIS defines a small establishment as one with less than $2.5 million in annual sales. (This definition does not coincide with the Small Business Association definition for a small business.) Using the FSIS criterion, 42.2 percent of processing plants (Federal and State) and 16.8 percent of slaughter plants would be considered small establishments. A medium establishment is defined as one with annual sales of more than $2.5 million and less than $50 million. A large establishment is one whose sales are greater than $50 million per year.

State establishments are all considered to be small establishments. Since figures on these plants' sales volumes were not available, the size determination was based on amount of production, which was below the average for Federal establishments with sales less than $2.5 million. FSIS invites comments on the State classifications.

3. Process Categories

In keeping with the process control principles inherent in HACCP, FSIS identified 14 process categories (see Table 6 at the end of this section.) There is a separate category for each of the nine actual slaughter and processing processes and for each of the five species slaughtered. FSIS believes the 14 categories encompass all the products of the regulated industry. Every plant must develop a HACCP plan for each applicable category. The estimated costs for plan development are based on the total number of processes in all plants.

4. Implementation Schedule

FSIS plans that the final rule will become effective. The near-term initiatives would go into effect three months after it is published in the **Federal Register** and remain in effect in each plant until that plant's HACCP program begins (except for the sanitation SOP's, which will continue with HACCP). HACCP implementation would be phased in by process over three years, from date of final rule promulgation, with each process category assigned a slot in that time frame when its HACCP plan would be implemented. Small plants would have the option of implementing the plans for all their processes three years from promulgation instead of implementing plans for individual processes according to the time frame for medium and large plants.

5. Compliance

Some establishments may find that their present process(es) cannot consistently produce product that meets the specified interim target. This target, although a new ''measure'' of safety, is

based on levels currently achieved by many industry plants and is considered by the Agency to represent the current acceptable level of safety. An establishment whose product does not meet the target under the proposed requirements must, as it must do under current regulations, take action to adjust its process to produce product that meets this standard. The cost of taking this action is not considered a cost of the proposed requirement.

6. Equipment and Materials

The proposed rule does not make any existing equipment obsolete. (Some modification may be necessary, however, such as increasing cooling capacity for complying with the time-and-temperature requirements.) The proposal does require establishments to systematically monitor their processes. Costs of the necessary materials, such as thermometers and test kits, are estimated at $10 to $20 per establishment.

7. Wages

The hourly wage rates used in estimating costs are based on data from the Bureau of Labor Statistics and *Meat and Poultry Magazine*. They are $25.60 for a quality control manager, $18.13 for a quality control technician, and $12.87 for a laborer. They include a 33 percent overhead rate.

8. Cost Offsets

Because many establishments are currently operating or capable of operating quality control systems and programs, total costs are reduced to the extent that establishments already have the required plan development, monitoring, record keeping, and training.

9. TQC Overtime Costs

With the publication of the rule, TQC plants could lose their authority to produce and ship product after their normal shift production time. As a result, 287 active TQC establishments could begin to incur annual overtime charges.

B. Costs of the Near-term Initiatives

Costs associated with the four near-term initiatives can be thought of as pre-implementation HACCP costs. Since these interventions or similar controls will for the most part be incorporated into HACCP systems, their cost will reduce the overall cost of HACCP. Total cost of these initiatives is estimated at $358.9 million, including $266.7 for Federal establishments and $92.3 million for State establishments. The estimated cost to small establishments is $172.9 million. The four initiatives and their estimated costs are described below.

1. Sanitation Standard Operating Procedures

Federal plants—$81.1 million
State plants—21.0 million
Total—$102.1 million
Small establishments—$50.4 million

The SOPs would not add new sanitation standards but would require documentation of cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. This would serve as a basis for the plant's monitoring and the inspector's verification. An establishment's owner or manager would be required to detail in a written plan how the basic sanitation requirements would be met. Establishment employees would record results of the daily sanitation checks on a checklist, which would be made available to the inspector.

The amount of time to develop the plan would vary by establishment size, equipment, production capacity, and the process being performed. Plan development costs are one-time costs which would be incurred in the six months before the effective date of the regulation. They are estimated at $1.99 million for Federal establishments and $0.522 million for State establishments. Establishments now following a written sanitation program are not considered in the one-time or the recurring cost estimates.

Training establishment employees in the requirements of the SOP intervention program would represent another one-time cost incurred in the six months before the regulation takes effect. The training cost for Federal establishments is estimated at $1.1 million and for State establishments $0.251 million.

Recurring SOP costs would involve recordkeeping. Annual record keeping costs are estimated at $19.5 million for Federal establishments and $5.1 for State establishments.

2. Antimicrobial Treatments

Federal plants—$58.7 million
State plants—0.6 million
Total—$59.4 million
Small establishments—$2.7 million

Slaughter establishments would be required for the first time to provide antimicrobial treatments before the carcasses enter the chiller or cooler. Costs are reduced by the number of establishments already meeting these requirements. In estimating the resulting costs, it is assumed that the establishments would use the most cost-effective treatment. For meat establishments the cost analysis is based on the hot water system, at a cost of $.08 per carcass. For poultry establishments it is based on a hypochlorination system at $.0125 per carcass.

3. Time and Temperature Requirements

Federal plants—$26.5 million
State plants—22.9 million
Total—$49.4 million
Small establishments—$28.8 million

These requirements are already in effect for poultry plants, so would affect only the meat industry. An establishment would be required to maintain the cooled carcass and raw meat at the specified temperature throughout handling, holding, and shipping to other official establishments. Costs are reduced by the number of meat establishments already meeting these requirements. First-year costs for Federal establishments are estimated at $13.7 million, which covers developing a plan, training employees, upgrading cooling equipment, and keeping records. For State establishments the estimate is $18.9 million.

4. Microbiological Testing

Federal plants—$100.3 million
State plants—47.8 million
Total—$148.1 million
Small establishments—$91.1 million

FSIS would mandate testing and reporting procedures to determine the pathogen incidence rate for each process at each establishment that slaughters livestock or poultry or produces raw, ground meat or poultry products. One-time costs for plan development and employee training are estimated at $6.7 million.

Specimens would be collected once a day at the end of the production process and tested for the presence of the target organism (*Salmonella*) in the establishment's own laboratory or in a commercial/contract laboratory. The sample collection and analysis cost in the first year after promulgation of the rule is estimated at $67.5 million. This includes $46.4 for Federal establishments and $21.1 million for State establishments. The cost for small establishments represents 59 percent of the total, or $39.8 million.

First-year costs for record keeping are estimated at $2.4 million. Large establishments account for only about 10 percent of this total, since most of them are already performing quality control functions which require continuous records.

C. Costs of the Long-term HACCP Intervention

Federal plants—$279.7 million
State plants—88.5 million
Total—$368.2 million
Small establishments—$157.6 million

The near-term initiatives are a prelude to the types of activities that are required under a HACCP process control system. The HACCP costs above, which represent the full 36-month implementation period, include continuing components of the previous initiatives and the new costs listed below:

1. Industry HACCP Training

FSIS would require that each establishment have at least one person complete a course of at least three days in the application of HACCP principles. The total estimated cost of $27.9 million was calculated by multiplying a per-course cost of $2,514 (for tuition, travel expenses, and labor replacement) by the number of Federal and State establishments now lacking someone with the necessary training (assumed to be 95 percent of establishments).

2. Plan Development

FSIS would require each inspected establishment to have and implement a HACCP plan that is specific to each kind of meat or poultry process performed in the establishment. The Agency is aware that the requirement may be especially burdensome to small establishments producing small amounts of a variety of products.

In estimating the cost of the plans, FSIS considered the difficulty of writing a plan for each of the 14 HACCP processes that encompass all meat and poultry products. The cost for developing a plan ranges from $2,000 to $15,000 according to the degree of difficulty and its order of development. The overhead costs of developing the plant's first plan do not appear again for its subsequent plans.

Total plan development costs are estimated at $42.9 million: $30.7 million for Federal establishments and $12.2 million for State establishments. (In the absence of production information for State establishments, it was assumed that each will have 1.5 plans.) The total for small establishments is $21.6 million.

3. Aseptic Training

Plants not covered by the near-term microbiological testing requirement and that do not have their own quality control laboratory would have to train an employee to collect specimens for analysis. Estimated costs are $1.5 million for Federal plants and $.6 million for State plants. The total for small establishments is $1.5 million. (This cost is related to product testing. See item 4 below.)

4. Product Testing

The pre-HACCP product testing in slaughter plants and plants producing raw, ground product would continue under HACCP as described above under short-term initiatives. In addition, the Agency intends to require product testing in the processing plants not covered by the short-term requirement. Although the precise nature of this testing is not yet known, the Agency expects that in every establishment, at least one sample a day would have to be taken for each process. This would amount to nearly six million samples a year, at an estimated annual cost of $149.8 million. Although this testing requirement is not included in the proposed rule, it is discussed in the preamble and is included in the proposed costs in order to give a realistic estimate of the ultimate costs of the effort that is being initiated by this proposal.

5. Recordkeeping

A fundamental HACCP principle calls for recording and reviewing observations at critical points in the manufacturing process on an ongoing basis. The cost of recording this information is expected to total $47.9 million annually: $41.7 million for Federal establishments and $6.3 million for State establishments. The recording costs for small establishments are estimated at $11.9 million.

The cost of reviewing the records generated is expected to total $28.0 million annually: $24.5 million for Federal establishments; $3.5 for State establishments. The annual reviewing cost for small establishments is estimated at $6.7 million.

The annual cost of maintaining (storing) HACCP records as required would be $671,813: $575,852 for Federal establishments; $95,961 for State establishments.

6. FSIS HACCP Training

FSIS would provide employees with awareness training and HACCP inspection activity training. The estimated cost is $416,880.

D. Estimated Costs Per Plant

The following charts show the estimated costs for the near-term initiatives and for HACCP that would be incurred by various types of plants. The following steps can be followed to estimate, on the basis of FSIS estimates of cost, how much a particular establishment could expect to spend on one-time and recurring costs during the implementation period:

1. Determine the establishment's size (small, medium, or large) according to its annual sales volume, using the following criteria:

Small=less than $2.5 million sales
Medium=$2.5–$50 million sales
Large=over $50 million sales

2. Using the table for that size plant, find the column that describes its function (meat slaughter, poultry slaughter, or processing). Note that each type of operation is subdivided into two groups: those with and those without their own quality control laboratory. Plants with a laboratory will not have to spend as much in some cost categories. On the table for small plants, it is assumed that none have their own laboratory. On the table for large plants, it is assumed that all processing but not all slaughter plants have their own laboratory.

3. In meat slaughter plants, the HACCP costs for plan development and record keeping are per process, with each species counted as a separate process. For meat plants slaughtering more than one species, both costs must be multiplied by the number of species.

In poultry slaughter plants, only the HACCP cost for record keeping should be multiplied by the number of species slaughtered (chicken, turkey, and/or duck).

4. In processing plants, the HACCP costs for plan development and record keeping vary from process to process according to whether the process—and thus its HACCP plan—is easy, moderate, or difficult. To calculate a plant's total HACCP plan development and record keeping costs, perform these steps:

- For each process, use Table 6 to determine its degree of difficulty, and then, again using the relevant plant-size chart, find the plan development cost and the record keeping cost for that process. Write them down.
- Add all the plan development costs.
- Add all the record keeping costs.

Use the two sums instead of the table's per-process costs when the plant's total HACCP costs are calculated.

5. Under near-term interventions, note that modifying a cooler to comply with time-and-temperature requirements would cost an estimated $6,000. Any plant needing such modification should add $6,000 to the near-term interventions subtotal.

TABLE 6.—DEGREE OF DIFFICULTY FOR DEVELOPING A HACCP PLAN

Plan No.	HACCP process	Degree of difficulty
1	Raw: Ground	Easy.
2	Raw Other: Inclusive	Easy.
3	Thermally processed	Difficult.
4	All other shelf stable: not heat treated	Difficult.
5	Fully cooked: not shelf stable	Moderate.
6	Shelf stable: heat treated, other	Moderate.
7	Non-shelf stable: heat treated, not fully cooked	Moderate.
8	Non-shelf stable: with secondary inhibitors	Moderate.
9–14	Slaughter	Easy.

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TABLE 7. NEAR-TERM INTERVENTIONS AND HACCP COSTS FOR A SMALL PLANT*

INTERVENTION	FACTOR TO MULTIPLY BY	MEAT SLAUGHTER		POULTRY SLAUGHTER		PROCESSING**	
		QC LAB	NO LAB	QC LAB	NO LAB	QC LAB	NO LAB
NEAR-TERM INTERVENTION							
SANITATION		NA	$1,429	NA	$1,429	NA	$1,429
ANTIMICROBIAL TREATMENT PER HEAD * AVG. HEAD SLAUGHTERED***		NA	$590	NA	$37,894	NA	NA
TIME AND TEMPERATURE		NA	$762	NA	$762	NA	$762
T/T COOLER MODIFI. NEEDED = $6,000	YES/NO	NA		NA		NA	
MICRO. TEST. PLAN DEVELOPMENT****		NA	$512	NA	$512	NA	$512
MICRO. TESTING SAMPLE FOR 260 DAYS****	NUMBER OF SPECIIES/PROCESS	NA	$8,811	NA	$9,078	NA	$8,811
NEAR-TERM INTERVENTION COSTS		NA	$12,104	NA	$49,675	NA	$11,514
HACCP							
HACCP TRAINING		NA	$2,514	NA	$2,514	NA	$2,514
ASEPTIC TRAINING*****		NA	$403	NA	$403	NA	$403
MICRO. TESTING SAMPLE FOR 260 DAYS****	NUMBER OF SPECIIES/PROCESS	NA	$8,533	NA	$8,800	NA	$8,533

HACCP PLAN SPECFIC COSTS BY PLAN DEGREE OF DIFFICULTY		MEAT SLAUGHTER EASY PROCESS (5 CCPs)		POULTRY SLAUGHTER EASY PROCESS (5 CCPs)		PROCESSING** EASY PROCESS (6 CCPs)		MODERATE PROCESS (8 CCPs)		DIFFICULT PROCESS (10 CCPs)	
PLAN DEVELOPMENT	NUMBER OF SPECIIES/PROCESS	NA	$2,000	NA	$2,000	NA	$2,000	NA	$4,000	NA	$6,250
RECORD KEEPING	NUMBER OF SPECIIES/PROCESS	NA	$2,195	NA	$2,242	NA	$2,629	NA	$3,498	NA	$4,366
HACCP COSTS		NA	$15,645	NA	$15,959	NA	$16,079	NA	$18,948	NA	$22,066
TOTAL COSTS		NA	$27,749	NA	$65,634	NA	$27,593	NA	$30,462	NA	$33,580

* SIZE BY 1993 SALES VOLUME: SMALL = < $2.5 MILLION, MEDIUM = < $50 MILLION, LARGE = > $50 MILLION.

** SEE HACCP PROCESS DEFINITIONS AT TABLE 6.

*** PER CARCASS COSTS ARE $0.08 PER CARCASS AND $0.0125 PER POULTRY CARCASS.

**** NEAR-TERM INTERVENTION IS FOR ALL SLAUGHTER ESTABLISHMENTS AND RAW GROUND MEAT AND POULTRY PROCESSING.

***** DOES NOT PERTAIN TO SLAUGHTER OR RAW GROUND MEAT AND POULTRY PRODUCT PROCESSES.

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TABLE 8. NEAR-TERM INTERVENTIONS AND HACCP COSTS FOR A MEDIUM PLANT*

INTERVENTION	FACTOR TO MULTIPY BY	MEAT SLAUGHTER		POULTRY SLAUGHTER		PROCESSING**	
		QC LAB	NO LAB	QC LAB	NO LAB	QC LAB	NO LAB
NEAR-TERM INTERVENTION							
SANITATION		$2,619	$2,619	$2,619	$2,619	$2,619	$2,619
ANTIMICROBIAL TREATMENT PER HEAD * AVG. HEAD SLAUGHTERED***		$1,869	$1,869	$126,269	$126,269	NA	NA
TIME AND TEMPERATURE		$2,091	$2,091	$2,091	$2,091	$2,091	$2,091
T/T COOLER MODIFI. NEEDED = $6,000	YES/NO						
MICRO. TEST. PLAN DEVELOPMENT ****		$256	$512	$256	$512	$256	$512
MICRO. TESTING SAMPLE FOR 260 DAYS****	NUMBER OF SPECIES/PROCESSES	$5,459	$8,811	$5,836	$9,078	$5,459	$8,811
NEAR-TERM INTERVENTION COSTS		$12,294	$15,902	$137,071	$140,569	$10,425	$14,033
HACCP							
HACCP TRAINING		$2,154	$2,154	$2,154	$2,154	$2,154	$2,154
ASEPTIC TRAINING*****		NA	$403	NA	$403	NA	$403
MICRO. TESTING SAMPLE FOR 260 DAYS	NUMBER OF SPECIES/PROCESSES	$5,069	$8,533	$5,446	$8,800	$5,069	$8,533

HACCP PLAN SPECFIC COSTS BY PLAN DEGREE OF DIFFICULTY	FACTOR TO MULTIPY BY	MEAT SLAUGHTER EASY PROCESS (5 CCPs)		POULTRY SLAUGHTER EASY PROCESS (5 CCPs)		PROCESSING** EASY PROCESS (6 CCPs)		MODERATE PROCESS (8 CCPs)		DIFFICULT PROCESS (10 CCPs)	
PLAN DEVELOPMENT	NUMBER OF SPECIES/PROCESSES	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$4,000	$4,000	$6,250	$6,250
RECORD KEEPING	NUMBER OF SPECIES/PROCESSES	$2,242	$2,242	$2,242	$2,242	$2,676	$2,676	$3,521	$3,521	$4,413	$4,413
HACCP COSTS		$11,465	$15,332	$11,842	$15,599	$11,899	$15,766	$14,744	$18,611	$17,886	$21,753
TOTAL COSTS		$23,759	$31,234	$148,913	$156,168	$22,324	$29,799	$25,169	$32,644	$28,311	$35,786

** SIZE BY 1993 SALES VOLUME: SMALL = < $2.5 MILLION, MEDIUM = < $50 MILLION, LARGE = > $50 MILLION.

** SEE HACCP PROCESS DEFINITIONS AT TABLE 6.

*** PER CARCASS COSTS ARE $0.08 PER MEAT CARCASS AND $0.0125 PER POULTRY CARCASS.

**** NEAR-TERM INTERVENTION IS FOR ALL SLAUGHTER ESTABLISHMENTS AND RAW GROUND MEAT AND POULTRY PROCESSING.

***** DOES NOT PERTAIN TO SLAUGHTER OR RAW GROUND MEAT AND POULTRY PRODUCT PROCESSES.

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[FR Doc. 95-2366 Filed 1-31-95; 8:45 am]
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TABLE 9. NEAR-TERM INTERVENTIONS AND HACCP COSTS FOR A LARGE PLANT*

INTERVENTION	FACTOR TO MULTIPLY BY	MEAT SLAUGHTER		POULTRY SLAUGHTER		PROCESSING**	
		QC LAB	NO LAB	QC LAB	NO LAB	QC LAB	NO LAB
NEAR-TERM INTERVENTION							
SANITATION		$5,115	$5,115	$5,115	$5,115	$5,115	NA
ANTIMICROBIAL TREATMENT PER HEAD * AVG. HEAD SLAUGHTERED***		$62,146	$62,146	$427,980	$427,980	NA	NA
TIME AND TEMPERATURE		$3,791	$3,791	$3,791	$3,791	$3,791	NA
T/T COOLER MODIFI. NEEDED = $6,000	YES/NO						
MICRO. TEST. PLAN DEVELOPMENT****		$256	$512	$256	$512	$256	NA
MICRO. TESTING SAMPLE FOR 260 DAYS	NUMBER OF SPECIES/PROCESSES	$5,459	$8,811	$5,836	$9,078	$5,459	NA
NEAR-TERM INTERVENTION COSTS		**$76,767**	**$80,375**	**$442,978**	**$446,476**	**$14,621**	**NA**
HACCP							
HACCP TRAINING		$2,514	$2,514	$2,514	$2,514	$2,514	NA
ASEPTIC TRAINING*****		NA	$403	NA	$403	NA	NA
MICRO. TESTING SAMPLE FOR 260 DAYS	NUMBER OF SPECIES/PROCESSES	$5,069	$8,533	$5,446	$8,800	$5,069	NA

HACCP PLAN SPECFIC COSTS BY PLAN DEGREE OF DIFFICULTY		MEAT SLAUGHTER EASY PROCESS (5 CCPs)		POULTRY SLAUGHTER EASY PROCESS (5 CCPs)		PROCESSING** EASY PROCESS (6 CCPs)		MODERATE PROCESS (8 CCPS)		DIFFICULT PROCESS (10 CCPs)	
PLAN DEVELOPMENT	NUMBER OF SPECIES/PROCESSES	$2,000	$2,000	$2,000	$2,000	$2,000	NA	$4,000	NA	$6,250	NA
RECORD KEEPING	NUMBER OF SPECIES/PROCESSES	$2,242	$2,242	$2,242	$2,242	$2,676	NA	$3,521	NA	$4,413	NA
HACCP COSTS		**$11,825**	**$15,692**	**$12,202**	**$15,959**	**$12,259**	**NA**	**$15,104**	**NA**	**$18,246**	**NA**
TOTAL COSTS		**$ 88,59**	**$96,067**	**$455,180**	**$462,435**	**$26,880**	**NA**	**$29,725**	**NA**	**$32,867**	**NA**

* SIZE BY 1993 SALES VOLUME: SMALL = < $2.5 MILLION, MEDIUM = < $50 MILLION, LARGE = > $50 MILLION.

** SEE HACCP PROCESS DEFINITIONS AT TABLE 6.

*** PER CARCASS COSTS ARE $0.08 PER MEAT CARCASS AND $0.0125 PER POULTRY CARCASS.

**** NEAR-TERM INTERVENTION IS FOR ALL SLAUGHTER ESTABLISHMENTS AND RAW GROUND MEAT AND POULTRY PROCESSING ONLY.

***** DOES NOT PERTAIN TO SLAUGHTER OR RAW GROUND MEAT AND POULTRY PRODUCT PROCESSES.

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Federal Register

Friday
February 3, 1995

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310

Vaginal Contraceptive Drug Products for Over-the-Counter Human Use; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 80N–0280]

RIN 0905–AA06

Vaginal Contraceptive Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would require manufacturers of over-the-counter (OTC) vaginal contraceptive drug products to obtain approved applications for marketing of their products. The agency is taking this action because the effectiveness of these products is dependent upon the final formulation. Therefore, each product must be tested in appropriate clinical trials under actual conditions of use. This action will ensure the maximum effectiveness of OTC vaginal contraceptive drug products for consumers. This proposed rulemaking does not affect the current marketing status of OTC vaginal contraceptives. Thus, persons who are using or wish to use these drug products may do so. However, on the effective date of a final regulation, an OTC vaginal contraceptive drug product that is not the subject of an approved application would be regarded as a new drug and subject to regulatory action. Manufacturers will have adequate time to conduct studies and submit applications before the effective date of the final rule. Under existing procedures, there is a minimum of 26 months from today before a final rule could become effective. Despite this timeframe, manufacturers are urged to contact the agency regarding submission of their application as soon as possible. OTC contraceptives that are marketed for use with or as part of a device, e.g., diaphragm, condom, or contraceptive cervical cap will not be addressed in this document but will be addressed in a separate publication. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products, public comments on an advance notice of proposed rulemaking that was based on those recommendations, and evolving new information about these products. This proposal is part of the ongoing review of OTC drug products conducted by FDA. While this document does not address the use of vaginal contraceptive drug products for prophylaxis against human immunodeficiency virus (HIV) and other sexually transmitted diseases (STD's), FDA is aware of literature reports and other data relative to such use. FDA strongly encourages manufacturers to evaluate these products for use in the prevention of infectious diseases.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by June 5, 1995. New data by February 5, 1996. Comments on the new data by April 3, 1996. Written comments on the agency's economic impact determination by June 5, 1995.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 12, 1980 (45 FR 82014), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC vaginal contraceptive drug products, together with the recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in OTC vaginal contraceptive drug products. Interested persons were invited to submit comments by March 12, 1981. Reply comments in response to comments filed in the initial comment period could be submitted by April 13, 1981.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, six drug manufacturers, two governmental agencies, two reproductive health groups, one trade association, one chemical company, and one consumer submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** on December 12, 1980, was designated as a ''proposed rule'' in order to conform to terminology used in the OTC drug review regulations § 330.10. Similarly, the present document is designated in the OTC drug review regulations as a tentative final rule. Its legal status, however, is that of a proposed rule. To establish new § 310.535 by this notice of proposed rulemaking, FDA responds to public comment and states, for the first time, its position on OTC vaginal contraceptive drug products. Final agency action on this matter will occur with the publication, at a future date, of a final rule relating to OTC vaginal contraceptive drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC vaginal contraceptive drug products as modified on the basis of the comments received, the agency's independent evaluation of the Panel's report, and evolving new information on these products. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC drug procedural regulations (§ 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms ''Category I'' (generally recognized as safe and effective and not misbranded), ''Category II'' (not generally recognized as safe and effective or misbranded), and ''Category III'' (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term ''monograph conditions'' is used; in place of Category II or III, the term ''nonmonograph conditions'' is used.

Based on all information available to date, the agency has tentatively concluded that any OTC vaginal contraceptive drug product should be regarded as a new drug and be subject to regulatory action unless it is the

subject of an approved application or abbreviated application (hereinafter called application).

The agency has concluded that although nonoxynol 9 and octoxynol 9 kill sperm in vitro and in vivo, the spermicidal activity and resulting effectiveness of these contraceptive active ingredients cannot be considered separately from a product's vehicle. Studies show that these active ingredients lose some of their effectiveness in humans when the spermicide in final formulation is diluted by varied amounts of genital secretions during coitus. Thus, clinical studies are necessary to establish the effectiveness of the spermicide's final formulation when used in humans. (See discussion in section I.A., comment 3 of this document.) Such clinical studies would determine the influence of the potential interactions among the genital secretions, microorganisms, and contraceptive product vehicle.

The agency recognizes a need for consumers to continue to have access to OTC vaginal contraceptive drug products and to avoid disruption in the marketplace. The majority of OTC vaginal contraceptive drug products currently marketed contain nonoxynol 9. At the present time, two approved applications exist for OTC vaginal contraceptives: Delfen Contraceptive Foam (new drug application (NDA) 14–349) and Today® Sponge (NDA 18–683). The NDA for Delfen Contraceptive Foam was approved a number of years ago, and the product as currently marketed uses a different formulation from the one approved in the NDA. The manufacturer of this product will be required to provide additional information. The manufacturer of the Today® Sponge recently announced that it plans to discontinue production of this product. However, the firm has not indicated to FDA that it plans to withdraw its application.

Only a few vaginal contraceptive drug products contain octoxynol 9, and none have approved applications. Because the final rule for this class of OTC drug products will be effective 12 months after the date of its publication in the **Federal Register**, FDA strongly recommends that manufacturers of products not having an approved application consult with the agency as soon as possible concerning the content of these applications. Elsewhere in this issue of the **Federal Register**, the agency is announcing the availability of a guidance document that is intended to help manufacturers of vaginal contraceptive drug products develop data in support of new drug applications.

OTC vaginal contraceptive products that are marketed for use with or as part of a condom, diaphragm, or a contraceptive cervical cap will not be subject to the final rule. When labeled for use only with a device such as a condom (see 21 CFR 884.5310), diaphragm (see 21 CFR 884.5350), or cervical cap (a premarket approval application has been approved for a cervical cap for use as a barrier method of contraception, when used with a spermicidal cream or jelly), a spermicide is considered an accessory to a device. The regulation of spermicides for use only with a device will be addressed at a future date by the agency. In the interim, manufacturers of such products should direct inquiries to the Obstetrics/Gynecology Branch (HFZ–471), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–594–1180.

The agency has determined that nonoxynol 9 and octoxynol 9 would be appropriate ingredients for an approved application. This determination is based on: (1) The findings of the Panel (nonoxynol 9 and octoxynol 9 were recommended as Category I active ingredients), and (2) the history of use of drug products with approved NDA's containing nonoxynol 9.

Applications for products containing these ingredients will not need to include preclinical data, but, instead, may refer to the Panel's report as a general basis for the safety of these ingredients. The applications will need to include the results of clinical studies that establish the effectiveness of the contraceptive ingredient in the product's final formulation. These studies to establish the effectiveness of the product's final formulation need to comply with the requirements of 21 CFR part 314. The clinical studies should contain evidence of the effectiveness of the spermicide in final formulation in normal volunteers or patients that is consistent with correct use of the product. In addition, the agency is aware that the use of either of the contraceptive ingredients addressed in this proposed rulemaking may be associated with varying degrees of vaginal irritation under certain conditions of use and it is unclear whether this may play a role in the transmission of STD's (Refs. 1 through 5). Therefore, as part of the application for approval of these products for contraceptive use, information regarding the rate of occurrence and degree of vaginal irritation should be presented. FDA encourages manufacturers to consult with the agency as soon as possible concerning the content of these applications. Inquiries should be directed to the Division of Metabolism and Endocrine Drug Products (HFD–510), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3490.

The Department of Health and Human Services has published the ''13th Edition of Approved Drug Products with Therapeutic Equivalence Evaluations,'' commonly called ''the Orange Book,'' which identifies currently marketed products approved by FDA on the basis of safety and effectiveness data. The main criterion for the inclusion of any product in the Orange Book is that the product is the subject of an approved application that has not been withdrawn for safety or effectiveness reasons. For vaginal contraceptive drug products for which there is a previously approved listed drug product in the Orange Book, an abbreviated application may be submitted. The abbreviated application must contain information to show bioequivalence to the listed drug product. Further, the abbreviated application may contain labeling only for the claims approved for the product, i.e. a contraceptive. None of the products containing nonoxynol 9 that are listed in the Orange Book has a claim for the prevention of infectious disease. Manufacturers should consult with the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0340, to determine the procedures for obtaining approval of abbreviated applications. For vaginal contraceptive drug products for which there is no previously approved listed drug product in the Orange Book, an abbreviated application may not be submitted. For these products, an application that includes adequate and well-controlled clinical studies of the effectiveness of the specific formulation of the vaginal contraceptive must be submitted. Manufacturers of such products should direct inquiries to the Division of Metabolism and Endocrine Drug Products, as noted above.

Both types of applications, i.e., full or abbreviated, would also have to include information on the drug product's formulation, manufacture, and quality control procedures to ensure that the applicant has the ability to manufacture a safe and effective OTC vaginal contraceptive drug product. (Also, see section I.C., comment 15 of this document.)

The agency is aware of literature reports and other data concerning the

use of certain contraceptive active ingredients to prevent sexual transmission of infectious diseases (Refs. 1 through 17). However, none of these products currently has an approved indication for this use. Although this document is not intended to address the use of vaginal contraceptive drug products in preventing the transmission of STD's, the identification of safe and effective products to prevent the transmission of HIV and other STD's is a high priority public health concern. Therefore, FDA strongly encourages evaluation of OTC contraceptive products for this use. Manufacturers who wish to submit applications for such use should be aware that the study designs for effectiveness as a contraceptive and for prevention of infectious disease may be different. Therefore, manufacturers should consult with the agency concerning the content of contraceptive applications that also include an indication for prevention of infectious disease. Inquiries regarding use for prevention of infectious disease for antiviral prophylaxis should be directed to the Supervisory Consumer Safety Officer, Division of Antiviral Drug Products (HFD–530), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–9550, and inquiries regarding bacterial and other nonviral pathogens should be directed to the Division of Anti-Infective Drug Products (HFD–520), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4310.

If this proposal is adopted as a final rule, the agency advises that the conditions under which the drug products that are subject to this rule are not generally recognized as safe and effective and are misbranded (nonmonograph conditions) will be effective 12 months after the date of publication of the final rule in the **Federal Register**. On or after that date, no OTC drug product that is subject to the rule may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the final rule that is repackaged or relabeled after the effective date of the final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the proposed rule at the earliest possible date.

All ''OTC Volumes'' cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of May 16, 1973 (38 FR 12840) or to additional information that has come the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

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I. The Agency's Tentative Conclusions on the Comments

A. General Comments on OTC Vaginal Contraceptive Drug Products

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464 at 9471 through 9472), and in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696 to 698 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. Referring to the Panel's recommendation on the advertising of OTC vaginal contraceptive drug products (45 FR 82014 at 82025), one comment agreed that labeling should be truthful and nondeceptive but disagreed that only those words adopted by the Panel be allowed in OTC drug advertising. The comment pointed out that on February 11, 1981, the Federal Trade Commission (FTC) declined to propose a rule which would require that

only FDA-approved words be used in advertisements for OTC drugs, and some of the Commissioners expressed doubt that approved OTC drug labeling would be appropriate for OTC drug advertising.

FTC has the primary responsibility for regulating OTC drug advertising. However, FDA does have the authority to regulate OTC drug advertising that constitutes labeling under the Federal Food, Drug, and Cosmetic Act (the act). Under the act, a manufacturer can be prohibited from advertising a drug to treat a condition for which there are not adequate directions for use on the label. See, e.g., *United States* v. *Article of Drug * * * B–Complex Cholinos Capsules*, 362 F.2d 923 (3d Cir. 1966); *V. E. Irons, Inc.* v. *United States*, 244 F.2d 34 (10th Cir.), *cert. denied*, 354 U.S. 923 (1957). In addition, if advertising for an OTC vaginal contraceptive drug product offers the product for conditions not included in FDA approved labeling, the drug product could be subject to regulatory action by FDA. (See also section I.C., comment 11 of this document for discussion of FDA's labeling policy.)

3. A number of comments disagreed with the agency's position that clinical testing of all final formulations, conducted under the provisions of a new drug application, may be the only means of assuring effectiveness of OTC vaginal contraceptive drug products. Several of these comments argued that the Panel's recommended in vitro testing procedures are sufficient to demonstrate effectiveness. One comment stated that requiring manufacturers to submit an application contradicts the agency's stated purpose of the monograph process. Another comment was concerned that requiring clinical testing might mean that new clinical trials would be needed each time a manufacturer made changes in a product's inactive ingredients. The comment maintained that this would be costly, would not benefit consumers, and would stifle a manufacturer's incentive to improve products.

Two comments advocated requiring clinical testing of OTC vaginal contraceptives. One comment asserted that such testing would provide needed quantitative effectiveness data and ''user information.'' This comment also questioned how appropriate directions for use could be determined based only on in vitro testing. The other comment claimed that research has shown that certain OTC drug products judged to be effective by standard in vitro testing were in fact largely ineffective when evaluated by standard in vivo testing procedures. The comment also contended that in vitro testing is of limited usefulness because anatomic and physiologic changes in the vagina during sexual arousal, which can affect the distribution of the contraceptive, are not considered. The comment proposed using a particular in vivo testing procedure prior to full clinical testing.

One comment suggested that the agency require an in vitro test other than that recommended by the Panel, claiming that the Panel's test is ''inadequately sensitive in that it only provides pass or fail end-point information, and does not quantitate the spermicidal potency of the contraceptive formulation.'' Another comment opposed requiring clinical testing, but stated that if such testing is to be required, a recognized postcoital test would be sufficient.

The agency has reviewed the available data and information regarding in vitro testing procedures for vaginal contraceptive drug products and tentatively concludes that in vitro testing is not sufficient to assure effectiveness of the product when used in humans. Although in vitro testing will provide a measure of a product's potential effectiveness, reports in the literature (Refs. 1 through 14) indicate that such in vitro tests will not adequately describe the effectiveness of the final formulation when it is used in humans. In these reports, certain OTC vaginal contraceptives found to be effective when tested in vitro were shown to be ineffective when tested in vivo.

Formulations differ in the speed of distribution in the vagina and the degree of surface coverage and these and other factors have a significant impact on effectiveness (Refs. 3, 15, and 16). Homm et al. (Ref. 3) compared seven marketed vaginal contraceptives (foams, suppository, cream, jelly) in in vitro and in vivo (rabbit) studies and concluded that the dosage form of a vaginal contraceptive product is of considerable importance in its contraceptive potency. Homm et al. found that foam products were more available than suppository products, which were more potent than jelly products. However, the authors stated that these comparative ratings could only be regarded as generalizations because the in vivo contraceptive potencies found in the rabbits were difficult to relate to human contraceptive effectiveness. At present, there is no in vitro test available that can be considered a reliable reflection of in vivo conditions. There is also no reliable in vivo animal model that can simulate the human condition. Bassol (Ref. 15) compared the rupture time of two types of soft jelly capsules containing nonoxynol 9 after vaginal insertion in 96 women. The authors found that vaginal conditions associated with alkaline pH, multiparity, and vaginal dryness have an important role in the rupture of the capsules. The study points out the importance of the contraceptive vehicle as well as other conditions of the vaginal environment in determining the effectiveness of vaginal contraceptive drug products.

Stone and Cardinale (Ref. 16) conducted a study using a series of in vitro and in vivo tests to evaluate the effectiveness of a suppository product compared to a cream or foam product having the same active ingredient, nonoxynol 9. The authors found some evidence indicating that the solubility of the suppository may vary from subject to subject depending on, for example, the volume of vaginal secretions. In the in vitro study, instant immobilization of all sperm was obtained when foam, cream, or effervescent vaginal suppository foam was mixed with 2 milliliters of semen. In the in vivo study, a good volume of foam covering the external os of the cervix was observed in only 11 of the 20 patients in whom the suppository was inserted. However, very little if any foam was observed in the other nine women, and the suppository was removed almost intact after the 15-minute observation period. The authors commented that in vitro and laboratory evaluations of chemical contraceptives do not correlate well to their effectiveness in clinical trials in different populations. In addition, they noted that formulations containing a highly effective spermicidal agent but that do not diffuse well are less effective.

Postcoital tests in humans have been considered as an alternative to clinical trials. However, the agency does not believe that the currently available postcoital tests can be relied upon. The Sims-Huhner test (SHT) is an in vivo postcoital test that is used to diagnose certain types of infertility and assess the presence, quality, and motility of sperm in the cervical mucus. References in the medical literature indicate that the SHT has poor predictive value because a negative SHT does not confirm the absence of sperm (Refs. 17, 18, and 19). Kably et al. (Ref. 17) stated that they had found the results of the SHT to ''paradoxical'' relative to conception. Therefore, the authors examined whether sperm were present or absent in the peritoneal fluid of five subjects with good SHT's and five subjects with poor or negative SHT's. In three of five subjects with a positive SHT and in four of five subjects with a poor SHT, sperm were found in the aspirate.

Asch (Ref. 18) also reported that pregnancy frequently occurs in women with a negative or poor SHT. Asch reported the recovery of mature, morphologically normal sperm from the peritoneal fluid of six of the eight women who had a negative SHT. In three other women who had a poor SHT, sperm were also recovered in the aspirate. Griffith and Grimes (Ref. 19) reviewed the literature and evaluated the validity of the postcoital test for predicting infertility. The authors concluded that the SHT has poor validity, its reproducibility is unknown, and its suffers from a lack of standardized methodology and a uniform definition of normal. Because the absence of sperm in the SHT frequently has been associated with subsequent pregnancy, the agency concludes that this in vivo postcoital test is not reliable for evaluating the efficacy of a vaginal contraceptive.

Because of the difficulties that arise in trying to simulate the human condition in an in vitro test and determine the influence of the potential interactions among the sperm, cervical mucus, microorganisms, and contraceptive vehicle on the effectiveness of the contraceptive, the results of in vitro testing cannot be relied upon to reach conclusions about effectiveness in humans. For example, due to the varied amounts of cervical mucus and semen that may be present in humans during sexual arousal, the concentration of the contraceptive in the vagina is not always equivalent to the concentration used in in vitro testing. Furthermore, in vitro testing cannot determine the following important information: How long before intercourse the contraceptive should be inserted; if the intravaginal distribution of the contraceptive is sufficient to assure effectiveness; or how long the contraceptive remains effective in the vaginal environment. Therefore, the agency has determined that clinical studies in humans are necessary to establish the effectiveness of final formulations of OTC vaginal contraceptive drug products.

The results of such testing should be submitted in the form of an application that complies with all of the requirements that are necessary to establish the safety and effectiveness of the product's final formulation, as discussed above. Reference to the Panel's report and this document, as appropriate, may be used to satisfy the requirements of portions of the application related to the safety of the active ingredient.

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4. One comment stated that FDA does not have the authority to enforce § 351.30(f) of the Panel's recommended monograph, which would require manufacturers to retain the in vitro effectiveness testing data and permit FDA to inspect these data. The comment requested that § 351.30(f) be deleted.

As discussed in section I.A., comment 3 of this document, the agency is proposing that each OTC vaginal contraceptive drug product should be the subject of an approved application prior to marketing. Therefore, there will be no monograph and the comment's request is moot.

5. Two comments objected to the Panel's statement questioning the safety and effectiveness of quaternary ammonium compounds for use as preservatives in OTC vaginal contraceptive drug products (45 FR 82014 at 82042). The comments stated that the Panel's concern stems solely from a review of eight reports (45 FR 82042) suggesting that the use of quaternary ammonium compounds may be associated with outbreaks of *Pseudomonas* infections because they do not inhibit the growth of *Pseudomonas*. The comments argued that the Panel failed to state that these reports resulted from the contamination of solutions that were employed in laboratory and hospital settings to sterilize medical devices used in urinary and cardiac catheterization or cystoscopic or related invasive procedures. Such procedures are usually conducted on patients whose normal body defenses have been compromised. Because *Pseudomonas* infections occur primarily in debilitated patients and *Pseudomonas* does not cause vulvovaginitis, the comments stated that it is scientifically inappropriate to cite these reports and through extrapolation conclude that the use of quaternary ammonium compounds in vaginal contraceptive drug products presents a health hazard to normal individuals. The comments cited several references to support the argument that the Panel's concern, with respect to vaginal contamination by *Pseudomonas* in the presence of quaternary ammonium compounds, is not supported by the weight of scientific and medical opinion (Refs. 1 through 4).

The comments concluded that the agency should affirm the safety of quaternary ammonium compounds and reclassify these ingredients in Category I for use as preservatives in OTC vaginal drug products.

Although the comments requested that the agency affirm the safety of quaternary ammonium compounds for use as preservatives and reclassify them as Category I, the agency points out that the OTC drug review is primarily a review of active ingredients, not inactive ingredients. However, because the purpose of the OTC drug review process is to determine the safety and effectiveness of OTC drugs, the OTC advisory review panels occasionally made recommendations with respect to inactive ingredients. These recommendations were made to call attention to those inactive ingredients that could potentially interfere with the safety and effectiveness of the product.

In the case of the quaternary ammonium compounds, the agency agrees with the comments' reasoning that the reports cited by the Panel cannot be used to conclude that the use of these compounds as preservatives in OTC vaginal contraceptive drug products may present a health hazard to normal individuals.

As discussed in section I.A., comment 3 of this document, the agency is proposing that each OTC vaginal contraceptive drug product should be the subject of an approved application prior to marketing. Information regarding the appropriateness of ingredients used in the product as preservatives should be included in the application.

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6. Several comments disagreed with the Panel's recommendations that inactive ingredients and the quantity of the ingredient be listed in the labeling of OTC vaginal contraceptive drug products. The comments argued that a list of inactive ingredients would be meaningless to all but a few consumers and that such a list might overemphasize the importance of the inactive ingredients; obscure more meaningful information such as warnings, directions for use, and the name and quantity of the active ingredients; and be more confusing than helpful. The comments also stated that if the quantity of the inactive ingredients had to be listed there would be an additional problem and expense of changing the labels whenever the quantity of an inactive ingredient is changed.

The act does not require the identification of all inactive ingredients in the labeling of OTC drug products. Section 502(e) of the act (21 U.S.C. 352(e)) does require disclosure of active ingredients and of certain ingredients, whether included as active or inactive components in a product. Although the act does not require the disclosure of all inactive ingredients in the labeling of OTC drug products, the agency agrees with the Panel that listing of inactive ingredients in OTC drug product labeling would be useful information for some consumers. Consumers with known allergies or intolerances to certain ingredients would then be able to identify substances that they may wish to avoid.

The Nonprescription Drug Manufacturers Association (formerly known as The Proprietary Association), the trade association that represents approximately 85 OTC drug manufacturers who reportedly market between 90 and 95 percent of the volume of all OTC drug products sold in the United States, has established guidelines (Ref. 1) for its member companies to list voluntarily inactive ingredients in the labeling of OTC drug products. Under another voluntary program begun in 1974, the member companies of the Association have been including the quantities of active ingredients on OTC drug labels. The agency is not at this time proposing to require the listing of inactive ingredients in OTC drug product labeling. However, the agency commends these voluntary efforts and urges all other OTC drug manufacturers to similarly label their products.

Reference

1. ''Guidelines for Disclosure of Inactive Ingredients in OTC Medicines,'' The Proprietary Association, Washington, July 12, 1984, in OTC Vol. 11ATFM.

7. One comment urged that the label of OTC vaginal contraceptive drug products contain a list of all active ingredients, arguing that consumers have a right to an informed choice when buying such products.

As discussed in section I.A., comment 6 of this document, listing of active ingredients is required for all drug products under section 502(e)(1) of the act (21 U.S.C. 352(e)(1)).

B. Comments on OTC Vaginal Contraceptive Active Ingredients

8. Three comments supported the Panel's Category I classification of menfegol and disagreed with the agency's conclusion that menfegol is a new drug because it is a new molecular entity, never before marketed as a drug in the United States. The comments stated that a lack of United States' marketing experience does not preclude a drug from being considered generally recognized as safe and effective nor require a drug to be considered a new drug. One comment argued that data on the marketing of vaginal contraceptive drug products in foreign countries can be equated to marketing in this country because the mode of action of these products is based on the spermicidal activity of an ingredient in the vagina and not on the medical problems, diets, customs, and environments of other countries. The comment urged FDA to reconsider its decision to refuse to recognize data on the marketing of a product outside the United States regardless of the ingredient, type of product, or its mode of action. Another comment added that the act defines a new drug as any drug not generally recognized as safe and effective among experts, whereas menfegol was so recognized by a panel of experts.

The Panel's Category I classification of menfegol was based on its review of safety and effectiveness data. The Panel's recommendation did not address the issue whether menfegol meets the statutory requirement concerning use of a drug. Menfegol was determined to be a new drug within the meaning of section 201(p)(2) of the act (21 U.S.C. 321(p)(2)), which defines a new drug as: * * * ''any drug * * * that * * * has become so recognized, but which has not * * * been used to a material extent or for a material time under such conditions.'' The agency's longstanding interpretation of section 201(p)(2) of the act has been that marketing outside the United States cannot fulfill this independent statutory requirement of use to a ''material extent'' and for a ''material time.'' Currently, based on several petitions to another OTC drug review rulemaking (Refs. 1, 2, and 3), the agency is reevaluating this interpretation of the act. (See section II.C., comment 34 of this document, in the tentative final

monograph for OTC sunscreen drug products published in the **Federal Register** of May 12, 1993, 58 FR 28194 at 28210). The agency will discuss its decision on this matter in a future issue of the **Federal Register**. Thus, the agency is reconsidering its policy on foreign marketing data, as the comment requested. However, in view of the agency's tentative conclusion that all vaginal contraceptive drug products will need an approved application for marketing, this issue, as it relates to menfegol, is moot.

References

1. Citizen Petition, submitted by BASF AG, March 16, 1990, coded CP2, Docket No. 78N–0038, Dockets Management Branch.

2. Citizen Petition, submitted by Haarmann and Reimer Corp., July 27, 1990, coded CP3, Docket No. 78N–0038, Dockets Management Branch.

3. Citizen Petition, submitted by Givaudan Corp., October 31, 1990, coded CP4, Docket No. 78N–0038, Dockets Management Branch.

9. Two comments submitted data and information on the safety of nonoxynol 9 (Ref. 1). These data were submitted after publication of the Panel's report in response to concerns regarding the potential teratogenicity or carcinogenicity of this ingredient (Refs. 2, 3, and 4).

Although nonoxynol 9 was classified by the Panel as a Category I ingredient for use as an OTC vaginal contraceptive, concern over the possible carcinogenicity of nonoxynol 9 surfaced in relation to the agency's approval of an application for a vaginal contraceptive sponge product containing this ingredient. In reviewing the data in support of the application, the agency learned that nonoxynol 9 may contain low levels of the suspected carcinogens 1,4-dioxane and ethylene oxide as residuals from the manufacturing process. The concern that the agency had approved an application for a product containing suspected carcinogens was one of the bases of a congressional hearing held by the Subcommittee on Intergovernmental Relations and Human Resources on July 13, 1983. At that hearing, FDA presented testimony and evidence that the levels of 1,4-dioxane and ethylene oxide contained in the sponge product are within the residue limits that are considered acceptable by the agency.

However, because the presence of 1,4-dioxane and ethylene oxide is not unique to the sponge product and it is possible that other products could contain different levels of these contaminants, the agency believes that manufacturers should submit as part of the application required for these products (see section I.A., comment 3 of this document) data and information specifying the levels of 1,4-dioxane and ethylene oxide that are contained in the finished product.

The concern over possible teratogenicity of OTC vaginal contraceptives was also raised at the congressional hearing. The agency explained at the hearing that animal teratogenicity data and recent epidemiological data indicate that nonoxynol 9 is not teratogenic. However, FDA stated that it was considering a special warning concerning the use of any spermicide by women who suspect that they may be pregnant. Data and information on the possible teratogenicity of vaginal spermicides were subsequently presented to the agency's Fertility and Maternal Health Drugs Advisory Committee to determine if any of the studies contains sufficient evidence to warrant a special warning in the labeling concerning the use of vaginal spermicides during pregnancy. At its December 15, 1983 meeting (Ref. 5), the committee decided that such a warning was not warranted. The agency concurs with the advisory committee's conclusion.

References

1. ''Nonoxynol 9 Safety Information,'' Advanced Care Products, Division of Ortho Pharmaceutical Corp., coded RPT and RPT002, Docket No. 80N–0280, Dockets Management Branch.

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3. Rothman, K. J., ''Spermicide Use and Down's Syndrome,'' *American Journal of Public Health*, 72:399–401, 1982.

4. Citizen Petition, submitted by A. Lione, Associated Pharmacologists and Toxicologists, June 20, 1983, coded CP2, Docket No. 83P–0187, Dockets Management Branch.

5. Minutes of the Meeting of the Fertility and Maternal Health Drugs Advisory Committee, National Center for Drugs and Biologics, FDA, pp. 1–3, December 15, 1983, copy included in OTC Vol. 11ATFM.

10. Two comments disagreed with the Panel's intention that data submitted on the safety of phenylmercuric acetate be regarded as equally relevant for all related mercury compounds, such as phenylmercuric nitrate (45 FR 82014 at 82031). One comment stated that the greatest part of the Panel's discussion on phenylmercuric acetate and related compounds is devoted to a discussion of the reported toxicity of orally ingested alkylmercury compounds and that this discussion unjustifiably imputes toxicity to arylmercury compounds when used in topically applied preparations under ordinary conditions. The comments further stated that, although the Panel acknowledged that alkylmercury compounds and inorganic mercury salts have greater toxicity than arylmercury compounds, it should be recognized that differences also occur between mercury compounds within the aryl series. Therefore, the comments argued, conclusions should be limited to the compound specifically considered, phenylmercuric acetate, when used specifically for its spermicidal action and should not condemn phenylmercuric nitrate by association.

The agency acknowledges the comments' concern regarding the varying toxicities of the different mercury compounds, but concurs with the Panel that mercury-containing compounds, when used as active ingredients in vaginal contraceptive drug products, are unsafe. The Panel recommended that all vaginal contraceptives containing mercury compounds as active ingredients be placed in Category II because such compounds are potentially hazardous to the fetus and the breast-fed infant (45 FR 82014 at 82038). Because data in animals and humans indicate that phenylmercuric acetate is absorbed from the vagina into the system and partially metabolized to inorganic mercury in the blood and various tissues where it may accumulate (Refs. 1 through 4), the Panel concluded that mercury-containing compounds related to phenylmercuric acetate, such as phenylmercuric nitrate, may be expected to behave in a similar manner. Other than the comments' contention, no data or information was submitted to demonstrate that phenylmercuric nitrate and related mercury-containing compounds react by a different mechanism or are not absorbed from the vagina. Although no overt symptoms of mercury poisoning from the use of vaginal preparations containing mercury compounds have been detected in infants and children, there are sufficient animal data to suggest that inorganic mercury from mercury-containing compounds can be transferred to the fetus and to breast-fed offspring. (See 45 FR 82014 at 82033 and 82035.) In addition, the Panel cited animal teratology studies that showed a higher percentage of fetal abnormalities when phenylmercuric acetate was administered either vaginally or intravenously (45 FR 82034). The Panel also cited cases of congenital mercury poisoning in humans following ingestion of mercury compounds by the mother (45 FR 82032). These studies are at least suggestive, regardless of the

method of administration, of the potential hazard of mercury to offspring when the drug is systemically absorbed by the mother. Therefore, because of the possibility that mercury-containing compounds which can be metabolized to inorganic mercury may pose a risk to fetuses and nursing infants, the agency concurs with the Panel that such compounds are unsafe for use in vaginal contraceptive drug products.

References

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2. Fukuchi, H. et al., ''The Absorption of Organomercurial Compounds from the Vaginal Route of the Rabbits. I. Comparative Study on the Effect of Suppository Vehicles on the Absorption of *Omega*–Ethylmercurithio-*n*-undecanoic Acid, Phenylmercuric Acetate and Ethylmercuric Chloride after Single Dose Administration,'' *Chemical and Pharmaceutical Bulletin*, 12:540–548, 1964.

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C. Comments on Labeling of OTC Vaginal Contraceptive Drug Products

Although the proposed rule included in this document does not include monograph conditions, the responses to the following comments should be considered as FDA's tentative position on the labeling of OTC vaginal contraceptive drug products. FDA has considered the Panel's labeling recommendations and the following comments in developing the agency's position on labeling for OTC vaginal contraceptive drug products. This document will serve as the basis for the development of guidelines for the content and format of the labeling of OTC vaginal contraceptive drug products similar to those currently available for oral contraceptive drug products. (See 54 FR 22585 and 22624, May 25, 1989.) The agency intends to complete these guidelines for OTC vaginal contraceptive drug products after the comments to this proposal are evaluated.

11. One comment noted its continuing position that FDA lacks statutory authority to prescribe exclusive lists of terms from which indications for use for OTC drug products must be drawn and to prohibit labeling terminology which is truthful, accurate, not misleading, and intelligible to the consumer. A second comment stated that it would be inappropriate to restrict manufacturers to the specific wording recommended by the Panel for package insert statements.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either: (1) The specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated ''APPROVED USES''; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated ''APPROVED USES''; or (3) the approved monograph language on indications, which may appear within a boxed area designated ''APPROVED USES,'' plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). There will be no monograph for OTC vaginal contraceptive drug products, and all labeling for these products will be approved via applications. Therefore, the comments are moot with respect to this current rulemaking.

12. Several comments agreed with the Panel that quantitative claims of effectiveness should not be required in the labeling of OTC vaginal contraceptive drug products because of the difficulty in conducting the studies that would be necessary to substantiate such claims. The size of the sample that would be needed, the variations in subject motivation, varying methods of product use, and the lack of an adequate representative population of American women were specifically cited in the comments as factors that would make such studies difficult to conduct. The comments also pointed out that the consensus of the participants in the symposium on vaginal contraception, held by the Panel on April 28 and 29, 1978, was that quantitative effectiveness claims should not be required.

A number of comments indicated that quantitative effectiveness claims should not be required, but that manufacturers should be permitted to use these claims at their own discretion. Several of these comments also objected to the Panel's recommendation that such claims be permitted in labeling only after prior approval by FDA through the new drug procedures.

Two comments questioned whether the quantitative effectiveness claims could be written in a manner that would be understood by consumers. Providing consumers with actual numbers relevant to method effectiveness, use effectiveness, and extended-use effectiveness was specifically cited as a potential source of confusion.

One comment pointed out that the patient labeling of oral contraceptives is required to contain a discussion comparing the effectiveness of different contraceptive methods and, therefore, it would be inconsistent for FDA to conclude that there are insufficient data available to support the validity of comparative effectiveness claims in the labeling of OTC vaginal contraceptive drug products.

The agency believes that consumers should be provided with the most informative labeling available when choosing a contraceptive drug product. After reviewing the complete administrative record for this rulemaking, including the record of the Panel's symposium on vaginal contraception and the comments submitted to the Panel's report on this issue, the agency concludes that the most informative labeling for users of vaginal contraceptive drug products is information on the relative effectiveness of the various methods of contraception. The agency is currently working to create a consistent and understandable presentation of this important information to include in the labeling of all marketed contraceptive products, drugs, and devices.

13. Two comments objected to the Panel's labeling recommendations for the outer and primary containers of OTC vaginal contraceptive drug products (45 FR 82014 at 82031). The comments questioned the propriety of the Panel in specifying the order of appearance and location of the various required statements. The comments also objected to the number of required labeling statements. One comment stated that listing of all the recommended labeling statements would require the use of small illegible typeface. The second comment noted that if space were

limited, listing of all items in the recommended order would preempt those labeling statements required by law. The second comment also requested that the general warning statements, ''Keep this and all drugs out of the reach of children'' and ''In case of accidental ingestion call a Poison Control Center, emergency medical facility, or a doctor,'' not be included in the Panel's priority system of labeling. The comment pointed out that warnings similar to these are already required by 21 CFR 330.1(g), which only requires that these warnings appear somewhere in the labeling. The comment stated that there is no basis for special treatment of these warnings for OTC vaginal contraceptive drug products.

Existing regulations (21 CFR 201.15 and 21 CFR part 201, subpart C—Labeling Requirements for Over–the–Counter Drugs) adequately address the placement and prominence of labeling statements. While there may be certain selected situations where it is necessary to alter these general requirements, the agency is unaware of any data demonstrating that it is necessary in the case of OTC vaginal contraceptive drug products. In addition, the labeling statements required by § 330.1(g) are similar to those recommended by the Panel and the agency considers the labeling requirements in § 330.1(g) to be appropriate for OTC vaginal contraceptive drug products.

14. One comment suggested that the accidental ingestion warning recommended by the Panel be changed from ''In case of accidental ingestion, call a Poison Control Center, emergency medical facility, or a doctor immediately'' to ''In case of accidental ingestion of large amounts by children, call a Poison Control Center or emergency medical facility, or call a doctor.'' The comment contended that because of the well-established safety of OTC vaginal contraceptive drug products the Panel's recommended warning is unnecessarily alarming to adult users.

The agency does not believe that the Panel or the comment have presented sufficient data or information to warrant a change from the accidental ingestion warning required by § 330.1(g) or § 369.9 for all OTC drug products.

15. One comment agreed with the Panel that the labeling of an OTC contraceptive drug product should contain an expiration date and information on the product's appropriate storage condition.

To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, existing FDA regulations at 21 CFR 211.137 require an expiration date for the product, except for OTC drug products for human use whose labeling does not bear dosage limitations and which are stable for at least 3 years as supported by appropriate stability data. In addition, the expiration date is also required to relate to any storage conditions stated on the labeling. As discussed in section I.A., comment 3 of this document, the agency is proposing that each OTC vaginal contraceptive drug product should be the subject of an approved application prior to marketing. Information relating to dosage limitations, stability conditions, and storage conditions should be included in the application.

16. Three comments agreed with the Panel that the labeling of OTC vaginal contraceptive drug products should contain precise directions that can be easily understood by the average consumer. One of these comments added that diagrams on proper use of the contraceptive might also be useful.

The agency agrees that vaginal contraceptives should contain precise directions that are understandable to consumers, including diagrammed instructions, as appropriate, to show the proper method of application.

17. One comment suggested that the Panel's recommended directions statement in § 351.56(a)(3), which reads, ''If this product is used together with another contraceptive method, there will probably be better protection against pregnancy,'' be modified to include examples of various contraceptive methods, such as a diaphragm, condom, or intrauterine device.

As discussed in section I. C., comment 12 of this document, the agency believes that the labeling of OTC vaginal contraceptive drug products should contain a summary of the effectiveness of the various methods of contraception. In light of this, the agency considers the modification recommended by the comment to be unnecessary.

18. One comment stated that if the indication recommended by the Panel in § 351.56(b)(5), which reads, ''Extra protection for women who forget to take one or more contraceptive pills,'' is adopted, the labeling of the product should also refer the user to the directions for use of the oral contraceptive. The comment reasoned that a woman who has missed more than two consecutive pills should discontinue taking them, whereas the use of the word ''extra'' implies that the pills should be continued. As an alternative to referring the user to the oral contraceptive's directions for use, the comment suggested revising the statement to read ''Extra protection for women who forget to take one or two contraceptive pills.''

The comment added that the indication in recommended § 351.56(b)(8), which reads, ''Effective contraceptive alone or in the event the contraceptive pill is forgotten,'' is more acceptable than the one in § 351.56(b)(5), but it appears to imply that vaginal and oral contraceptives provide equivalent protection. The comment recommended that both statements either be modified or deleted.

The agency believes that information regarding what to do when a contraceptive pill is forgotten is more appropriate for inclusion in the labeling of oral contraceptives. Such information is required to be included in the patient labeling of oral contraceptives. Therefore, the agency does not believe that this type of information is necessary for inclusion in the labeling for OTC vaginal contraceptive drug products.

19. Two comments urged deletion of the statement recommended by the Panel in § 351.56(a)(5), which reads, ''If douching is desired, always wait at least 6 hours after intercourse before douching.'' The comments claimed that there are no data or information in the scientific literature or from common usage demonstrating the need for such labeling. One of these comments specifically argued that the only supporting reference cited by the Panel (Ref. 1) discusses the persistence of sperm in the cervix and vagina following intercourse but does not express any concern about douching following the use of a vaginal spermicide. The comment added that this reference actually indicates that douching was ''associated with reductions in proportions of smears containing spermatozoa.'' Both comments also specifically noted that the Panel admitted that there are no data establishing the optimum time interval between use of a spermicide and douching.

Although the comments are correct that no data are available concerning the optimum time interval between intercourse and douching when using a vaginal spermicide product, it is generally accepted that douching too soon after intercourse could likely interfere with a spermicide by diluting it or removing it from the vagina. Therefore, the agency believes that a statement regarding the time interval between intercourse and douching would provide useful information to the consumer. The Panel stated that it is

generally accepted opinion that when vaginal contraceptives are used as the primary method of birth control, douching should be delayed for at least 6 hours after coitus (45 FR 82014 at 82030). The agency concurs.

Reference

1. Silverman, E. M. and A. G. Silverman, ''Persistence of Spermatozoa in the Lower Genital Tracts of Women,'' *Journal of the American Medical Association*, 240:1875–1877, 1978.

20. One comment suggested that the labeling of OTC vaginal contraceptive drug products include a warning specifying possible adverse allergic reactions such as itching and burning in the vaginal area and in the penile area. The comment also recommended that the warning advise consumers to discontinue use if these symptoms occur.

The agency agrees with the comment that consumers should be warned about possible allergic reactions such as burning and itching that may occur when using vaginal contraceptive drug products. The agency also agrees that the warning should advise consumers to discontinue use if these symptoms should occur. Furthermore, if the irritation persists after use has been discontinued, it could indicate a problem other than an allergic reaction to the product, so that a physician should be contacted. The agency believes the following warning is appropriate for inclusion in the labeling of OTC vaginal contraceptive drug products: ''If you or your partner develops irritation, such as burning or itching in the genital area, stop using this product. If irritation continues, contact your physician.''

21. One comment stated that the Category II labeling claims recommended by the Panel (45 FR 82014 at 82040) are not proper subject matter for the OTC drug review and should not be classified. The comment argued that these claims are not indications for use, but rather are statements of fact which are unrelated to the safety or effectiveness of a vaginal contraceptive drug. The comment added that the claims cannot legally be prohibited if truthful and should not be placed in Category II without a finding that they are inherently false or misleading.

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. One aspect of the program is to develop standards for certain parts of the labeling of OTC drug products. Because of time, resources, and other considerations, FDA has not set standards for all labeling found in OTC drug products. Accordingly, OTC drug monographs address only those labeling items that are related in a significant way to the safe and effective use of covered products by lay persons. These labeling items are the product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

Based on the discussion above, the agency tentatively concludes that the Panel's entire list of Category II labeling claims as well as certain descriptive terms included in the Panel's recommended list of other allowable statements (recommended § 351.56(c)), i.e., safe, effective, powerful, highly) would be outside the scope of a monograph, if one were being established. Because all OTC vaginal contraceptive drug products will require an approved application for marketing, such claims can be evaluated, during the approval process, on a product-by-product basis for compliance with section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading.

22. After reviewing the Panel's recommended labeling, the agency has tentatively determined that the following additional changes in the Panel's recommendations are warranted. Although the Panel recommended ''spermicide'' as an indication, the agency believes that it would be more appropriate as an optional statement of identity. In addition, although the Panel recommended a number of indications statements, the agency believes that the indication ''For the prevention of pregnancy'' is sufficient to convey to consumers the intended use of the product. The agency has also tentatively determined that the statement ''If your physician has told you that you should not become pregnant, ask your physician if you can use this product for contraception,'' should be a warning instead of a direction statement.

D. Comments on Combinations

23. One comment objected to the Panel's statement at 45 FR 82014 at 82026 that if two or more Category I vaginal contraceptive active ingredients are combined, the specific ingredients as well as the combination product must be subjected to laboratory and clinical testing according to the recommended testing guidelines. The comment argued that no useful purpose is served or information gained by clinical testing of single Category I ingredients and that such testing is not required under FDA's OTC combination policy.

As discussed in section I. D., comment 25 of this document, testing guidelines for conditions that industry wishes to upgrade to monograph status will not be included. However, criteria for establishing combinations of OTC drugs as generally recognized as safe and effective are provided in 21 CFR 330.10(a)(4)(iv). Guidance on OTC combination drug products has also been provided in the agency's General Guidelines for OTC Drug Combination Products (Ref. 1). Thus, two or more safe and effective OTC vaginal contraceptive active ingredients may be combined provided the final formulation of the product meets the combination policy in all respects. The Panel did not include any contraceptive combinations in its monograph because the data were insufficient for any of the combinations that were reviewed to be generally recognized as safe and effective. The agency concurs with the Panel's decision. Furthermore, as noted in section I. A., comment 3 of this document, the agency is proposing to require that all combination or single-ingredient OTC vaginal contraceptive drug products be subject to approved applications prior to marketing.

Reference

1. Food and Drug Administration, ''General Guidelines for OTC Drug Combination Products, September 1978,'' Docket No. 78D–0322, Dockets Management Branch.

24. One comment stated that the data on which the Panel based its Category II classification of the combinations: (1) Phenylmercuric acetate and boric acid; (2) phenylmercuric acetate, boric acid, and nonoxynol 9; and (3) phenylmercuric acetate, octoxynol 9, and sodium borate show that these combinations were so classified because of ''hazards'' associated with the use of phenylmercuric acetate rather than with the use of boric acid or sodium borate (Refs. 1 through 6). The comment added that it appears that the use of borates in vaginal contraceptives is for ''pH control.'' The comment also noted that boron compounds were listed as inactive ingredients in the Panel's report (45 FR 82014 at 82042) and were not placed in Category II, as were mercury-containing compounds.

The agency agrees that boron compounds should not have been included as active ingredients in the listing of Category II combinations. The submissions of data on OTC vaginal contraceptive drug products containing boron compounds (Refs. 1 through 6) indicate that the boron compounds are included in these products as

pharmaceutical necessities or preservatives and not as active ingredients.

References

1. OTC Vol. 110004.
2. OTC Vol. 110005.
3. OTC Vol. 110006.
4. OTC Vol. 110017.
5. OTC Vol. 110018.
6. OTC Vol. 110021.

E. Comments on Testing Guidelines

25. Numerous comments criticized the safety and effectiveness testing guidelines recommended by the Panel to upgrade a vaginal contraceptive ingredient from Category III to Category I (45 FR 82014 at 82020 and 82043). Generally, the comments stated that the guidelines are unclear, needlessly specific, unnecessary, or based on unsound logic. Some of the comments subsequently proposed using alternative testing methods, while others urged elimination of certain methods.

The agency has not addressed specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. However, in view of the agency's determination that all OTC vaginal contraceptive drug products should be the subject of approved applications prior to marketing, interested parties can use that forum to meet with the agency to discuss appropriate testing procedures, and the comments do not need to be addressed in this document. Also, elsewhere in this issue of the **Federal Register**, the agency is announcing the availability of a guidance document that is intended to help manufacturers of vaginal contraceptive drug products develop data in support of new drug applications.

II. The Agency's Tentative Conclusions on OTC Vaginal Contraceptive Drug Products

Dodecaethyleneglycol monolaurate, laureth 10S, methoxypolyoxyethyleneglycol 550 laurate, nonoxynol 9, octoxynol 9, phenylmercuric acetate, and phenylmercuric nitrate have been present as ingredients in OTC vaginal contraceptive drug products. Based on the available evidence, the agency has determined that clinical studies in humans are necessary to establish the effectiveness of final formulations of vaginal contraceptive drug products and, therefore, any drug product that is labeled, represented, or promoted for use as a vaginal contraceptive is regarded as a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)), for which an approved application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 of the regulations is required for marketing. In the absence of an approved application, such a product also would be misbranded under section 502 of the act (21 U.S.C. 352).

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order, and thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. There are a limited number of OTC vaginal contraceptive products that are not marketed for use with a condom, diaphragm, or contraceptive cervical cap. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC vaginal contraceptive drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC vaginal contraceptive drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on vaginal contraceptive drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In the **Federal Register** of December 12, 1980 (45 FR 82014 at 82047), the agency proposed that the monograph for OTC vaginal contraceptive drug products be included in subpart A of new part 351 of Title 21 of the Code of Federal Regulations. In the **Federal Register** of October 13, 1983 (48 FR 46694 at 46727), the agency proposed that a monograph for OTC vaginal drug products be included in subpart B of part 351. The current proposal supersedes subpart A of part 351 and, if finalized as proposed, Part 310—New Drugs would be amended to include OTC vaginal contraceptive drug products.

Interested persons may, on or before June 5, 1995 submit to the Dockets Management Branch written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before June 5, 1995. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before February 5, 1996, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before April 3, 1996. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations

for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final rule for OTC vaginal contraceptive drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on April 3, 1996. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final rule for OTC vaginal contraceptive drug products is published in the **Federal Register**, unless the Commissioner finds that good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.535 is added to subpart E to read as follows:

§ 310.535 Drug products containing active ingredients offered over-the-counter (OTC) for human use as a vaginal contraceptive.

(a) Dodecaethyleneglycol monolaurate, laureth 10S, methoxypolyoxyethyleneglycol 550 laurate, nonoxynol 9, octoxynol 9, phenylmercuric acetate, and phenylmercuric nitrate have been present as ingredients in OTC vaginal contraceptive drug products. The evidence currently available shows that clinical studies in humans are necessary to establish the effectiveness of nonoxynol 9 and octoxynol 9 in final formulation for use in OTC vaginal contraceptive drug products. There are inadequate data to establish the safety and effectiveness of any other ingredients offered for use as OTC vaginal contraceptive drug products.

(b) Any drug product that is labeled, represented, or promoted for OTC use as a vaginal contraceptive is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use as a vaginal contraceptive is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) After (date 12 months after date of publication in the **Federal Register** of the final rule), any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

Dated: January 10, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 95–2631 Filed 2–2–95; 8:45 am]

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Friday
February 3, 1995

Part IV

Department of Transportation

Office of the Secretary
Federal Aviation Administration

14 CFR Part 302

Policy Regarding Airport Rates and Charges; and Rules of Practice for Proceedings Concerning Airport Fees; Notice and Final Rule

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Federal Aviation Administration

[Docket No. 27782]

Policy Regarding Airport Rates and Charges

AGENCY: Office of the Secretary and Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Policy statement; request for comments.

SUMMARY: This document announces DOT and FAA policy on the fees charged by Federally-assisted airports to air carriers and other aeronautical users. The statement of policy was required by the Federal Aviation Administration Authorization Act of 1994, Public Law 103–305 (August 23, 1994). While the policy stated in this document is effective immediately, the Department is requesting further comment on the policy adopted because of substantial industry interest in the proposed policy and because the final policy adopted differs in several respects from the proposal, in response to comments received on the proposal.

DATES: Comments must be received by May 4, 1995.

ADDRESSES: Comments should be mailed, in quadruplicate, to: Federal Aviation Administration, Office of Chief Counsel, Attention: Rules Docket (AGC–10), Docket No. 27782, 800 Independence Avenue, SW., Washington, DC 20591. All comments must be marked: ''Docket No. 27782.'' Commenters wishing the FAA to acknowledge receipt of their comments must include a preaddressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 27782.'' The postcard will be date stamped and mailed to the commenter.

Comments on this Notice may be examined in room 915G on weekdays, except on Federal holidays, between 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: John Rodgers, Director, Office of Aviation Policy, Plans and Management Analysis, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591, telephone (202) 267–3274; Barry Molar, Manager, Airports Law Branch, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–3473.

SUPPLEMENTARY INFORMATION: On June 9, 1994, the Office of the Secretary of Transportation (OST) and the FAA issued two related notices on the subject of Federal policy on airport rates and charges. A notice of proposed policy entitled ''Proposed Policy Regarding Airport Rates and Charges'' listed and explained the principles that the Department believes define Federal policy on the rates and fees that an airport proprietor can charge to aeronautical users of the airport. Docket No. 27782 (59 FR 29874, June 9, 1994). Notice 94–18, a notice of proposed rulemaking entitled ''Rules of Practice for Federally Assisted Airports,'' proposed detailed procedures for the filing, investigation, and adjudication of complaints against airports for alleged violation of Federal requirements involving rates and charges and other airport-related requirements (59 FR 29880, June 9, 1994).

The FAA Authorization Act of 1994, Public Law 103–305 (1994 Authorization Act) was signed into law on August 23, 1994. In response to provisions in the 1994 Authorization Act that specifically address airport rates and charges, the Department issued a supplemental notice of proposed policy with revisions to reflect relevant provisions of the Act. (59 FR 51835, October 12, 1994). The relevant provisions of the 1994 Authorization Act were summarized in the October 12 notice.

The 1994 Authorization Act also required that the Secretary issue two other documents relating to airport fees and finances: first, procedural rules for the resolution of disputes between air carriers and airport owners and operators regarding airport fees; and second, policies and procedures for the enforcement of Federal restrictions on the use of airport revenue. The procedural rules are being published in the **Federal Register** on the same date as this Policy Regarding Airport Rates and Charges; the policies and procedures on revenue use and revenue diversion will be published within the next several weeks.

Summary of Policy Statement

The policy statement being adopted retains the structure of the proposed policy, and is organized into five general principles with supporting guidance for each. In brief, the first principle establishes the continued reliance on direct local negotiation between airports and aeronautical users. The Department is available to resolve the issues raised in a dispute when the airport and aeronautical users are unable to resolve disputes directly.

The second principle restates the legal requirement that rates, fees and charges to aeronautical users must be fair and reasonable, with more detailed guidance on the practices and restrictions that define ''fair and reasonable.'' The guidance for this principle incorporates flexibility to deviate from the proposed policy guidance based on agreement with aeronautical users; recognition that both compensatory and residual pricing approaches are legitimate; standards for the valuation of airport property in establishing rates; prescription of the kinds of costs that can be reflected in the rate base for aeronautical users; and guidance on subsidization of other airports. The policy makes certain distinctions in the reasonable accommodation of air carriers versus other aeronautical users, and does not establish fee standards for rates and charges for nonaeronautical users or limit the amount of revenues generated by nonaeronautical rates and charges.

The third principle restates the legal prohibition on unjustly discriminatory rates and charges.

The fourth principle restates the legal obligation of the airport sponsor to maintain a fee and rental structure that makes the airport as self-sustaining as possible. Supplemental guidance encourages the sponsor of an airport that is not currently self-sustaining to establish long-term goals and targets to make the airport financially self-sustaining. While the requirement that an airport be as self-sustaining as possible under the circumstances existing at the airport is required by statute to be included in each sponsor's grant assurances, and is subject to enforcement by the FAA in accordance with its grant compliance procedures, it is not the intent of the Department that this requirement alone be the grounds for a complaint as to the reasonableness of an airport fee.

The fifth principle restates the basic legal requirements for the application and use of airport revenues. Supplemental guidance on the use of airport revenue has been deleted from the statement of policy on airport fees, and instead will be incorporated in a separate statement of policy on the enforcement of the revenue use provisions of the Airport and Airway Improvement Act of 1982 and the 1994 FAA Authorization Act.

Comments on the Notices of Proposed Policy

The Department received more than 150 comments on the Notice and Supplemental Notice of Proposed Policy. Comments were received from all segments of the airport community, including airport operators and representative organizations;

associations representing air carriers and commuter airlines; representatives of other aeronautical businesses at airports; general aviation representatives; representatives of airport concessionaires; aviation consultants and law firms; and the staff of the Bureau of Economics of the Federal Trade Commission. Many of the comments from airport operators and representatives were similar, and all of the comments tended to focus on certain issues. Accordingly, the following discussion of comments is organized by issue rather than by commenter. Issues are grouped by their applicability generally or to one of the five principles stated in the policy. Airport proprietors and representatives who took the same position on an issue are collectively referred to as ''airports;'' the Air Transport Association (ATA) and other air carrier commenters are referred to as ''air carriers.'' The summary of comments is intended to represent the general divergence or correspondence in industry views on various issues, and is not intended to be an exhaustive restatement of the comments received. All comments received were considered by The Department even if not specifically identified in this summary.

Discussion of Comments Received

The final policy statement includes an expanded introduction that reflects the discussion below.

1. General: Scope of Policy and Procedures

A. Should the policy apply to all aeronautical users or just air carriers?

Airports commented that policy and related procedures should apply only to rates and charges imposed on air carriers. The policy is mandated by § 113 of the 1994 FAA Authorization Act; based on the terms of § 113, the policy should be limited to air carriers. If new policy guidance is needed for fees assessed on other aeronautical users, the issue should be addressed separately. The American Association of Airport Executives (AAAE) and some individual airports specifically objected to the inclusion of foreign air carriers. Commenters suggested that automatic inclusion of foreign air carriers would provide them with valuable rights ordinarily secured through negotiation of intergovernmental agreements.

General aviation commenters stated that the Department should provide the same rights and protections for all aeronautical tenants, not just air carriers. However, the policy should reflect differences in the relationships between air carriers and airports and those between other aeronautical businesses and airports. In particular, more access to evidentiary hearing procedures should be available to non-carrier complainants than proposed by the Department.

In the policy adopted, the Department has continued to apply the policy to rates and charges assessed against all aeronautical users. Existing grant assurances obligate airport proprietors to give access on fair and reasonable terms to all types, kinds, and classes of aeronautical uses. However, where differences exist as a practical matter between air carriers and other kinds of aeronautical users, those differences have either been reflected in the guidance stated in the policy, or the policy will be applied with sufficient flexibility to reflect those differences. Some commenters noted that § 113 of the 1994 Authorization Act applies only to air carriers and argued that the policy statement should be similarly limited. However, § 113 relates only to the procedures for special handling of airport-airline fee disputes; it does not define limits on the applicability of policy.

The policy adopted applies to foreign air carrier rates as well as those imposed on domestic air carriers. The principles and guidance contained in the policy statement are consistent with the provisions of bilateral air service agreements, and the application of the same policy on fair and reasonable airport fees to both foreign and U.S. air carriers is appropriate.

B. Should the policy and procedures apply to rates excluded by section 113?

Airports commented that the policy and implementing regulations should clearly exclude rates and charges specifically excluded by the statute, e.g., rates established by agreement; Congress directed that the policies and procedures not apply to such excluded rates; in addition, the policy should reflect § 47129(f), which states that that section shall not adversely affect the rights of any party under any existing written agreement between an airport and air carrier or the ability of an airport operator to meet its debt obligations.

Air carriers commented that the policy should recognize that it is common for airports to increase fees by asserting that the increase is a routine adjustment to a preexisting agreement, even if the agreement does not allow for such an increase; therefore; the policy should make clear that a dispute as to whether a fee increase is within the terms of a contract or not should be covered by the policy to the same extent as a fee increase imposed in the absence of any agreement.

The policy statement adopted applies to all fees charged to air carriers for aeronautical uses, although the policy itself makes clear that carriers and airport operators have wide latitude to agree on alternate arrangements. The rules for implementation of the dispute resolution procedure provided in § 113 of the 1994 Authorization Act clarify that expedited ALJ procedures will be not be applicable to rates and charges excluded by § 113. However, The Department will consider claims that a fee is not covered by the exclusion because it was not in fact ''imposed pursuant to a written agreement,'' even if a written agreement is in effect. Also, claims that are not subject to the § 113 dispute resolution procedure technically may still be brought under 14 CFR Part 13, which applies to complaints that an airport proprietor has violated the grant assurance that rates and charges for aeronautical users will be fair and reasonable.

C. Should the policy and procedures apply differently to different uses of the airport facilities by air carriers?

Several airports commented that elements of the policy may be appropriate when applied to the airfield and terminal, but would not be appropriate if applied to other facilities leased or used by carriers on the airport. The Department agrees, and the policy adopted makes distinctions, where applicable, between various kinds of facilities on the airport.

D. What airport users/tenants are included within the term ''aeronautical users''?

Airport commenters in particular stated that the term aeronautical user was not clearly defined, and that it was not clear whether the policy applied to certain businesses commonly found on an airport but which arguably are not ''aeronautical'' in nature. Also, representatives of concessionaires who commented on the proposal conceded that concessions such as car rentals were not aeronautical activity, but argued that the rates and charges policy and dispute resolution procedures should apply to concessions.

The final policy statement does not substantially differ from the proposal. The Department believes that in most cases it is immediately clear whether a particular airport business is an aeronautical activity or not within the definition given in the policy. Where an ambiguous situation exists, an airport operator or airport user may contact the FAA Office of Airport Safety and Standards, AAS–300, for a determination.

2. General: Proprietary Powers of Airport Operators

Airports commented that the policy adopted must preserve the airport's right, as landlord, to set fees and charges when consensus is not possible. If the policy establishes narrow federal standards, it would eliminate incentives to set fees and resolve disputes at the local level. Policies should not be so rigid as to stifle innovation that may lead to more efficient financing and management of airport facilities.

Airports argued that the Department especially should not allow carriers to invoke the policy to challenge the wisdom of particular infrastructure enhancement or airport expenditures. Such an outcome would be perceived in the capital market as shifting management prerogatives away from the airport and would result in higher financing costs. The policy, airports argued, should make clear that a fee to cover debt service for a completed project cannot be challenged as unreasonable after the project comes on line and the debt service costs are added to the rate base.

Airports are operated by state or local governmental entities to meet community and national needs. Prior Department statements, including the Government's *amicus curiae* brief to the Supreme Court in *Northwest Airlines* v. *County of Kent, Michigan* (510 U.S. _____; 114 S.Ct. 855; 127 L. Ed. 2d 183 (1994) ''*Kent County*'') and Secretary Peña's December 1993 letter, recognize that airport proprietors have latitude to set fees to meet immediate and longer-term needs of airports. Actions of state and local government are presumed at law to be reasonable and lawful. This same presumption, the airport commenters argued, should apply to the establishment of rates and charges, even when imposed unilaterally by a proprietor through ordinance or regulation. The Supreme Court, in the *Kent County* litigation, recently reaffirmed the standard of reasonableness first enunciated in the *Evansville* decision; this standard afforded substantial deference to the airport proprietor. Airport commenters further argued that in keeping with the presumption of validity, air carriers filing complaints under § 113 of the FAA Authorization Act should bear the burden of proving unreasonableness.

ATA stated that airports possess monopoly power, which in recent years has not been kept in check. Section 113 of the 1994 FAA Authorization Act was enacted to respond to this potential monopoly power by providing for active DOT involvement in airport-carrier disputes, ATA argued, and airports should not be permitted to adopt new fees unilaterally after failing to reach a consensus; such a policy would give airports carte blanche to impose an unreasonable fee.

General aviation representatives commented that at hundreds of general aviation airports operated by local governments, unreasonable economic requirements can be imposed without effective challenge.

In light of the enactment of § 113, the Department believes that it is not at all clear that the presumption of validity normally associated with governmental actions applies to the imposition of airport fees on air carriers. Even before enactment of § 113, some judicial decisions recognized that the traditional presumption may not apply in cases of airport rate-setting. See, for example, *Raleigh-Durham Airport Authority* v. *Delta Air Lines,* 429 F. Supp. 1069, 1083 (D.N.C., 1976); *New England Legal Foundation* v. *Massachusetts Port Authority,* 883 F.2d 157, 169 (1st Cir. 1989) (*Massport II*). In *Kent County,* the Supreme Court applied the relatively deferential standard of the *Evansville* decision in part because the parties invited its use, and the Court noted that the Secretary had discretion to ''apply some other formula (including one that entails more rigorous scrutiny).'' *Kent County,* at _____, n. 14. The policy adopted does not expressly affirm or displace the presumption of validity that may apply to local government actions. In response to comments relating to challenge of project decisions, the Department considers the dispute resolution process to apply to significant disputes actually related to fees, and do not intend to make the process available to challenge particular capital construction projects after the fact under the guise of challenging the reasonableness of associated rates and charges.

3. Local Negotiation and Consultation

Air carriers requested that the final policy include a more specific description of the information that airports are expected to provide to carriers in connection with a fee increase, and one carrier suggested that consultations and information exchange be required rather than just encouraged.

Airports commented that the statement that consultations should be conducted well in advance of changes to fees did not acknowledge that local governments must sometimes act quickly, to avoid revenue shortfalls or for other reasons.

The Department has included, in an appendix to the final policy statement, a brief list of the information that the Department believes would provide carriers the justification for a particular fee and sufficient information to assess the reasonableness of the fee. The information, in summary, is historic financial information for the two years prior to the change in the fee at issue; economic, financial and/or legal justification for the change; aeronautical cost information; numbers of passengers and aircraft operations for the two preceding years; and certain planning and forecasting information. The list is general, for adaptability to different airport and local government accounting and recordkeeping, and is not intended to include every category of information that may be relevant to each fee dispute.

The procedural rules adopted for the resolution of airport-air carrier fee disputes address the exchange of information. Following a complaint under 49 U.S.C. § 47129, if the airport proprietor has not previously made that information available to carriers, the rules provide for discovery. The Department has not acted to require disclosure of information on a fee increase by regulation, but the agency will reconsider that decision if experience indicates that airports are not providing sufficient information to carriers during consultation on fee increases.

In the statement on the timing of consultations, the Department has inserted ''if practical'' in the language suggesting consultation well in advance of a fee change. Finally, in response to the recommendation by several commenters for arbitration or mediation clauses in leases, the Department has added language encouraging the use of alternate dispute resolution in lease and use agreements.

4. Fair and Reasonable Rates: Compensatory and Residual Costs Methodology

Airport commenters generally supported the policy approach that recognizes the discretion of an airport proprietor to establish compensatory or residual methodology, or a combination of the two. Airports also generally accepted the policy that airports could not unilaterally impose a residual system absent carrier agreement, although two commenters suggested that § 113 gives an airport proprietor a right to impose a residual costing methodology even absent agreement.

Air carriers stated that the policy must deal realistically with the fact that excessive revenues can and will be generated by an airport's shifting of all costs to airlines and all profits to itself; the policy should not exclude from

consideration revenues derived from activities such as concessions and parking, which are also the product of aviation activities. Failure to consider such revenues to be ''aviation related,'' carriers argued, is inconsistent with the requirement in § 110 to take all airport revenue into consideration in setting aeronautical fees.

The Department has retained the policy as proposed. The approach requested by ATA was specifically rejected by the Supreme Court in the *Kent County* decision, and § 113 expressly preserves an airport proprietor's right to use a compensatory methodology, which does not require carrier agreement or the cross-crediting of concession revenues. Moreover, § 110 recognizes that airports may depend on revenue generated from non-aeronautical uses for airport capital improvements and other airport system purposes. Accordingly, the policy adopted does not define concessions and parking as aeronautical revenue or require the cross-crediting of concession revenue to carriers. However, as discussed below, terminal costs and other shared costs must be allocated fairly among aeronautical and nonaeronautical users.

5. Fair and Reasonable Rates: Allowable Capital Costs

Airports commented that capital costs allowed in the rate base should specifically include such ''indirect'' costs as debt coverage, cash and capital reserves, and allocation of some airport capital expenditures, *e.g.*, roadways, in the carrier rate base.

ATA did not comment specifically on what capital expenditures should be allocated to aeronautical users, but expressed concerns that airport proprietors are seeking unconstrained rights to generate ''excessive surpluses'' based on airport proprietors' assertions that adequate reserves are necessary.

The final policy clarifies that the reserves and coverage required in bond indentures and other debt instruments, as well as reserves to cover normal income fluctuations and unforeseen contingencies, may be included in the rate base. The final policy statement also clarifies policy regarding what some commenters referred to as ''indirect'' capital expenditures, which the Department understands to refer to airport facilities that support aeronautical use of the airport but which also receive nonaeronautical use, such as airport roads and fire-rescue facilities. The policy provides that costs allocable to both aeronautical and nonaeronautical uses, or shared costs, may be included in a particular rate base if the facility at issue supports the aeronautical activity being charged, and the allocation to aeronautical users is in proportion to the aeronautical purpose and use of the facility.

For example, the costs of roadways on the airport that provide public access to the passenger terminal could not be charged entirely to any class of aeronautical users. However, a portion of roadway costs could be included in the rate base for the terminal building, for example, so long as the portion of the shared costs allocated to terminal users does not exceed an amount that reflects the respective aeronautical and nonaeronautical use of the same facility. The Department does not expect the use of any particular formula for the determination of aeronautical portion of shared costs, because the circumstances may vary. For example, an airfield crash-fire-rescue facility may exist primarily to support Part 121 air carrier operations, but may actually be used primarily for landside public emergency calls. An airport proprietor must be able to justify the reason for the allocation used.

6. Fair and Reasonable Rates: Imputed Interest and Rate of Return

Airports argued that the final policy should expressly provide that while the rates charged to aeronautical users cannot exceed costs of providing services, those costs should be considered to include a reasonable rate of return on investment; the return should apply to all internally generated funds, regardless of source; a reasonable rate of return would permit an airport proprietor to accumulate cash reserves, which may be necessary as a condition of financing agreements and to compensate a proprietor for the risk of undertaking a particular investment; and allowance of rate of return will assure that the Department's policy is consistent with Article 10 of the United States-United Kingdom Air Services Agreement (''Bermuda 2''), which permits a competent charging authority to recover a reasonable return. Airport commenters further argued that airport proprietors should be permitted to recover the implicit cost of capital for internally generated funds without regard to source, aeronautical or nonaeronautical; in addition, the rate allowed should be the highest of either the rates of return available on the proprietor's investment at the time of the capital expenditure (lost investment opportunity rates) or the cost of borrowed funds available to the airport proprietor at the time of the expenditure; rates prevailing on bonds at similarly-sized airports is not appropriate because other airports may have different credit ratings and, therefore, different capital costs.

ATA argued that routine inclusion of ''implied capital costs'' is inconsistent with the concept of dedicated aviation resources; an airport should not be allowed to collect interest for use of its own reserves; allowance of implied capital costs is a device to generate more revenue than is needed for airport purposes in violation of the congressional direction that airports should not seek to accumulate excessive reserves.

The final policy adopted by the Department continues to permit the charge of imputed interest on the expenditure of airport funds generated from non-aeronautical sources, but not on those generated from aeronautical uses. While ATA is correct that all reserves must generally be used for airport purposes, Federal law does not require that the funds be used for aeronautical activities. Therefore, an airport decision to fund an aeronautical activity is an investment choice that benefits aeronautical users, and the reasonable costs of that investment, including imputed interest, are appropriately recoverable in the aeronautical rate base. The policy provides that the borrowing rate, rather than interest obtainable, is the appropriate measure of reasonable imputed interest for a public entity.

The Department does not agree with the comment that imputed interest should be allowed for the use of funds generated by aeronautical uses. First, a rate of return or imputed interest on the use of aeronautical revenues is not necessary for bond coverage and other reserves, because the policy adopted expressly allows the establishment of such reserves as a direct cost. Second, the use of any reserves generated from aeronautical revenues does not carry with it any implicit cost to the airport for the use of capital, since the reserve was generated by direct charge to users; the Department sees no justification for an additional charge for the use of these funds for the purposes for which they were collected.

To the extent that airports would justify a particular rate of return policy on the basis of bilateral agreements such as Bermuda 2, that reliance is misplaced; Bermuda 2 does not obligate the United States to permit its airports to earn a rate of return; rather the provision requires that each country recognize the other's authority to permit its airports to earn a rate of return on assets, after depreciation, to the extent provided by the domestic law of each country.

7. Fair and Reasonable Rates: Allowable Environmental Costs

Airport commenters stated that the proposed limitation of allowable costs to reasonable environmental costs should be stricken; the costs of compliance with all Federal, state, and local environmental mandates, including clean air and clean water requirements, mitigation required to obtain approvals for development projects, and all expenditures for noise mitigation should be includable in the rate base; the policy should clarify that mitigation (such as wetlands replacement) may occur on or off airports. Also, airports argued, because the airport proprietor is liable for noise damages, the sponsor's judgment in developing a noise mitigation program should be given deference. Airport commenters also argued that the limitation to *current* expenditures for environmental costs should be removed; airports should have discretion to include in the rate base reserves to fund any future liability for cleanup of environmental contamination likely to result from current operations.

The carrier view is that airport proprietors should not be permitted to prefund future environmental liability for environmental remediation, other than through documented self-insurance requirements, subject to standard industry conventions and practices.

The final policy statement adopted by the Department adds language clarifying that the following environmental costs, to the extent actually incurred by the airport proprietor, will be presumed to be reasonable costs:

- Costs of complying with Federal, state, and local environmental laws and regulations, provided that, in the case of local requirements, such requirements are applied to other similarly situated enterprises (to avoid possible impermissible use of airport revenues).
- Mitigation requirements on or off airport associated with airport development (for aeronautical use).
- Noise mitigation pursuant to an approved Part 150 program or other publicly-disclosed airport noise compatibility program;
- Costs of insurance or self-insurance for correction or cleanup of environmental damage. The Department agrees with carrier comments that considerations of forward financing of environmental cleanup costs do require some limitation on the charge to current users, and the policy limits self-insurance costs to costs incurred pursuant to a formal self-insurance program that meets applicable insurance industry standards.

8. Fair and Reasonable Rates: Facilities Currently in Use

Airports asserted that the only restriction in current law is that costs must relate to the development or improvement of an existing airport; the restriction to the costs of facilities in use is overly restrictive and not supported by law. Airports argued that land and construction costs should be recoverable before a facility is in use; the proposed policy does not even clearly permit recovery of costs for borrowing to finance improvements until project completion, which could lower bond ratings and postpone land acquisition, thereby increasing project costs.

Comair praised the currently-in-use limitation on the grounds that it would impose needed discipline on airport expansion policies that show little regard for airline profitability.

The Department continues to believe that the traditional approach of limiting recovery of costs to facilities in use is clear, easy to administer, widely accepted, and supported by judicial decisions. Accordingly, the final policy statement continues to provide that only the costs of facilities currently in use may be included in the rate base; financing costs incurred for construction, including debt service and reserves, may be recovered at the time a facility comes on line. Users may, of course, agree to incur present costs for a future facility. The policy continues to provide that current costs of planning for future facilities may be recovered as they are incurred.

9. Fair and Reasonable Rates: Asset Valuation

Airport comments: Airports commented that the proposed limitation on valuation of airport property to historic cost is unduly restrictive; is not required by existing legal interpretations; is inconsistent with existing airport practice and Department policies; is inconsistent with the objective of promoting efficient use of resources; and could interfere with the successful implementation of peak period pricing. Commenters stated that airports typically use various asset valuation methods for their assets, including current cost, fair market value, or the use of inflation indices (although few individual airport proprietors claimed to be using other than historical valuation). In addition, rates and charges for many aeronautical assets are based on percentage of gross revenue. The use of indices and gross revenue formulas is not generally expected to result in rates and charges that reflect historical cost asset valuation.

For many assets that are fully depreciated, including terminals, the use of historic cost valuation would result in a subsidy to carriers in the form of rental rates that did not reflect the value of the facilities. In addition, a strict historic cost requirement could expose airports to claims of unjust discrimination if carriers using newer facilities are charged more than carriers using older facilities that are fully depreciated. At a minimum, some airports urge that the policy make clear that blending of asset values is permitted to avoid this problem.

Further, airports claimed that the use of historic cost valuation may distort the perception of the relative value of existing and new facilities. A new facility may fail the test of economic feasibility based on the disparity between fees based on historic costs of the original facility and those based on current costs of a new facility. Moreover, in the case of gates and other terminal facilities and other facilities such as hangars or flight kitchens, air carriers themselves recognize the value of the facilities by subleasing at rates higher than historic value. A policy requiring airports to value their facilities at historic value would allow airlines to enjoy a windfall in the form of a differential between the market rates they can obtain for subleases and rates paid to the airport based on historic cost. The public interest would be better served, airports argued, if the airport proprietor were able to capture this appreciation through market-based rates and to apply the proceeds for the development of airport infrastructure.

It was also argued that historic cost valuation could limit the effectiveness of peak period pricing. If an airport is unable to reflect the opportunity costs of its scarce assets in its rate base, the maximum peak price that can be charged may not be enough to cause traffic to shift away from the peak period.

The proposed historic cost requirement, in the airports' view, is not supported in law or FAA policy. Decisional law is clear that results, not methodology, are significant in determining reasonableness. In addition, under the *Evansville* standard, a rate is considered reasonable if based on some fair approximation of use and not excessive in comparison with the government benefit conferred. A rate based on the standard of ''benefit conferred'' will in most cases be different from rate based on a facility's historic cost.

Airports also pointed to FAA policy statements that apparently support alternative valuation methods. FAA's Order 5190.6A recommends that long term leases include automatic escalation provisions based on recognized economic indicators. In addition, the Order identifies a fee for use of landing areas based on a specified percentage of ticket sales to enplaning passengers as acceptable. Neither of these methodologies would produce rates based on historic costs.

Finally, airports stated that the DOT Office of the Inspector General (DOT/OIG) has criticized the failure of airports to obtain fair market value for aeronautical rentals. The DOT/OIG position indicates that use of methodologies other than historic cost is at least permitted, if not mandated by assurances relating to maintaining a fee and rental structure that will make the airport as self-sustaining as possible.

Air carrier comments: Air carriers considered the concept of using historic costs for asset valuation to be sound and consistent with Federal law. While parties might mutually agree to another valuation method, the policy must provide that only historic cost valuation may be unilaterally used, to protect against rampant overcharging and accumulation of excess surpluses by airports. Airports have access to capital for replacement of assets without generating excess revenue from other valuation methodologies. The use of historical cost valuation is quickly and easily verifiable and eliminates instability in the rate base.

FTC comments: The staff of the Bureau of Economics of the Federal Trade Commission (FTC) submitted comments on the proposed policy, with the caveat that the comments do not necessarily represent the views of the Commission or of individual commissioners. FTC staff took the position that the requirement to use historic costs will not promote the efficient use of resources. Historic cost valuation will likely result in prices that are below the value of airport facilities. When prices are below the value of facilities, excess demand results. If a community is served by two airports built at different times and fees are based on historic costs, airlines will be attracted to the older, lower-cost airport and avoid the newer, more expensive one. Demand at the older airport would have to be rationed by nonprice means.

Carriers compete by offering connecting service over various hubs. Because fees charged by hub airports are a determinant of air fares, it is important that competition between carriers not be distorted by a pricing system for airport services that reflects the age of facilities, rather than true economic costs.

FTC staff recognized that airport services are not generally produced in competitive markets. Therefore, airport proprietors might possess monopoly market power in pricing their services. However, FTC staff maintained that there are effective means for the Department to regulate the pricing of airport services other than cost of service pricing based on historic costs.

While cost-of-service regulation based on historic costs has typically been used in the United States, FTC staff commented that this approach has a number of defects. Failure to use a pricing system that reflects opportunity costs could lead to greater levels of airport capacity than is warranted by economic efficiency, as excess demand leads to congestion and delays which in turn lead to calls for new capacity.

Even if a cost basis other than historic costs is used, FTC staff believed that cost-of-service regulation can be a source of economic inefficiency. One regulatory alternative that addresses some of these shortcomings is price-cap regulation. Under price-cap regulation, the regulator sets a price ceiling, but the firm is free to charge any price below this ceiling. The price ceiling is adjusted periodically by a factor that is independent of the firm. Price cap regulation has been used in the privatization of nationalized industries in the United Kingdom, including airports, and in the telecommunications industry in the United States.

Final policy statement: The final policy retains the historic valuation principle proposed; for property other than airfield and land, however, the policy permits airport operators to use other valuation methods if the methodology does not result in total aeronautical revenues exceeding total aeronautical costs and if the methodology is applied consistently for similar facilities. If an airport proprietor uses valuation other than historic costs for establishing any aeronautical charge, the airport operator will be responsible for demonstrating that the methodology is justified, upon complaint by an air carrier or other aeronautical user. Where similar facilities have a different historic cost basis, the cost may be averaged across all similar facilities to produce a common rate.

The Department recognizes, as many of the airports and FTC staff commented, that valuation based on other than historic cost may be justifiable in certain situations. Nonetheless, we continue to believe that the use of historic cost asset valuation methodology is consistent with the objectives and direction of the AAIA and Public Law 103-305, in addition to being the most widely accepted methodology under applicable standards for both public finance accounting and ratemaking. The financial and accounting standards issued by the Financial Accounting Standards Board and the Government Accounting Board, which form the basis of Generally Accepted Accounting Principles (GAAP), prescribe historic cost valuation as the accepted accounting convention for valuing the assets of local government enterprise functions such as airports. The valuation of assets for purposes of an accurate financial statement is somewhat different from the objective of establishing lease rates, but does indicate the longstanding general acceptance of historic cost valuation as the standard.

As recognized by commenters on both sides of the cost valuation issue, historic cost has also been the standard for use in the establishment of rates in regulated industries. However, as several commenters noted, the rates charged by airport proprietors are not perfectly analogous to public utility rates, and the Department has not strictly applied the principles of public utility ratemaking law in developing the policy. Nevertheless, many of the reasons for the use of historic cost apply to both public and private enterprise activities. Historic cost is the simplest, most direct, and easiest-to-verify measure of cost. Moreover, in a regulatory system in which the proprietor's revenue is limited to the costs of providing services, historic cost valuation provides for full reimbursement of actual costs incurred by the proprietor. The airport fee policy adopted by the Department does limit the revenue that can be generated from aeronautical uses to the costs of providing services, and historical cost valuation is, therefore, both sufficient and appropriate for determining the amount of revenue (and the limit on reasonable fees) that can be collected for aeronautical uses. The use of an alternative methodology such as replacement cost valuation, for example, would generate funds in excess of past and current costs, and could result in the accumulation of excess funds that could be used for the replacement of the facilities being used or for any other airport purpose. The accumulation of surplus aeronautical revenues for replacement of facilities is not permitted by the policy adopted, which limits charges to recovery of costs for facilities in use. Nor are the surplus funds that

would be generated by replacement cost pricing needed for other purposes, since aeronautical users can be charged directly for the amounts needed to maintain debt service and coverage reserves, working reserves for normal operations, and contingency funds. Also, surplus funds for any airport purpose can be accumulated from revenues generated by nonaeronautical uses, which are not covered by the policy. In summary, historical cost valuation is the most widely used and accepted valuation methodology; it reimburses the airport proprietor fully for costs incurred; and it is consistent with the policy's provision that fees charged to aeronautical users are limited to the costs of services provided.

The Department believes that many of the impacts of historic costs noted by airport commenters would not be as problematic as the commenters suggest. First, historic costs would result in rents substantially below market only where a facility has not been renovated, reconstructed, or replaced for many years. While there are such cases, it would be the exception for airport facilities. Second, increased use of shorter airport leases reduces the instance of potential windfall situations, in which a lessee who pays the airport proprietor a historic cost-based rate is able to sublease at market rates, because the airport proprietor can reallocate the property to the actual user after a shorter time. Third, the policy adopted expressly permits airport proprietors to average the historic cost basis of all property, new and old, in the same general category (e.g., terminal gates). Accordingly, lessees of similar facilities can be charged identical rates regardless of the age and original cost of each facility. Finally, the policy should not result in any significant disruption of existing practice. Historic cost is already the most widely accepted basis for asset valuation; also, existing airport-air carrier agreements and air carrier fees that were not in dispute as of August 23, 1994, are not subject to challenge under the special expedited procedures in any event.

That said, as airport commenters and the FTC staff noted, rates based on historic cost can potentially result in inefficiencies and unintended subsidies. Accordingly, the Department believes that it is reasonable that airport proprietors, where justification exists, have some flexibility to use an asset valuation other than historic cost for the purpose of ratesetting. However, for overall aeronautical fees to be consistent with the provisions of the policy, several limitations will necessarily apply when asset valuation other than historic cost is used to determine some rates. First, aeronautical revenues in the aggregate cannot exceed the cost of aeronautical facilities (valued at historic cost) and services provided, and the use of a valuation higher than historic cost would not increase the total limit on aeronautical revenues since the total cost of aeronautical facilities would continue to be calculated using historic cost. Therefore, charging a market rate not based on historic costs for one category of leased aeronautical facility may require charging less than a full compensatory rate for other facilities used by the same aeronautical users. Second, only historic cost valuation will be considered reasonable for airfield facilities and land. Any potential effects of inefficiency or subsidy would apply particularly to terminal and other landside facilities, which may be exclusively leased. Accordingly, the Department will consider the possibility that a fee based on valuation other than historic cost could be reasonable, but only with respect to facilities other than the airfield, and only to improvements, not land. Finally, because historic cost valuation remains the standard in both public finance accounting and in ratemaking methodology, historic cost asset valuation methodology will be presumed to be reasonable for facilities other than airfield facilities and land. Subject to the general limit on total aeronautical revenue, for facilities other than airfield facilities and land an airport proprietor may demonstrate that an alternate valuation methodology is justified in the circumstances existing at the airport.

The Department believes the policy adopted represents the most reasonable approach to valuation of airport assets, in consideration of the comments received and the policy direction in recent legislation. The policy applies a strict historical valuation standard to core aeronautical use facilities, i.e., the airfield and land. For terminal and exclusively leased areas of the airport the policy permits flexibility in rate methodology and avoids disruption of existing arrangements, while at the same time discouraging accumulation of excess revenues.

The policy adopted is intended to cover the fees for use of aeronautical facilities, and is not intended for strict application to a transfer of assets. The policy applies the general rule that subsequent airport proprietors will acquire the cost basis of assets used in the rate base at the original airport proprietor's historic cost. However, requests for approval of the transfer of airport assets may include requests for deviation from this policy with justification.

FTC staff acknowledged that the monopoly power of airport operators requires some pricing regulation. With respect to the use of price-cap regulation suggested by FTC staff, such an approach does not appear to be feasible. The examples cited by FTC staff represented monopoly or near monopoly regimes where a cap was being set for one, or at most a handful of firms. In contrast, there are more than 400 commercial service airports and thousands of obligated airports that may be subject to the airport fee policy. The Department cannot effectively establish a separate price cap regime for each regulated entity, and it is not clear that the benefits of a price cap regime would be available if the Department were to develop a single industry standard formula. In the U.K. airport context, the British determined different price-cap values for each of the airports covered by the price cap regulation. Finally, the U.S. Government's own experience with price cap regulation of airports in the United Kingdom demonstrates that in order to be effective in preventing excessive returns, price cap regulation must be implemented with care. Among other things, it is important to assure that the base prices relied on do not themselves reflect excessive profits, which in turn makes it necessary to undertake a cost-of-service evaluation of each firm's costs and revenues.

10. Fair and Reasonable Rates: Multiple Airport Systems in the Rate Base

Airports generally commented that it is unduly restrictive to require quantification of the benefits of the secondary airport for inclusion of subsidy costs in the first airport's rate base; benefits will be difficult to quantify, and should be presumed if the airport has been designated as a reliever in the FAA's National Plan of Integrated Airport Systems (NPIAS); also, the blending of rates of multiple airports is an accepted current practice and should continue to be considered reasonable.

The Airports Council International-North America (ACI–NA) requested that common ownership not be a prerequisite of inter-airport cost sharing. ACI–NA notes that FAA permits the transfer of AIP entitlement funds between airports under different sponsorship; there is no reason to impose stricter standards on the airport's own funds, as the benefits of a reliever airport are the same regardless of ownership. AAAE and individual operators of airport systems, including Kansas City and the Metropolitan Washington Airports Authority, agree

with the Department proposal that common ownership be required, but urge that the system proprietor be given wide latitude to blend rates.

Air carriers supported the proposed policy, arguing that while cross-subsidization has at times been troubling, airlines have generally been able to resolve issues at the local level. Carriers stated that the requirement of common ownership should not be eliminated; and commented that it is ironic that airports are interested in subsidizing other airports and at the same time claim insufficient funding to meet their own needs.

The Department has retained the policy as proposed, but have added the clarification that an airport designated by the FAA as a reliever will be presumed to confer a reasonable benefit on users of the primary airport. The Department continues to believe that the best means to assure that benefits of cross-subsidy are commensurate with costs is where cross-subsidy is the result of agreement. In the absence of such an agreement or designation by the FAA as a reliever in the NPIAS, the Department is reluctant to presume that benefit is commensurate, and believe it is reasonable to require that the subsidy reflect a showing of actual benefits.

The requirement for common ownership is retained. The basis for a reasonable fee is the compensation of the airport proprietor for the costs of facilities and services it provides; the proprietor is not providing facilities owned by another sponsor.

The analogy to the transfer of entitlement funds argued by airport commenters is not persuasive. Entitlement funds are Federal funds provided directly to the airport under special criteria for grants, and are not subject to the same standard of reasonableness that applies by statute to any cross-subsidy charged to aeronautical users.

11. Unjust Discrimination: Peak Pricing

Airports supported the recognition in the proposed policy that peak pricing is not per se impermissible; peak pricing can be an effective means of improving efficient use of existing infrastructure. FTC staff also argued that peak pricing would promote economic efficiency and avoid overbuilding of airport assets, and urged that rates during peak periods be permitted to reflect opportunity costs of using scarce resources during peak times.

ATA and the International Air Transport Association (IATA) urged that all references to peak pricing be eliminated; in light of the already complex issues surrounding rates and charges, the Department should not further complicate matters by bringing in extraneous matters in this policy statement. The Regional Airline Association (RAA) commented that peak pricing provides a cloak for unjust discrimination against smaller aircraft operators, since smaller aircraft are less able to absorb the price differential on a per-seat basis; commuter carriers are especially affected because they cannot practically use reliever airports and must schedule during peak times to meet connecting banks of jet operators; peak hour pricing will not expand capacity, and airport operators favor peak pricing because expanding capacity involves facing difficult political and environmental issues.

The National Air Transport Association (NATA) expressed concern that peak-hour pricing language will be used by airports to justify excessive fees to block or severely limit access by general aviation and on-demand charter operators.

The Aircraft Owners and Pilots Association (AOPA) objected to peak pricing, which would only serve to limit and ration capacity. Airline scheduling practices would remain unchanged, with peak prices being absorbed by the airlines system-wide. Noncommercial general aviation operations could be priced out, even though general aviation does not contribute to congestion at most airports; general aviation represents 5 to 10% of total flight operations at large hub airports and in many instances is able to use shorter parallel runways without affecting the long runways used by airlines.

The National Business Aircraft Association (NBAA) also opposed peak pricing, which it argued should not be used as a substitute for capacity enhancement, and should not be imposed with discriminatory impact on small aircraft operators.

The Department has adopted the policy statement essentially as proposed, although the term ''maximize'' efficient utilization of the airport has been changed to ''enhance'' efficient utilization, a more realistic standard. The peak pricing concept stated in the policy is adopted from the Department's decision in the Massport PACE decision (Order and Opinion, December 22, 1988), and represents no change in existing Department policy. Peak pricing is specifically included in the policy statement to clarify that the new policy language on unjust discrimination does not affect the existing policy on peak pricing.

12. Unjust Discrimination: Charging Differential Based on Status as Nonsignatory Carrier

Airports argue that existing practices and policy recognize an airport proprietor's authority to establish reasonable classifications of carriers, for example signatory and non-signatory carriers, and to charge differential rates accordingly. This practice should not be overturned, even if the premiums assessed result in a rate that exceeds allocated costs.

The Department acknowledges the existing practice, and the final policy statement clarifies that reasonable distinctions, such as between signatory and non-signatory carriers (i.e., carriers that respectively have and have not entered into a use agreement with the airport proprietor), are permitted. However, the limit on recovery of total costs would continue to apply.

13. Financially Self-sustaining: Requirement That General Aviation Airports be Self-sustaining

General aviation commenters expressed concern that the proposed policy did not recognize that commercial circumstances at many airports would not support a rate structure that would both make the airport self-sustaining and permit commercial operators at the airport to earn a profit; the policy should not require proprietors of such airports to adopt unreasonably high fees.

The Department agrees that the requested change is consistent with the intent of the proposed policy. The final policy statement includes language to clarify that Federal law does not require each obligated airport to be self-sustaining, and that the Department recognizes that some airports may not be able to achieve a self-sustaining condition.

14. Financially Self-sustaining: Generation of Surpluses

In general, airport comments supported the approach of the policy statement and endorsed the treatment of § 110 of the FAA Authorization Act as a matter under revenue generation, rather than as a matter relating to the reasonableness of fees. Airports note that some other provisions of the policy, for example the proposed historic cost requirement and limitation on rate of return, could hinder an airport in becoming as financially self-sustaining as possible. ACI–NA urged that the policy be modified to recognize that some airports may never be able to achieve self-sustaining status and that some aeronautical activities may be

beneficial to the public even though they do not produce enough revenue to pay fair market value. AAAE stated that the requirement to make the airport as self-sustaining as possible should be treated as the paramount principle in the review of airport fees; the remaining principles and guidance would follow from that statutory directive.

Air carriers found the statement of the self-sustaining principle in the proposed policy to be consistent with existing law, but urged that the requirement to be self-sustaining be defined in a manner that prohibited airports from accumulating massive surpluses.

Several general aviation commenters stated that the requirement to be self-sustaining should be clarified so that airport proprietors are not compelled to adopt unrealistic fee schedules that preclude aviation businesses from operating profitably.

The Department has retained the policy as proposed, but have modified the statement to clarify that an airport must only be as financially self-sustaining *as possible*; that this requirement does not permit an airport proprietor to establish fees that exceed costs associated with aeronautical users; and that an airport proprietor's decision to charge commercially feasible rates below what might be required to break even does not in itself violate the requirement to be as self-sustaining as possible. Language from § 110 of the 1994 FAA Authorization Act regarding the policy on accumulation of surplus, which was included under the use of revenue section of the proposal, has been moved under the self-sustaining principle in the final policy statement.

The Department does not agree with the AAAE comment that the requirement for an airport to be as self-sustaining as possible should be the primary principle for determination of airport fees, and the policy retains the general structure and emphasis of the proposed policy.

15. Use of Airport Revenues: General Approach.

Airports commented that discussion of the use of airport revenue should expressly refer to the grandfather provision of 49 U.S.C. 47107(b)(2); also, proposed paragraph 5.6 should be modified so that actions listed there are not considered to be revenue diversion per se, but only to warrant FAA inquiry about whether diversion is taking place. Airports further requested that the policy alluded to in the preamble—that FAA will consider accumulation of surpluses in awarding discretionary grants—should not be implemented; that policy is not required by § 507(3) of the AAIA and would penalize airports for preserving a sound financial position.

The City of Los Angeles Department of Airports commented that paragraph 5.6 should be clarified to permit airport revenue to be used to directly or indirectly influence use of the airport system, e.g., for promotional activity.

AAAE commented that the detailed discussion of permissible and impermissible uses of airport revenues should be deleted from the policy statement on rates and charges, on the grounds that Congress mandated a separate policy statement; existing paragraphs should be replaced with a simple statement referring to applicable law and a separate FAA policy statement on revenue use. AAAE further requested that the policies and procedures on revenue diversion should be issued through notice and comment rulemaking, in keeping with the severity of potential penalties.

Air carriers generally supported the proposal. IATA commented that paragraph 5.6 should be modified to state that listed practices are to be regarded as a minimum, and that more practices may be added.

The Department agrees with the AAAE recommendation to state agency policy on use of revenue in a separate document dedicated to revenue diversion policy, and not in the statement on airport fees. Accordingly, much of the language in the proposal has been deleted from the final policy statement. The policy does retain a basic statement of the revenue use requirement and a reference to the statute, and also the statement that the FAA may inquire into a progressive accumulation of surplus. As noted previously, language from § 110 of the 1994 FAA Authorization Act regarding policy on accumulation of surplus, which was included under the use of revenue section of the proposal, has been moved under the self-sustaining principle in the final policy statement.

FAA is issuing a separate policy statement on policies and procedures for enforcement against illegal revenue diversion, as required by § 112 of the 1994 FAA Authorization Act. That statement includes the practices that the Department considers to be diversion of revenue, including the four practices listed in § 112. The Department interprets § 112 as requiring the agency to define the listed practices as diversion, if not otherwise grandfathered, and not merely as a basis for inquiry as suggested by airport commenters. The revenue diversion policy statement includes a separate discussion of the ''grandfather provision'' of § 511(a)(12) of the AAIA. The statement also indicates that FAA's policy will continue to be to consider accumulation of surplus funds as one factor militating against award of discretionary grants.

16. Use of Airport Revenues: Policy on Accumulation of Surpluses

Airports commented that the provision that accumulation of reserves may warrant FAA inquiry should be deleted, as should the provision encouraging conversion of airport surplus into airport improvements, because accumulated surpluses provide tangible benefits to airports. As noted, AAAE requested deletion of the entire discussion of the use of airport revenue.

Air carriers argued that an admonition that accumulation of surplus may warrant an inquiry is not strong enough; the provision should be modified to state that accumulation of surplus *shall* trigger an investigation; encouragement of the use of accumulated surpluses to fund non-AIP eligible projects will exacerbate the tendency of airport proprietors to seek excessive revenues for questionable purposes.

The policy adopted includes the language in the proposal, which reflects existing FAA practice and represents a reasonable balance between the airport's interest in maintaining appropriate reserves and the Government's interest in preventing unnecessary accumulation of surplus funds.

Policy Statement Regarding Airport Fees

For the reasons discussed above, the Department adopts the following statement of policy for airport fees charged to aeronautical users:

Policy Regarding the Establishment of Airport Rates and Charges

Introduction

It is the fundamental position of the Department that the issue of rates and charges is best addressed at the local level by agreement between users and airports. By providing guidance on standards applicable to airport fees imposed for aeronautical use of the airport, the Department intends to facilitate direct negotiation between the proprietor and aeronautical users and to minimize the need to seek direct Federal intervention to resolve differences over airport fees.

Applicability of the Policy

A. Scope of Policy

Under the terms of grant agreements administered by the FAA for airport improvement, all aeronautical users are

entitled to airport access on fair and reasonable terms without unjust discrimination. Therefore, the Department considers that the principles and guidance set forth in this policy statement apply to all aeronautical uses of the airport. The Department recognizes, however, that airport proprietors may use different mechanisms and methodologies to establish fees for different facilities, e.g., for the airfield and terminal area, and for different aeronautical users, e.g., air carriers and fixed-base operators. The Department will take these differences into account if we are called upon to resolve a dispute over aeronautical fees.

B. Aeronautical Use and Users

The Department considers the aeronautical use of an airport to be any activity that involves, makes possible, is required for the safety of the operations of, or is otherwise directly related to, the operation of aircraft. Aeronautical use includes services provided by air carriers related directly and substantially to the movement of passengers, baggage, mail and cargo on the airport. Persons, whether individuals or businesses, engaged in aeronautical uses involving the operation of aircraft, or providing flight support directly related to the operation of aircraft, are considered to be aeronautical users.

In addition, the Department considers that the operation by air carriers or foreign air carriers of facilities such as a reservations center, headquarters office, or flight kitchen on an airport does not constitute an aeronautical activity subject to the principles and guidance contained in this policy statement with respect to reasonableness and unjust discrimination. Such facilities need not be located on an airport. A carrier's decision to locate such facilities is based on the negotiation of a lease or sale of property. Accordingly, the Department relies on the normal forces of competition for commercial or industrial property to assure that fees for such property are not excessive.

C. Applicability of § 113 of the FAA Authorization Act of 1994

Section 113 of the Federal Aviation Authorization Act of 1994 (''Authorization Act''), 49 U.S.C. 47129, directs the Secretary of Transportation to issue a determination on the reasonableness of certain fees imposed on air carriers in response to carrier complaints or a request for determination by an airport proprietor. Section 47129 further directs the Secretary to publish final regulations, policy statements, or guidelines establishing procedures for deciding cases under § 47129 and the standards to be used by the Secretary in determining whether a fee is reasonable. Section 47129(e) excludes from the applicability of § 47129 a fee imposed pursuant to a written agreement with air carriers, a fee imposed pursuant to a financing agreement or covenant entered into before the date of enactment of the statute (August 23, 1994), and an existing fee not in dispute on August 23, 1994. Section 47129(f) further provides that § 47129 shall not adversely affect the rights of any party under existing air carrier/airport agreements or the ability of an airport to meet its obligations under a financing agreement or covenant that is in effect on August 23, 1994.

The Department does not interpret § 47129 to repeal or narrow the scope of the basic requirement that fees imposed on aeronautical users be reasonable and not unjustly discriminatory. Sections 47219(e) and (f) specifically apply the expedited hearing procedures mandated by § 47129(b) and (c) to air carriers, but do not preclude the adoption of policy guidance applicable to fees imposed on aeronautical users other than air carriers.

Therefore, the Department will apply the policy guidance in the case of a dispute over any aeronautical fee, including those described in § 47129(e) and (f).

In addition, as the statute provides, a dispute over matters described by § 47129(e) and (f) will not be processed under the procedures mandated by § 47129. Rather those disputes will be processed under procedures applicable to airport compliance matters in general.

Principles Applicable to Airport Rates and Charges

1. In general, the Department relies upon airport proprietors, aeronautical users, and the market and institutional arrangements within which they operate, to ensure compliance with applicable legal requirements. Direct Federal intervention will be available, however, where needed.

2. Rates, fees, rentals, landing fees, and other service charges (''fees'') imposed on aeronautical users for aeronautical use of airport facilities (''aeronautical fees'') must be fair and reasonable.

3. Aeronautical fees may not unjustly discriminate against aeronautical users or user groups.

4. Airport proprietors must maintain a fee and rental structure that in the circumstances of the airport makes the airport as financially self-sustaining as possible.

5. In accordance with relevant Federal statutory provisions governing the use of airport revenue, airport proprietors may expend revenue generated by the airport only for statutorily allowable purposes.

Local Negotiation and Resolution

1. In general, the Department relies upon airport proprietors, aeronautical users, and the market and institutional arrangements within which they operate, to ensure compliance with applicable legal requirements. Direct Federal intervention will be available, however, where needed.

1.1 The Department encourages direct resolution of differences at the local level between aeronautical users and the airport proprietor. Such resolution is best achieved through adequate and timely consultation between the airport proprietor and the aeronautical users. Airport proprietors should engage in adequate and timely consultation with aeronautical users about airport fees.

1.1.1 Airport proprietors should consult with aeronautical users well in advance, if practical, of introducing significant changes in charging systems and procedures or in the level of charges. The proprietor should provide adequate information to permit aeronautical users to evaluate the airport proprietor's justification for the change and to assess the reasonableness of the proposal. For consultations to be effective, airport proprietors should give due regard to the views of aeronautical users and to the effect upon them of changes in fees. Likewise, aeronautical users should give due regard to the views of the airport proprietor and the financial needs of the airport.

1.1.2 To further the goal of effective consultation, Appendix 1 of this policy statement contains a description of information that the Department considers would be useful to the carriers and other aeronautical users to permit meaningful consultation and evaluation of a proposal to modify fees.

1.1.3 Airport proprietors should consider the public interest in establishing airport fees, and aeronautical users should consider the public interest in consulting with airports on setting such fees.

1.1.4 Airport proprietors and aeronautical users should consult and make a good-faith effort to reach agreement. Absent agreement, airport proprietors are free to act in accordance with their proposals, subject to review by the Secretary or the Administrator on complaint by the user or, in the case of

fees subject to 49 U.S.C. § 47129, upon request by the airport operator, or, in unusual circumstances, on the Department's initiative.

1.1.5 To facilitate local resolution and reduce the need for direct Federal intervention to resolve differences over aeronautical fees, the Department encourages airport proprietors and aeronautical users to include alternative dispute resolution procedures in their lease and use agreements.

1.1.6 Any newly established fee or fee increase that is the subject of a complaint under 49 U.S.C. § 47129 that is not dismissed by the Secretary must be paid to the airport proprietor under protest by the complainant. Unless the airport proprietor and complainant agree otherwise, the airport proprietor will obtain a letter of credit, or surety bond, or other suitable credit instrument in accordance with the provisions of 49 U.S.C. 47129(d). Pending issuance of a final order determining reasonableness, an airport proprietor may not deny a complainant currently providing air service at the airport reasonable access to airport facilities or services, or otherwise interfere with that complainant's prices, routes, or services, as a means of enforcing the fee, if the complainant has complied with the requirements for payment under protest.

1.2 Where airport proprietors and aeronautical users have been unable, despite all reasonable efforts, to resolve disputes between them, the Department will act to resolve the issues raised in the dispute.

1.2.1 In the case of a fee imposed on one or more air carriers or foreign air carriers, the Department will issue a determination on the reasonableness of the fee upon the filing of a written request for a determination by the airport proprietor or, if the Department determines that a significant dispute exists, upon the filing of a complaint by one or more air carriers or foreign air carriers, in accordance with 49 U.S.C. 47129 and implementing regulations. Pursuant to the provisions of 49 U.S.C. 47129, the Department may only determine whether a fee is reasonable or unreasonable, and may not set the level of the fee.

1.2.2 In the case of fees imposed on other aeronautical users, the Department will first offer its good offices to facilitate parties reaching a successful outcome in a timely manner. Prompt resolution of these disputes is always desirable since extensive delay can lead to uncertainty for the public and a hardening of the parties' positions. Air carriers and foreign air carriers may request the assistance of the Department in advance of or in lieu of the formal complaint procedure described in 1.2.1.; however, the 60-day period for filing a complaint under § 47129 is not extended or tolled by such a request.

1.2.3 In the case of fees imposed on other aeronautical users, where negotiations between the parties are unsuccessful and a complaint is filed alleging that airport fees violate an airport proprietor's federal grant obligations, the Department will, where warranted, exercise the agency's broad statutory authority to review the legality of those fees and to issue such determinations and take such actions as are appropriate based on that review.

1.3 Airport proprietors must retain the ability to respond to local conditions with flexibility and innovation. An airport proprietor is encouraged to achieve consensus and agreement with its airline tenants before implementing a practice that would represent a major departure from this guidance. However, the requirements of any law, including the requirements for the use of airport revenue, may not be waived, even by agreement with the aeronautical users.

Fair and Reasonable Fees

2. Rates, fees, rentals, landing fees, and other service charges (''fees'') imposed on aeronautical users for the aeronautical use of the airport (''aeronautical fees'') must be fair and reasonable.

2.1 Revenues from aeronautical fees (aeronautical revenues) may not exceed the costs to the airport proprietor of providing airport services and facilities currently in aeronautical use (aeronautical costs) unless otherwise agreed to by the affected aeronautical users.

2.1.1 Aeronautical users may receive a cross-credit of nonaeronautical revenues only if the airport proprietor agrees. Agreements providing for such cross-crediting are commonly referred to as ''residual agreements'' and generally provide a sharing of nonaeronautical revenues with aeronautical users. The aeronautical users may in turn agree to assume part or all of the liability for non-aeronautical costs, or an airport proprietor may cross-credit nonaeronautical revenues to aeronautical users even in the absence of such an agreement, but an airport proprietor may not require aeronautical users to cover losses generated by nonaeronautical facilities except by agreement.

2.1.2 In other situations, an airport proprietor assumes all liability for airport costs and retains all airport profits for its own use in accordance with Federal requirements. This approach to airport financing is generally referred to as the compensatory approach.

2.1.3 Airports frequently adopt charging systems that employ elements of both approaches.

2.1.4 Federal law does not require a single approach to airport financing. Rates may be set according to a residual or compensatory rate-setting methodology, or any combination of the two, or according to a new rate-setting methodology, as long as the methodology used is applied consistently to similarly situated aeronautical users and as otherwise required by this policy. Airport proprietors may set rates for aeronautical use of airport facilities by ordinance, statute or resolution, regulation, or by agreement.

2.2 The ''rate base'' is the total of all aeronautical costs that may be recovered from aeronautical users through aeronautical fees. Airport proprietors must employ a reasonable, consistent, and ''transparent'' (i.e., clear and fully justified) method of establishing the rate base and adjusting the rate base on a timely and predictable schedule.

2.3 In the absence of an agreement with aeronautical users, costs that may be included in the rate base (allowable costs) are limited to all operating and maintenance expenses directly and indirectly associated with the provision of aeronautical facilities and services (including environmental costs, as set forth below); all capital costs associated with the provision of aeronautical facilities and services currently in use, as set forth below; and current costs of planning future aeronautical facilities and services.

2.3.1 Where airport proprietors have expended funds from nonaeronautical sources to finance capital investments for aeronautical use, the implicit capital cost of these funds may be included in the aeronautical rate base in addition to the cost of the asset. The Department considers it reasonable to use, as a measure of the implicit capital cost, the rate of interest prevailing on bonds issued for a comparable purpose at the time of the expenditure at that airport or at another airport with similar bond rating.

2.3.2 Airport proprietors may include reasonable environmental costs in the rate base to the extent that the airport proprietor incurs a corresponding actual expense. All revenues received based on the inclusion of these costs in the rate base are subject to Federal requirements on the use of airport revenue. Reasonable environmental costs include, but are not necessarily limited to, the following:

(a) The costs of investigating and remediating environmental contamination caused by aeronautical operations at the airport at least to the extent that such investigation or remediation is required by or consistent with local, state or federal environmental law, and to the extent such requirements are applied to other similarly situated enterprises.

(b) The cost of mitigating the environmental impact of an airport development project (if the development project is one for which costs may be included in the users' rate base), at least to the extent that these costs are incurred in order to secure necessary approvals for such projects, including but not limited to approvals under the National Environmental Policy Act and similar state statutes;

(c) The costs of aircraft noise abatement and mitigation measures, both on and off the airport, including but not limited to land acquisition and acoustical insulation expenses, to the extent that such measures are undertaken as part of a comprehensive and publicly-disclosed airport noise compatibility program; and

(d) The costs of insuring against future liability for environmental contamination caused by current aeronautical activities. Under this provision, the costs of self-insurance may be included in the rate-base only to the extent that they are incurred pursuant to a self-insurance program that conforms to applicable insurance industry standards for self-insurance practices.

2.3.3 Airport proprietors are encouraged to establish fees with due regard for economy and efficiency.

2.3.4 The airport proprietor may include in the rate base amounts needed to fund debt service and other reserves and to meet cash flow requirements as specified in financing agreements or covenants (for facilities in use); to fund cash reserves to protect against the risks of cash-flow fluctuations associated with normal airport operations; and to fund reasonable cash reserves to protect against other contingencies.

2.3.5 The airport proprietor may include in the rate base capital costs in accordance with the following guidance, which is based on the principle of cost causation:

(a) Costs of facilities directly used by the aeronautical users may be fully included in the rate base, in a manner consistent with this policy. For example, the capital cost of a runway may be included in the rate base used to establish landing fees.

(b) Costs of airport facilities used for both aeronautical and non-aeronautical uses (shared costs) may be included in a particular aeronautical rate base if the facility in question supports the aeronautical activity reflected in that rate base. The portion of shared costs allocated to aeronautical users should not exceed an amount that reflects the aeronautical purpose and proportionate aeronautical use of the facility in relation to nonaeronautical use of the facility, unless the affected aeronautical users agree to the allocation. Aeronautical users may not be allocated all costs of facilities that are used by both aeronautical and nonaeronautical users unless they agree to that allocation.

2.4 Airport proprietors must comply with the following practices in establishing the rate base, provided, however, that one or more aeronautical users may agree to a rate base that deviates from these practices in the establishment of those users' fees.

2.4.1 Airport assets included in the rate base must be valued according to their historic cost to the original airport proprietor. Subsequent airport proprietors generally shall acquire the cost basis of an asset at the original airport proprietor's historic cost.

(a) For facilities other than airfield facilities and land, an airport proprietor may use valuation methodologies other than historic cost valuation as set forth above, so long as total aeronautical revenues do not exceed the total costs (based on historic costs) included in the aeronautical rate base, and so long as the valuation method is justified and applied on a consistent basis to comparable facilities.

(b) Where comparable assets, e.g., two runways or two terminals, were built at different times and have different historic costs, the airport proprietor may combine the cost basis of the comparable assets to develop a single cost basis applicable to all such facilities.

2.4.2 The costs of facilities not yet built and operating may not be included in the rate base. However, the debt-service and other carrying costs incurred by the airport proprietor during construction may be capitalized and amortized once the facility is put in service. The airport proprietor may include in the rate base the costs of land that facilitates the current operations of the airport.

2.4.3 The rate base of an airport may include costs associated with another airport currently in use only if: (1) The proprietor of the first airport is also the proprietor of the second airport; (2) the second airport is currently in use; and (3) the costs of the second airport to be included in the first airport's rate base are reasonably related to the aviation benefits that the second airport provides or is expected to provide to the aeronautical users of the first airport.

(a) Element no. 3 above will be presumed to be satisfied if the second airport is designated as a reliever airport for the first airport in the FAA's National Plan of Integrated Airport Systems (NPIAS).

2.5 At all times, airport proprietors must comply with the following practices:

2.5.1 Indirect costs may not be included in the rate base unless they are based on a reasonable, transparent cost allocation formula calculated consistently for other units or cost centers of government.

2.5.2 The costs of airport development or planning projects paid for with government grants and contributions and passenger facility charges (PFCs) may not be included in the rate base.

2.5.2(a) In the case of a PFC-funded project for terminal development, for gates and related areas, or for a facility that is occupied by one or more carriers on an exclusive or preferential use basis, the fees paid to use those facilities shall be no less than the fees charged for similar facilities that were not financed with PFC revenue.

Prohibition on Unjust Discrimination

3. Aeronautical fees may not unjustly discriminate against aeronautical users or user groups.

3.1 Unless aeronautical users agree, aeronautical fees imposed on any aeronautical user or group of aeronautical users may not exceed the costs allocated to that user or user group under a cost allocation methodology adopted by the airport proprietor that is consistent with this guidance.

3.1.1 The prohibition on unjust discrimination does not prevent an airport proprietor from making reasonable distinctions among aeronautical users (such as signatory and non-signatory carriers) and assessing higher fees on certain categories of aeronautical users based on those distinctions (such as higher fees for non-signatory carriers, as compared to signatory carriers).

3.2 A properly structured peak pricing system that allocates limited resources using price during periods of congestion will not be considered to be unjustly discriminatory. An airport proprietor may, consistent with the policies expressed in this policy statement, establish fees that enhance the efficient utilization of the airport.

3.3 Relevant provisions of the Convention on International Civil

Aviation (Chicago Convention) and many bilateral aviation agreements specify, inter alia, that charges imposed on foreign airlines must not be unjustly discriminatory, must not be higher than those imposed on domestic airlines engaged in similar international air services and must be equitably apportioned among categories of users. Charges to foreign air carriers for aeronautical use that are inconsistent with these principles will be considered unjustly discriminatory or unfair and unreasonable.

3.4 Allowable costs—costs properly included in the rate base—must be allocated to aeronautical users by a transparent, reasonable, and not unjustly discriminatory rate-setting methodology. The methodology must be applied consistently and cost differences must be determined quantitatively, when practical.

3.4.1 Common costs (costs not directly attributable to a specific user group or cost center) must be allocated according to a reasonable, transparent and not unjustly discriminatory cost allocation formula that is applied consistently, and does not require any air carrier, foreign air carrier or other aeronautical user group to pay costs properly allocable to other users.

Requirement To Be Financially Self-Sustaining

4. Airport proprietors must maintain a fee and rental structure that in the circumstances of the airport makes the airport as financially self-sustaining as possible.

4.1 If market conditions or demand for air service do not permit the airport to be financially self-sustaining, the airport proprietor should establish long-term goals and targets to make the airport as financially self-sustaining as possible.

4.1.1 Airport proprietors are encouraged, when entering into new or revised agreements or otherwise establishing rates, charges, and fees, to undertake reasonable efforts to make their particular airports as self sustaining as possible in the circumstances existing at such airports.

(a) Absent agreement with aeronautical users, the obligation to make the airport as self-sustaining as possible does not permit the airport proprietor to establish aeronautical fees that exceed the airport proprietor's aeronautical costs.

4.1.2 At some airports, market conditions may not permit an airport proprietor to establish fees that are sufficiently high to recover aeronautical costs and sufficiently low to allow commercial aeronautical services to operate at a profit. In such circumstances, an airport proprietor's decision to charge rates that are below those needed to achieve self-sustainability in order to assure that services are provided to the public is not inherently inconsistent with the obligation to make the airport as self-sustaining as possible in the circumstances.

4.2 In establishing new fees, and generating revenues from all sources, airport owners and operators should not seek to create revenue surpluses that exceed the amounts to be used for airport system purposes and for other purposes for which airport revenues may be spent under 49 U.S.C. 47107(b)(1), including reasonable reserves and other funds to facilitate financing and to cover contingencies. While fees charged to nonaeronautical users may exceed the costs of service to those users, the surplus funds accumulated from those fees must be used in accordance with § 47107(b).

Requirements Governing Revenue Application and Use

5. In accordance with relevant Federal statutory provisions governing the use of airport revenue, airport proprietors may expend revenue generated by the airport only for statutorily allowable purposes.

5.1 Additional information on the statutorily allowed uses of airport revenue is contained in separate guidance published by the FAA pursuant to § 112 of the FAA Authorization Act of 1994, which is codified at 49 U.S.C 47107(l).

5.2 The progressive accumulation of substantial amounts of airport revenues may warrant an FAA inquiry into the airport proprietor's application of revenues to the local airport system.

Issued in Washington, DC, on January 30, 1995.

Federico Peña,

Secretary of Transportation.

David R. Hinson,

Administrator, Federal Aviation Administration.

Appendix 1—Information for Aeronautical User Charges Consultations

The Department of Transportation ordinarily expects the following information to be available to aeronautical users in connection with consultations over changes in airport rates and charges:

1. Historic Financial Information covering two fiscal years prior to the current year including, at minimum, a profit and loss statement, balance sheet and cash flow statement for the airport implementing the charges.

2. Justification. Economic, financial and/or legal justification for changes in the charging methodology or in the level of aeronautical rates and charges at the airport. Airports should provide information on the aeronautical costs they are including in the rate base.

3. Traffic Information. Annual numbers of terminal passengers and aircraft movements for each of the two preceding years.

4. Planning and Forecasting Information.

(a) To the extent applicable to current or proposed fees, the long-term airport strategy setting out long-term financial and traffic forecasts, major capital projects and capital expenditure, and particular areas requiring strategic action. This material should include any material provided for public or government reviews of major airport developments, including analyses of demand and capacity and expenditure estimates.

(b) Accurate, complete information specific to the airport for the current and the forecast year, including the current and proposed budgets, forecasts of airport charges revenue, the projected number of landings and passengers, expected operating and capital expenditures, debt service payments, contributions to restricted funds, or other required accounts or reserves.

(c) To the extent the airport uses a residual or hybrid charging methodology, a description of key factors expected to affect commercial or other nonaeronautical revenues and operating costs in the current and following years.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 302

[Docket No. 49830]

RIN 2105–AC18

Rules of Practice for Proceedings Concerning Airport Fees

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: This final rule establishes specific procedural rules under which the Department of Transportation will handle complaints by air carriers and foreign air carriers for a determination of the reasonableness of a fee increase or newly established fee imposed upon the carrier by the owner or operator of an airport. It also establishes rules that would apply to requests by the owner or operator of an airport for such a determination. The final rule responds to the mandate in the recently enacted Federal Aviation Administration Authorization Act of 1994 requiring the Department to issue regulations establishing procedures for acting upon such complaints by air carriers and requests by airport owners and operators.

EFFECTIVE DATE: This rule is effective on February 3, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Klothe, Office of Regulation and Enforcement, Office of the General Counsel, United States Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590, telephone (202) 366–9307.

SUPPLEMENTARY INFORMATION:

Background

This rulemaking had its origins in two related notices on the subject of Federal policy on airport rates and charges issued by the Office of the Secretary of Transportation (OST) and the Federal Aviation Administration on June 9, 1994. A jointly-issued notice entitled ''Proposed Policy Regarding Airport Rates and Charges'' (Proposed Policy) listed and explained the proposed Federal policy on the rates and charges that an airport proprietor can charge to aeronautical users of the airport. (59 FR 29874); a supplemental notice concerning the proposed policy was issued on October 12, 1994 (59 FR 51836). The FAA also issued a notice of proposed rulemaking entitled ''Rules of Practice for Federally Assisted Airports'' setting forth procedures for the filing, investigation, and adjudication of complaints against airports for alleged violation of Federal requirements under the Airport and Airway Improvement Act of 1982, as amended, and the Anti-Head Tax Act provisions of the Federal Aviation Act (59 FR 29880); subpart J of the proposed rule provided special procedures for the expedited review of complaints by airlines involving the fees charged by an airport proprietor.

Subsequently, Congress passed the FAA Authorization Act of 1994, which was signed into law on August 23, 1994. Section 113 of the FAA Authorization Act included specific provisions for the resolution of airport-air carrier disputes concerning airport fees. The procedures contemplated by the FAA Authorization Act were substantially different from those proposed by the FAA. Accordingly, the FAA withdrew its NPRM on September 16, 1994, insofar as it applied to the resolution of the reasonableness of airport fees charged to air carriers. (59 FR 47568). However, the remaining procedures proposed in the FAA NPRM, which would apply to the various other kinds of complaints filed against airports relating to Federal requirements, are not affected by the FAA Authorization Act, and the comment period on the remaining proposals closed on December 1, 1994.

In lieu of the procedures proposed by the FAA for handling air carrier complaints about airport rates and charges, the Office of the Secretary issued a new NPRM on October 24, 1994. As contemplated by the FAA Authorization Act, the October 24 NPRM stated that the procedures contained in 14 CFR Part 302 would generally govern air carrier complaints as well as requests by airport owners or operators for a determination of the reasonableness of airports fees and charges.

Discussion of Comments

The Department received twelve comments on the NPRM. They were submitted by the Air Transport Association (ATA), the Aircraft Owners and Pilots Association (AOPA), the Airports Council International—North America (ACI–NA), the American Association of Airport Executives (AAAE), the General Aviation Manufacturers Association (GAMA), the International Air Transport Association (IATA), Japan Airlines Company (JAL), the Los Angeles Department of Airports, the Maryland Aviation Administration, the Massachusetts Port Authority (Massport), the Metropolitan Washington Airports Authority, and the National Business Aircraft Association, Inc. (NBAA).

Although there were numerous requests for changes to particular provisions, the comments generally expressed support for the overall concept of the proposed rule. The proposed regulatory approach, *i.e.*, consolidating all complaints as soon as the first carrier files a complaint under the new subpart, received several supporting comments and no opposition. Accordingly, the final rule follows this approach with only minor modifications. We turn now to a discussion of the issues most widely addressed in the comments. Other comments are addressed in the section-by-section analysis.

Party Status

A number of commenters addressed issues involving who should be able to make use of the expedited procedures contained in the new subpart. JAL expressed specific support for our proposal to allow foreign air carriers to use the expedited procedures along with U.S. air carriers. AAAE stated that it considers this proposal acceptable, and ACI–NA also indicated that it did not object, although ACI–NA added that ''a foreign air carrier, like any other carrier, which initiates or joins a case should not be allowed to pursue remedies in other forums, in order to avoid duplicative proceedings which could lead to inconsistent or conflicting results.'' Only the Los Angeles Department of Airports opposed including foreign air carriers. It claims that ''Congress intentionally provided the expedited procedures only to U.S. carriers,'' and suggests that making this forum available to foreign carriers forfeits a bargaining position for the United States and contravenes the principle of international reciprocity.

The final rule adopts the proposal to allow foreign air carriers to file complaints under subpart F. As we noted in the NPRM, we anticipate that both domestic and foreign carriers will dispute airport fees they believe to be unreasonable. Since the economic and other issues involved in determining the reasonableness of a fee are essentially the same whether the complainant carrier is U.S. or foreign, it will be simpler for the carriers, the airport and the Department to make that determination in a single proceeding. Therefore, while the FAA Authorization Act was only directed at complaints by U.S. carriers, we will include foreign carriers on our own initiative.

With respect to the comment that foreign carriers filing claims under subpart F should be barred from seeking remedies in other forums, we note that the various bilateral agreements on air service between the United States and

other countries govern the rights of foreign air carriers in this regard.

GAMA, AOPA, and NBAA all argue that we should further expand the applicability of this subpart to cover complaints by general aviation operators. In their view, the arguments for including foreign air carriers apply with equal force to general aviation users. While we recognize that there may be cases in which an airport imposes essentially similar fees on both general aviation and air carrier operations, we cannot grant the request to expand the expedited procedures to general aviation operators. The FAA Authorization Act requires the Secretary to determine the reasonableness of a challenged fee within 120 days after a complaint is filed and indicates a preference for oral evidentiary procedures, to the extent that such procedures are consistent with the 120-day timeframe. Our procedures must carry out the Congressional intent. If general aviation operators are permitted to make use of this subpart, however, the scope of the hearing would be dramatically expanded. It is possible that there would be dozens, conceivably even hundreds, of additional parties, possibly with divergent interests. If this happened, it would so overwhelm the Department's resources that it could become impossible for the Department to meet the statutory deadline.

The Metropolitan Washington Airports Authority argues that there is an integral relationship between the fees paid by ''signatory'' and ''non-signatory'' carriers. (Signatory carriers are airlines that have entered into a use or operating agreement with the airport operator.) Therefore, ''it is important for the procedures to specify that the airport can join as indispensable parties the signatory airlines when the airports rates and charges are challenged by a non signatory airline.'' The final rule does not incorporate this suggestion. If a carrier (signatory or otherwise) would be affected by the outcome of a complaint filed by another carrier at the same airport, it may well choose to participate in the proceeding, such as by filing an answer to the complaint. The NPRM's proposal to require service of any complaint on other carriers (discussed more fully below) was made partly to facilitate such participation. But there is no reason to require the participation of carriers with no complaint of their own and no interest in the fee being challenged.

Evidence To Be Submitted With Complaints, Requests and Answers

A number of commenters addressed the proposal in the NPRM that carrier complaints should contain all supporting evidence and testimony, and that answers should similarly be complete with all evidence and testimony on which the party intends to rely.

IATA commented that a carrier might not have access to much of the information necessary to its complaint unless the airport had agreed to furnish it. IATA requested that the final rule make clear that information within the custody of the airport could be used by the carrier if it was able to obtain the information only after the complaint was filed. ATA raised the same issue, but suggested that we provide for a formal discovery process within the 30-day period following the complaint.

The Department's Policy Regarding Airport Rates and Charges, published in today's **Federal Register**, states that airports should consult with carriers in advance of changing fees, and should provide adequate information to permit carriers to evaluate the justification for the change and the reasonableness of the new or increased fee. We expect that airports will comply with this policy.

The Department finds the IATA and ATA concerns valid. However, we believe that the conduct of discovery in the 30-day period following the complaint would be a burden to the airport owner or operator and to the government. Moreover, any discovery conducted would be unnecessary, and therefore excessive, if the complaint is subsequently dismissed because the Secretary determines that there is no significant dispute. Accordingly, the Department will provide, where necessary, special procedures for the exchange or disclosure of information by the parties.

Airport parties had equivalent objections with respect to the proposed requirements for the timing and completeness of answers. ACI–NA, AAAE, the Los Angeles Department of Airports, and Massport all argued that airports should not have to submit their entire response with the answer. They believe that answering parties should only have to submit a brief in response to a complaint, and should be able to supplement their submission with exhibits and testimony at a later point in the proceeding.

In addition, they claim that it is unfair that complainants will have up to 60 days to gather evidence and prepare exhibits and testimony, while, under the proposal, respondents would be required to submit their complete response seven calendar days after the complaint is filed. AAAE and ACI–NA suggested that we allow answers to be filed 21 days after the initial complaint. The Los Angeles Department of Airports agreed, and also suggested the recommended 21-day period should not start until the last day that complaints could be filed (*i.e.*, on the 60th day after notice of the fee or the seventh day after the first complaint is filed). This would give parties a total of up to 28 days to file answers. Massport asked for a 14 calendar-day answer period, and the Metropolitan Washington Airports Authority recommended 14 days for the initial complaint and seven days for any additional complaints. The Maryland Aviation Administration requested seven business days instead of seven calendar days.

We will retain the requirement that answers contain all testimony and exhibits on which the answering party intends to rely. The carriers pointed out that airport owners and operators possess much of the information that they might need to introduce in challenging a fee. However, there is no fee information in the hands of the carriers that an airport would need to support the reasonableness of the fee. In view of the extremely short decisional deadlines imposed by the FAA Authorization Act, it is important that we have the most information possible at the beginning of a proceeding. While it is true, as commenters noted, that complaining carriers have up to 60 days to file complaints, we do not agree that this gives complainants an unfair advantage. We expect airports to have all the economic evidence they need in support of a new or increased fee before the fee is increased rather than after a complaint is filed. While an answer must, of course, respond to the specific matters raised in a complaint, an airport should not have to generate significant new data.

On the other hand, we believe that it is reasonable to allow some additional time to prepare and submit answers. In the case of complaints, it will be easier for both the answering party and the Department if answers are consolidated to address both the initial complaint and any follow-on complaints. Accordingly, the final rule provides that answers will be due 14 calendar days after the initial complaint is filed. Thus, if there are follow-on complaints, the answering parties will still have a minimum of seven days to address them. We will also allow 14 days for answers to requests for determination.

Determination of ''Significant Dispute''

Within 30 days after a carrier files a complaint, the FAA Authorization Act requires the Department to determine whether there is a ''significant dispute;'' if not, the statute requires the Secretary

to dismiss the complaint. Accordingly, a number of commenters addressed issues associated with the Secretary's determination.

IATA pointed out that the language in proposed § 302.611 stated that the Secretary would issue an order within 30 days determining whether a carrier complaint presented a significant dispute, but there was no corresponding language on requests for determination submitted by an airport owner or operator. As the preamble in the NPRM indicated, it has been our intention to issue such orders within 30 days. However, as provided in § 302.619(c), when both a complaint and a request for determination have been filed with respect to the same airport fee, the statutorily-imposed 120-day schedule for resolving *complaints* controls the course of the proceeding. That is, as required by the FAA Authorization Act, the Secretary will determine whether there is a significant dispute within 30 days of the date the first complaint is filed. In such cases, the determination may come more than 30 days after the date of the airport request. In light of IATA's comment, we have revised the language of § 302.613 to clarify this point.

The comments of both IATA and ATA ask that any order dismissing a complaint for lack of a significant dispute should be clearly stated to be final and appealable. IATA goes on to argue the proposed rule would leave an airport owner or operator in a better position following dismissal of a request for determination than a carrier would be following dismissal of a complaint. We disagree, and we find that no change is necessary in the final rule. If the Secretary dismisses a complaint after finding that there is no significant dispute within the meaning of the FAA Authorization Act, the order of dismissal is subject to the same judicial review as any other order of the Secretary. (If the Secretary instead finds that the complaint fails to meet the procedural requirements of this subpart, the order will set forth the conditions under which a revised complaint may be filed.)

IATA asks that § 302.611 ''provide some reasonably accurate guidelines and standards of review'' under which the Secretary will review complaints to determine whether they present a significant dispute. ATA suggests that we employ the standards of Federal Rule of Civil Procedure 12(b)(6), accepting any complaint as constituting a significant dispute as long as it ''states a claim for relief under Section 47129.'' In the alternative, it suggests we employ the standards for grant of summary judgment under Federal Rule of Civil Procedure 56. Under this approach, as ATA states, ''a 'significant dispute' would exist whenever there was a genuine issue of material fact or law.''

Accepting either of ATA's recommendations would mean that the Department would set for hearing virtually all complaints brought, no matter how trivial. We believe that this is inconsistent with the statutory intent. If Congress had meant for the Department to hear every complaint in which a claim is made, it surely would not have mandated in § 47129(c)(2) that ''the Secretary *shall dismiss* any complaint if no significant dispute exists.'' (Emphasis added.) Congress established the extraordinary dispute resolution program in § 47129 to ensure that carriers and airports can obtain a prompt decision when there is an important fee dispute. It plainly understood that the Department has limited resources; if the expedited procedures are employed any time a complainant can state a claim or establish that there is a fact in dispute, the Department could be unable to respond adequately when there are truly significant fee disputes. Moreover, while we are sympathetic to IATA's request for clear guidelines and standards for review, we believe that the circumstances at each airport and the facts behind each fee dispute vary too widely for us to be able to set out specific standards in the final rule. As we proposed, however, § 302.611 states that we will set forth our reasoning in any order dismissing a complaint on the grounds that the alleged dispute is not significant.

AAAE objected to the statement in the preamble that one piece of evidence that a dispute is significant would be that the complaining carrier had attempted to resolve the dispute with the airport but had been unsuccessful. AAAE points out, ''Airports and their tenant air carriers can have legitimate, and even vehement disagreements about issues that are, objectively, minor.'' We agree with AAAE that the intensity of the discussions between airports and carriers does not by itself mean that there is a significant dispute within the meaning of § 47129. Nevertheless, as the preamble to the NPRM stated, the failure of direct negotiations ''would be some indication, although not necessarily proof, that there is a significant dispute.''

ACI–NA and IATA disagree sharply on our authority to dismiss airport requests for determination when there is no significant dispute. ACI–NA stated that the Department was correct in determining that the FAA Authorization Act makes no provision for dismissal on that basis (in contrast with its specific requirement to dismiss carrier complaints that do not present a significant dispute). IATA, on the other hand, claimed that our failure to provide for dismissal of an airport owner or operator's request ''is clearly arbitrary and capricious.'' As IATA's comments note, however, the statutory language on dismissals, in § 47129(c)(2), ''*on its face* appears to be applicable *only* to complaints and air carriers.'' (Emphasis in original.) While IATA suggests that this ''may be the result of legislative oversight,'' we believe this language is plain, and we will adopt the NPRM's proposal to proceed to a final order on the merits when an airport properly submits a request for determination.

Service of Documents

In order to ensure compliance with the extremely short time frames provided by the FAA Authorization Act for action on fee disputes, the NPRM proposed special service requirements. The proposal contained three main elements: (1) Complaints and requests for determination would have to be served on all carriers providing service to the airport; (2) For most filings, service would have to be made by hand, by electronic transmission, or by overnight express delivery; and (3) Parties would actually have to receive the documents no later than the day they are filed.

The NPRM stated that the Department realized that these service requirements could pose a burden in some situations, but it also expressed our belief that they are necessary to permit a consolidated hearing for all complaints. Nevertheless, we specifically invited comment on the service proposals, and particularly on an additional proposal to substitute service of complaints or requests for determination on members of any airline negotiating committee at the airport rather than on all carriers serving the airport. A number of commenters responded to this invitation.

To begin with, AAAE and ACI–NA supported the proposal to allow service of documents on airline committee members at those airports having such committees. The Metropolitan Washington Airports Authority claimed that it should be adequate to serve the committee itself, without serving the individual carrier members. ATA, however, strongly argued that service on the airline committee members would not provide adequate notice to other carriers serving the airport; it advocated requiring service on all carriers serving the airport, preferably at their

headquarters' offices. Complaints by carriers drive the schedule for determining the reasonableness of airport fees. It is essential that carriers have adequate notice when a document is filed, particularly an initiating complaint, which starts the seven-day period for follow-on complaints. In light of ATA's comments, therefore, the final rule does not provide for serving the members of the airport's carrier committee.[1] Nevertheless, we continue to be concerned about the potential burden of a literal application of a requirement to serve ''all carriers.'' As the comments of the Metropolitan Washington Airports Authority pointed out, ''the requirement to serve 'all' carriers could become an unnecessary procedural hurdle that prevents the expeditious resolution of a fee dispute,'' because it could be read to require service on even the most infrequent users of the airport. The Metropolitan Washington Airports Authority recommended that service be limited to carriers that operated at the airport within the 30 days prior to the filing, while AAAE and ACI–NA suggested using the Air Carrier Activity Information System (ACAIS) as the basis for determining which carriers should be served. As these parties note, airports already use the list of carriers on the ACAIS in determining which carriers to serve with respect to Passenger Facility Charges under 14 CFR Part 158. Accordingly, we believe that the ACAIS list can similarly serve as the basis for an acceptable means of compliance with the service requirements of subpart F as well.

While the ACAIS list provides an objective and convenient starting point for parties needing to serve all carriers, it must be recognized that the list is based on carriers that served the airport during the preceding year, and thus may not include new entrants. In addition, carriers operating under 14 CFR Part 135 are not required to submit data for ACAIS, although many do so voluntarily. Therefore, as ACI–NA proposed, any party intending to make use of the ACAIS list for service must also serve any other carrier known to be operating at the airport but not on the list. This is the same practice that is followed with respect to PFC applications.

[1] For the same reason, we will not adopt ATA's contingent suggestion to allow carriers to serve only a written notice that a complaint had been filed, along with instructions on how to obtain complete copies. We believe interested persons must have immediate, full information about the filing. (In any event, ATA stated that its suggestion assumed additional time would be allowed for follow-on complaints).

The ACAIS list is routinely made available to airport operators. However, since carriers do not file PFC applications, we recognize that they have not previously used the ACAIS list to identify carriers for the purposes of service. The Department's Office of Aviation Analysis will provide the names of the carriers on the most recently published ACAIS list at the request of a carrier considering filing a complaint about a newly established or newly increased airport fee. Not all information from ACAIS will be available on request. Much of the data is potentially sensitive, and we believe most carriers would not want it made available to competitors. Therefore, only carrier identities will be released through this process.

The Los Angeles Department of Airports objected to the requirement to certify that the parties served have actually received the documents, arguing that it cannot know when a document will be received. It argued that parties should only have to certify that the documents were sent. We disagree. The short response time required by these procedures makes it essential that the receiving party receives the maximum notice possible that a complaint, request, or responsive document has been filed. Moreover, while we recognize that this constitutes an additional burden on the filer, that burden is not insurmountable. All three of the specified service methods allow the sender to ascertain quickly that the receiving party has received the filing. In the case of hand delivery, receipt is obvious. For electronic transmission, both facsimile machines and many electronic mail systems provide for receipts from the recipients. And the availability of immediate proof of delivery is a widely-advertised service of major overnight express delivery companies.

The Los Angeles Department of Airports also argues that hand delivery and overnight express may not be available to serve foreign air carriers, and it suggests that we permit utilization of ''the next most-expeditious, commercially available manner for sending documents to the country in which the foreign air carrier must be served.'' Since in many cases this would make it difficult or impossible to achieve service in time to allow meaningful responsive pleadings, we cannot agree. Overnight express delivery is increasingly available commercially throughout the world, although it is true that the service is not available everywhere. However, that is one reason why the NPRM also proposed to permit service by electronic transmission. There are few if any places in the world where facsimile service and/or electronic mail are unavailable. Indeed, it is hard to imagine in today's market that a carrier could conduct international operations without having some capacity to receive electronic communications. Moreover, many carriers, even foreign air carriers, will not need to be served with complaints or requests for determination in their home country. Unless a carrier indicates that a different person should receive service for the purposes of this subpart, the final rule authorizes service on the person responsible for communicating with the airport on behalf of the air carrier or foreign air carrier about airport fees. This person will be familiar with fee disputes involving the airport, and is a logical contact point for routing the document quickly to other key carrier personnel.

In addition to the foregoing, one additional point warrants mention with regard to the service of documents. All exhibits and briefs prepared on electronic spreadsheet or word processing programs should be accompanied by standard-format computer diskettes containing those submissions. Word processing and spreadsheets files must be readable by current versions of one or more of the following programs, or in such other format as may be specified by notice in the **Federal Register**: Microsoft Word, Word Perfect, Ami Pro, Microsoft Excel, Lotus, Quattro Pro, or ASCII tab-delineated files. Parties should submit one copy of each diskette to the docket section, one copy to the office of the Chief Administrative Law Judge (M–50), and one copy to the Chief, Economic and Financial Analysis Division (X–55), of the Office of Aviation Analysis. Submissions in electronic form will assist the Department and the administrative law judge in quickly analyzing the record and in preparing decisions under these expedited procedures. The paper copy will be the official record copy, but filers shall certify that files on the diskette are true copies of the data file used to prepare the printed versions of the exhibits or briefs. Filers should ensure that files on the diskettes are locked.

Section-by-Section Analysis

Section 302.601 Applicability

Section 302.601 describes the kinds of proceedings for which the Department will employ the expedited procedures contained in subpart F. ATA complained that we should not be issuing a procedural rule separate from

the policy statement that will govern consideration of airport fee disputes. (As noted above, the FAA's Supplemental Notice of Proposed Policy was published in the **Federal Register** on October 12, 1994 (59 FR 51836). The comment period closed on the proposed policy on October 26, 1994, and a final policy statement is published elsewhere in today's **Federal Register**.) ATA urges us to consolidate these proceedings and allow additional comment on a consolidated proposal. We disagree. Because of the extremely short deadline for issuing rules governing these proceedings, the Department decided that the best course was to proceed in this two-stage fashion. Relatively few changes were needed in the proposed policy statement after the adoption of the FAA Authorization Act, while the FAA's previously proposed procedures had to be completely rewritten. If we had waited until the new proposed procedures were ready so that we could issue a consolidated document, the highly-abbreviated public comment period that was necessary in this proceeding would have had to apply to both the proposed procedures and the proposed policy statement.

As discussed above, the final rule adopts the proposal to include complaints by foreign air carriers, but complaints by other airport users would not be heard under this subpart. Subpart F also contains the procedural rules for reviewing an airport owner or operator's request for a determination of the reasonableness of an airport fee.

By statute, a fee is subject to review under this subpart only after it has been ''imposed'' on air carriers. As was proposed, § 302.601(a) states that a fee is considered to be imposed as soon as the airport owner or operator has taken all steps necessary under its procedures to establish the fee. Under the FAA Authorization Act in new 49 U.S.C. 47129(a)(1)(B), one essential element to those procedures is providing written notice to carriers of any new or increased fee. Also as proposed, the 60-day filing period for complaints begins to run as soon as the requirements for imposing a fee are met, whether or not the fee is being paid by the carriers. ACI–NA points out that this ''may help resolve fee disputes before the airport is actually counting on receiving the amounts in dispute, and would thus be less disruptive of airport planning and financing.'' To the extent that it encourages airports to avoid raising fees on short notice, it should be less disruptive of carrier planning as well.

AAAE commented that the language in § 302.601 should be made consistent with the final language in the policy statement. Specifically, it suggests adding the words ''for aeronautical use'' to describe the kinds of fees imposed by airports on carriers that may be challenged under this subpart. The Department agrees that the language of the procedural rule should be parallel to that in the policy statement, and the suggested change has been adopted.

Paragraph (b) of § 302.601 sets out the three limitations on applicability contained in the Authorization Act. The Secretary would not entertain complaints about a fee imposed pursuant to a written agreement with carriers using the facilities of an airport; a fee imposed pursuant to a financing agreement or covenant entered into prior to August 23, 1994, or any other existing fee not in dispute as of August 23, 1994. August 23, 1994 is the date the Authorization Act was enacted.

Some commenters suggested additional provisions. ACI–NA, for example, recommends that ''Airlines should not be allowed to challenge a fee increase that is the result of the recalculation of airline fees due to the airport's loss of one or more air carriers, or the substantial diminution of service by one or more air carriers.'' We do not agree that this should be added to the final rule. If a fee is increased as a result of a proper recalculation of charges, the increase will be found reasonable. However, that is no basis for denying a carrier's right to file a complaint under this subpart. ATA would have us limit the exclusions on using subpart F to challenge fees imposed pursuant to agreements with carriers or pursuant to a financing agreement. These exclusions should apply, ATA believes, only if the agreements contain a basis for determining how fees are to be set. ''[S]ome airports require air carriers to sign operating agreements that provide * * * that the carrier is required to pay whatever fees are established by the airport operator.'' We will not adopt ATA's comment; the statutory language is clear that these rules may not be used to challenge fees based on agreements.

Section 302.603 Complaint by an Air Carrier or Foreign Air Carrier; Request for Determination by an Airport Owner or Operator

This section describes the requirements for carrier complaints and airport requests for determination. In keeping with the proposal, paragraph (a) states that both complaints and requests would be submitted in accordance with the usual technical requirements of proceedings under 14 CFR Part 302. (14 CFR § 302.3 specifies such matters as the number of copies to be filed, the size of pages that may be used, and the filing address.) ATA's comments stated that the proposed rule failed ''to specify the type and form of briefs to be presented upon the filing of complaints.'' ATA is thus incorrect.

As noted above, no commenter objected in principle to the basic procedure proposed in the NPRM for consolidating all complaints and any request for determination once any carrier has filed a complaint under this subpart. The final rule adopts the language of the NPRM. Following the first complaint, other air carriers or foreign air carriers wishing to file their own complaints would have seven days to do so. An airport owner or operator's request for determination would also have to be submitted no later than seven days after a carrier complaint. The Authorization Act specifies that all complaints would have to be submitted within 60 days of the written notice, even if this is less than seven days after the initial complaint. The law does not provide for entertaining later complaints. No potential complainant, having had 54 or more days to prepare, will be disadvantaged by the immutability of the 60-day filing limit. As indicated above, JAL's request to extend the statutory deadline for foreign carriers is denied. While there is no statutory limitation on submitting airport requests for determination, no commenter objected to our proposal to impose a similar 60-day limit on such requests, and that proposal is also made final here. As noted in the NPRM, airport fee increases become incontestable under this subpart 60 days after the airport provides written notice to carriers of the imposition of a new or increased fee. The early determination of the reasonableness of a fee, which is the purpose of the Act, would be undermined by allowing more time. There is no point in expending Departmental resources on airport requests brought after that date.

Section 302.605 Contents of Complaint or Request for Determination

Most of the issues pertaining to this section have been fully discussed above. The following is only a brief summary of the requirements in the final rule.

Carriers filing complaints and airports filing requests for determination will generally be expected to submit documentation that contains the filing party's entire position and supporting evidence. We recognize, however, that an airport may control information or documents that a complaining carrier would need. If that is the case, and the carrier has unsuccessfully attempted to obtain the necessary information, § 302.605 now provides that the carrier

must state that fact in the complaint. As discussed above, the Department anticipates that airports will promptly disclose any necessary information.

The carrier filing the complaint or the airport owner or operator filing the request must serve the complaint or request and accompanying documents on all carriers serving the airport using the expedited procedures proposed in the NPRM. If a complaint has already been filed with respect to a particular airport's fees, additional complaints are due seven days after the initial complaint. All complaints must be filed within 60 days after the carrier has received written notice of a new or increased fees.

The final rule retains the language that the filing carrier or airport would have to certify that it had previously attempted to resolve any fee dispute directly. In addition, as noted above, the filing party must certify that any submission on computer diskette is a true copy of the data file used to prepare the brief or exhibit.

Section 302.607 Answers to a Complaint or Request for Determination

As discussed above, the most significant change in this section involves the time for filing answers to complaints or requests for determination. Answers will be due 14 days after the first complaint is filed rather than seven days after each complaint. Answers are to respond to both the initiating complaint and any follow-on complaints, which will continue to be due seven days after the initial complaint. This will respond to requests that we make it possible for parties to submit a consolidated answer to all complaints, while still allowing the Department sufficient time to review complaints or requests and the answers submitted.

Under the final rule, therefore, upon receiving a copy of a complaint filed by another carrier, an air carrier or foreign air carrier could file its own complaint within seven days or an answer to the first complaint within 14 days. As noted in the preamble to the NPRM, it is technically permissible for a party to submit both its own complaint and an answer to the initiating complaint. However, because of the limited time available for the Department to review complaints and answers, parties are strongly urged to avoid duplicative filings. Naturally, answers, including answers in support of a complainant's position, do not give the answering party status as an additional complainant, nor may answers raise new objections to a fee or fees in dispute. A carrier that wants to raise any new arguments in opposition to the fee should do so in a follow-on complaint under § 302.603.

Both the airport owner or operator and any carrier serving the airport may file an answer to a complaint under this subpart. In the case of an airport request for determination, any carrier serving the airport would be authorized to file an answer. While only carriers subject to a new or increased fee at the airport may submit a follow-on complaint under § 302.603, any carrier at the airport may submit an answer.

As stated above, answering parties would generally be expected to set out all of their responsive arguments, testimony and exhibits in their answer.

The answering party will serve the complaining carrier or carriers or the airport owner or operator requesting the determination by hand, by electronic transmission, or by overnight express delivery. The answering party must certify that the answer and accompanying documents will be received no later than the day the answer is due, and that any submission on computer diskette is a true copy of the data file used to prepare the brief or exhibit. Answers need only be served on the party to which the answer is directed.

Section 302.609 Replies

ACI–NA argued that we should eliminate the opportunity to file replies, claiming that they are unnecessary, and that the requirement that they be filed two calendar days after the answer makes the opportunity to reply illusory. We see no need to eliminate the opportunity to file replies, although we emphasize that replies are voluntary submissions.

While no other party suggested eliminating replies altogether, Massport, the Maryland Aviation Administration, and AAAE all recommended that we allow two business days rather than two calendar days. In part, it appears that this recommendation may stem from a misunderstanding of our procedures. AAAE, for example, states that ''The rules as proposed would require that a party replying to an answer filed on a Friday file its reply on Sunday evening, when the agency is not even open for business.'' This is simply wrong. As provided in our rules of practice (14 CFR § 302.16), any filing that would be due on a Saturday, Sunday, or government holiday is automatically due instead on the next business day. Accordingly, when an answer is due on a Thursday or Friday, any reply to the answer would be due by close of business on the following Monday (or the first business day thereafter). In such a case, the replying party would thus have at least three calendar days to prepare and submit its reply, although we recognize that two of those days are on the weekend.

In accordance with our proposal, only the carrier originating a complaint or the airport originating a request for determination would be authorized to file a reply. Except as provided in subpart A of 14 CFR Part 302, replies by any other party would not be accepted, nor would further responsive pleadings. For that reason, the NPRM did not propose to require that replies be served under the expedited procedures required for complaints, requests for determination, and answers. The NPRM specifically invited commenters to address whether expedited procedures were necessary for replies, but no party did so. We conclude that ordinary service as provided by 14 CFR § 302.8 (including service by mail) will suffice for replies. As with complaints, requests for determination, and answers, however, the replying party must certify that any submission on computer diskette is a true copy of the data file used to prepare the brief or exhibit.

Section 302.611 Review of Complaints

As was proposed, paragraph (a) of § 302.611 provides that the Secretary will determine within 30 days after a complaint is filed whether a significant dispute exists and whether the complaint meets the procedural requirements of subpart F. If the Secretary determines that there is no significant dispute, he or she will issue an order dismissing the complaint, as required by the FAA Authorization Act. The Secretary's order will include an explanation of the reasons for the determination. If the Secretary determines that the complaint does not meet the procedural requirements of this subpart (for example, the complaint was not properly served on the airport owner or operator), the Secretary will dismiss the complaint without prejudice. In this case, the order would explain any conditions necessary for the complaint to be re-filed.

When one or more properly filed complaints have been submitted, the Secretary will issue an instituting order consolidating all complaints that raise significant issues and any request for determination. The instituting order will assign the consolidated case to an administrative law judge and describe the issues to be considered and the parties that will participate.

In addition, § 302.611 now provides that the instituting order may contain special provisions for exchange or disclosure of information by the parties.

As discussed above, the Department presumes that airports will provide all information necessary for carriers to understand the basis and justification for any new or increased airport fee. However, we have included this provision to clarify the Department's ability to ensure that adequate information is made available.

Finally, the Secretary's order will state when the administrative law judge must issue a recommended decision (60 days after the instituting order, unless the order specifies a shorter period).

Section 302.613 Review of Requests for Determination

An airport owner or operator's request for determination of the reasonableness of an airport fee will generally be handled in the same manner as a carrier complaint. As discussed above, we have revised the language of § 302.613 to clarify the timing for action on an airport's request.

When only an airport request has been filed, and not a carrier complaint, the Secretary will determine within 30 days whether there is a significant dispute and whether the procedural requirements of the subpart have been met. Properly submitted requests raising a significant dispute will be assigned to an administrative law judge in the same manner as carrier complaints, with appropriate guidelines on the scope of the issues and the parties to participate. If there is a procedural deficiency, the request will be dismissed without prejudice, and the order of dismissal will set forth the terms and conditions under which a revised request could be filed.

However, when both an airport request and one or more carrier complaints have been filed, the Secretary will proceed under the statutorily prescribed schedule for resolving the complaint. As required by the FAA Authorization Act, the Secretary will determine whether any complaint presents a significant dispute within 30 days after the first complaint is submitted. If the first complaint is filed after the airport owner or operator's request, the request will be reviewed in conjunction with the complaints, and the consolidated instituting order may be issued more than 30 days following the request.

As discussed above, the Secretary will not dismiss an airport owner or operator's request for determination on the basis that it does not raise a significant issue. In such cases, the Secretary would usually proceed directly to issue a final order determining whether the fee is reasonable. While this determination would ordinarily not require any additional procedures, the Secretary would retain discretion to require whatever additional procedures are necessary in a particular case.

ACI–NA notes that paragraph (b) differs from paragraph (c) in that the latter specifies that the Secretary's determination with respect to reasonableness will be issued within 120 days after the airport request is filed. ACI–NA asks that we insert the 120-day language in paragraph (b) as well. While ACI–NA is correct that the two provisions should be parallel, § 302.619(b) contains the completion time applicable to all requests for determination. Therefore, to avoid confusion, the final rule deletes the last sentence of proposed paragraph (c).

Section 302.615 Decision by Administrative Law Judge

As provided by the FAA Authorization Act, § 302.615 requires the administrative law judge to issue a recommended decision within 60 days after the case is assigned by the Secretary for hearing, unless the instituting order specifies a shorter period.

ATA asked that we set out in this subpart specific requirements for hearings on airport fee disputes. It recommended that ''the Rule provide clear definition as to the nature of these hearings and a standardized approach to the resolution of the complicated factual and legal issues raised by airport fee disputes. As presently crafted, the NPRM would apparently rely upon the Secretary's order to draft a different approach in each and every case. Aside from the logical impracticality of such an unpredictable approach, we believe it to be so lacking in procedural guidance as to be fundamentally inconsistent with the requirements of Section 47129. As an alternative, we propose that the Secretary incorporate the procedures governing hearings set forth in 14 CFR part 302, subpart A, as modified in order to meet the time constraints imposed by Section 47129.''

ATA appears to be suggesting that the Department lacks authority to impose specific requirements on the conduct of individual proceedings. This is simply incorrect, and indeed one important purpose of an instituting order is to tailor the general rules to the needs of a particular case. However, with respect to ATA's alternative suggestion that we rely generally on subpart A procedures, no change from the NPRM language is necessary. We have made it clear throughout this rulemaking that subpart A procedures will apply in the absence of a specific applicable provision in this subpart or a direction in the instituting order. As the FAA Authorization Act expressly states, following assignment of the proceeding to an administrative law judge, ''the matter shall be handled in accordance with part 302 of title 14, Code of Federal Regulations, or as modified by the Secretary to ensure an orderly disposition of the matter within the 120-day period and any specifically applicable provisions of this section.'' (49 U.S.C. 47129(c)(2)). Similarly, subpart A of part 302 states as follows:

> Subpart A of this part sets forth general rules applicable to all types of proceedings. Each of the other subparts of this part sets forth special rules applicable to the type of proceedings described in the title of the subpart. Therefore, for information as to applicable rules, reference should be made to subpart A and to the rules in the subpart relating to the particular type of proceeding 14 CFR 302.1(b).

ACI–NA argued that a prehearing conference should be mandatory for all parties in any proceeding brought under this subpart in which an oral hearing is scheduled. Although ACI–NA points out that this is common practice in the federal courts and many state courts, we do not believe that it is desirable to include this requirement in the rule. Once the case is assigned for hearing, we anticipate that the administrative law judge will frequently choose to order a prehearing conference. There might even be situations in which it would be appropriate for the Secretary to require a prehearing conference, in which case the instituting order will direct one be held. However, there is no reason for the final rule to make a prehearing conference mandatory in all cases.

Section 302.617 Petitions for Discretionary Review

The Los Angeles Department of Airports objected to our proposal to provide for the filing of petitions for discretionary review of the administrative law judge's recommended decision. Instead, it argues that the FAA Authorization Act mandates Secretarial review of the recommended decision. It advocated allowing seven days for parties to provide exceptions to the recommended decision, and an additional seven days in which to file cross-exceptions.

As we stated in the preamble to the NPRM, we anticipate that the Secretary will issue all final orders in proceedings under subpart F. Nevertheless, we do not agree that the Authorization Act makes this mandatory. In fact, the statute specifically anticipates that the Secretary might not issue a final order: It provides that the administrative law

judge's recommended decision is to be considered the Secretary's final order if the Secretary does not act within 120 days after a complaint is filed. Accordingly, we will adopt the proposed structure of providing for discretionary review of the recommended decision.

As we proposed, a party to the proceeding will be able to file a petition for discretionary review of the administrative law judge's decision within five days after the recommended decision is served. The petitioner will serve all parties by hand, electronic transmission or overnight express delivery, and will certify that all parties had received the petition or would receive it by the date of filing. Any other party could then submit an answer, which would be due four days after the petition is filed. AAAE and ACI–NA stated that answers should be subject to the same expedited service requirements as petitions, but they did not explain why this would be necessary. The Department does not anticipate permitting further pleadings at this stage of the proceeding, and we do not believe that the burden of expedited service is justified.

Section 302.619 Completion of Proceeding

This section sets out the completion dates for proceedings conducted under this subpart. No comments were submitted on it, and it is unchanged from the NPRM.

Paragraph (a) states that the Secretary will issue a final order determining whether the disputed fee is reasonable within 120 days after the filing of a complaint by an air carrier or foreign air carrier, unless the complaint is dismissed as provided in proposed § 302.611. This is the time limit for resolving air carrier complaints set forth in the FAA Authorization Act.

Paragraphs (b) and (c) address proceedings involving requests for determination by airport owners and operators. Although the FAA Authorization Act does not impose a time limit on such requests, § 302.619 provides a 120-day limit on these proceedings as well. When an airport has filed a request for determination but there are no carrier complaints with respect to the same fee, paragraph (b) states that the Secretary would issue a final order within 120 days of the request. However, as noted in § 302.613, the Department will consolidate proceedings concerning the same airport fee or fees that are the subject of both a carrier complaint and an airport request for determination. In this situation, paragraph (c) provides that the timetable for resolving carrier complaints would control the schedule for action by the Department. Thus, if a carrier complaint is filed before the airport request, the Department would issue a final order in the consolidated proceeding in less than 120 days after the airport's request for determination. If one or more carriers file a complaint after the airport request, the 120-day period would begin on the day the first carrier complaint is filed.

Section 302.621 Final Order

Following review of the recommended decision, the Secretary will issue a final determination with respect to the reasonableness of an airport fee that is the subject of a complaint or a request under this subpart. The Secretary's order will set forth the reasoning underlying the determination, and, if a fee is determined to be unreasonable, the order will provide for a refund or credit of the unreasonable charge. As noted in the NPRM, the exact terms under which the refund or credit would be ordered would vary with the particular circumstances of each case, but the Department intends to ensure prompt action.

The FAA Authorization Act, in new 49 U.S.C. Section 47129 (a) (3), limits the Secretary's order to determining reasonableness, and the order would not set the level of the fee. The Maryland Aviation Administration expressed concern in its comments that disputes may not really be resolved within the 120-day limit unless the Department states what a reasonable fee would be. In the absence of such a statement, a revised fee would still be subject to challenge. Because the limitation on the Secretary's authority is a matter of statute, there is nothing we can do in this rulemaking to change it. However, the Secretary's order will attempt to set out the analysis underlying the decision as clearly as possible. If a fee is found unreasonable, we hope and expect that parties will be able to establish a reasonable fee after reviewing the decision and analysis.

The Maryland Aviation Administration also states that ''the Department, or as may be required, the framers of the underlying statutory scheme, should consider whether the Department should award costs to airports'' when a disputed fee is found reasonable. As the commenter appears to appreciate, the Department does not have authority to award costs to the prevailing party in a fee dispute under subpart F. Accordingly, the comment is beyond the scope of this rulemaking.

ACI–NA asks that the rule clarify that ''any finding of unreasonableness resulting from a complaint filed by a non-signatory carrier does not affect the underlying rates for signatory carriers, since the signatory fees may not be challenged.'' No rule change is needed here. However, it is obvious that no fee will be found to be unreasonable under subpart F unless it is the subject of a complaint or a request for determination.

As stated above, the Department expects the Secretary to issue all final orders. However, if the Secretary fails to issue an order within 120 days after a complaint is filed, the FAA Authorization Act requires that the administrative law judge's decision be deemed the final order of the Secretary. Section 302.621(c) restates this requirement. There is no corresponding legislative requirement with respect to airport requests for determination. Therefore Section 302.621 does not contain any provision for automatic adoption of the administrative law judge's decision. The Department nevertheless intends to resolve airport requests for determination within 120 days after they are filed.

Justification for Immediate Effectiveness

Section 553 of the Administrative Procedure Act provides that the effective date of a new rule should be at least 30 days after it is published, unless the agency finds good cause for a shorter period.

In enacting the FAA Authorization Act, the Congress made it clear that it intends for fee disputes between carriers and airports to be resolved promptly. Congress required that the Department issue this rule within 90 days of enactment of the Authorization Act, and mandated that all proceedings brought under the new procedures lead to a final order within 120 days. The Department will be unable to process any carrier complaints under this subpart until the procedures are effective. Accordingly, the Department finds that good cause exists to make this rule effective on publication in the **Federal Register**.

Regulatory Evaluation Summary

This final rule contains new procedures for the filing and adjudication of complaints by air carriers and foreign air carriers alleging that an airport has imposed an unreasonable fee or charge on the complaining carrier. It also sets forth corresponding procedures under which an airport owner or operator may request and receive a determination of the reasonableness of a fee or charge it

has imposed on one or more air carriers or foreign air carriers. The new procedures replace existing procedures under 14 CFR part 13, and impose no new substantive requirements on either carriers or airports. The only commenter to question the tentative conclusion in the NPRM that the economic effect of the proposed rule would be minimal was the Maryland Aviation Administration, which argues that ''[t]he cost to provide expert witnesses and legal counsel if it is determined that there is a 'significant dispute' may well prove to be material.'' The Maryland Aviation Administration did not attempt to quantify the costs it believed involved. More importantly, it did not establish that the costs are actually the result of the procedural rules at issue here rather than the general cost of the litigation authorized by 49 U.S.C. 47129. Accordingly, the Department concludes that the economic impact of the final rule is minimal and that further calculation of the economic effects is not warranted.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily or disproportionately burdened by government regulations. The RFA requires a Regulatory Flexibility Analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. This rule contains procedural requirements for processing carrier complaints and airport requests. The Department concludes that the rule will not have a significant economic impact on a substantial number of small entities.

Federalism Implications

The final rule will not 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. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

This rule contains no information collection requirements that require approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3507 *et seq.*).

Conclusion

Although the Department has concluded that the economic effects of this rulemaking are minimal, this rule is considered significant under Executive Order 12866 because of the public interest in this rulemaking. The Department certifies that this rule 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. This rule is considered significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1978).

List of Subjects in 14 CFR Part 302

Administrative practice and procedure, Air carriers, Airports, Postal Service.

The Amendments

Accordingly, the Department of Transportation amends 14 CFR part 302 as follows:

PART 302—RULES OF PRACTICE IN PROCEEDINGS

1. The authority citation for 14 CFR Part 302 is revised to read:

Authority: 5 U.S.C. 551 *et seq.*; 39 U.S.C. 5402; 42 U.S.C. 4321; 49 U.S.C. 40101, 40102, 40113, 40114, Chapters 411–415, 41702, 41705, 41706, 41901, 41907, 41909, 41910, 42111, 46301, 46302, 46303, 46105, 47129.

2. A new subpart F is added to 14 CFR Part 302 to read as follows:

Subpart F—Rules Applicable to Proceedings Concerning Airport Fees

Sec.

302.601 Applicability of this subpart.
302.603 Complaint by an air carrier or foreign air carrier; request for determination by an airport owner or operator.
302.605 Contents of complaint or request for determination.
302.607 Answers to a complaint or request for determination.
302.609 Replies.
302.611 Review of complaints.
302.613 Review of requests for determination.
302.615 Decision by administrative law judge.
302.617 Petitions for discretionary review.
302.619 Completion of proceedings.
302.621 Final order.

Subpart F—Rules Applicable to Proceedings Concerning Airport Fees

§ 302.601 Applicability of this subpart.

(a) This subpart contains the specific rules that apply to a complaint filed by one or more air carriers or foreign air carriers, pursuant to 49 U.S.C. 47129 (a), for a determination of the reasonableness of a fee increase or a newly established fee for aeronautical uses that is imposed upon the air carrier or foreign air carrier by the owner or operator of an airport. This subpart also applies to requests by the owner or operator of an airport for such a determination. An airport owner or operator has imposed a fee on an air carrier or foreign air carrier when it has taken all steps necessary under its procedures to establish the fee, whether or not the fee is being collected or carriers are currently required to pay it.

(b) This subpart does not apply to—

(1) A fee imposed pursuant to a written agreement with air carriers or foreign air carriers using the facilities of an airport;

(2) A fee imposed pursuant to a financing agreement or covenant entered into prior to August 23, 1994; or

(3) Any other existing fee not in dispute as of August 23, 1994.

§ 302.603 Complaint by an air carrier or foreign air carrier; request for determination by an airport owner or operator.

(a) Any air carrier or foreign air carrier may file a complaint with the Secretary for a determination as to the reasonableness of any fee imposed on the carrier by the owner or operator of an airport. Any airport owner or operator may also request such a determination with respect to a fee it has imposed on one or more air carriers. The complaint or request for determination shall conform to the requirements of this subpart and § 302.3 concerning the form and filing of documents.

(b) If an air carrier or foreign air carrier has previously filed a complaint with respect to the same airport fee or fees, any complaint by another carrier and any airport request for determination shall be filed no later than 7 calendar days following the initial complaint. In addition, all complaints or requests for determination must be filed on or before the 60th day after the carrier receives written notice of the imposition of the new fee or the imposition of the increase in the fee.

(c) To ensure an orderly disposition of the matter, all complaints and any request for determination filed with respect to the same airport fee or fees will be considered in a consolidated proceeding, as provided in §§ 302.611 and 302.613.

§ 302.605 Contents of complaint or request for determination.

(a) The complaint or request for determination shall set forth the entire grounds for requesting a determination of the reasonableness of the airport fee.

The complaint or request shall include a copy of the airport owner or operator's written notice to the carrier of the imposition of the fee, a statement of position with a brief, and all supporting testimony and exhibits available to the carrier on which the filing party intends to rely. In lieu of submitting duplicative exhibits or testimony, the filing party may incorporate by reference testimony and exhibits already filed in the same proceeding.

(b) All exhibits and briefs prepared on electronic spreadsheet or word processing programs should be accompanied by standard-format computer diskettes containing those submissions. Word processing and spreadsheets files must be readable by current versions of one or more of the following programs, or in such other format as may be specified by notice in the **Federal Register**: Microsoft Word, Word Perfect, Ami Pro, Microsoft Excel, Lotus, Quattro Pro, or ASCII tab-delineated files. Parties should submit one copy of each diskette to the docket section, one copy to the office of the Chief Administrative Law Judge (M–50), and one copy to the Chief, Economic and Financial Analysis Division (X–55), of the Office of Aviation Analysis. Filers should ensure that files on the diskettes are unalterably locked.

(c) When a carrier files a complaint, it must also submit the following certifications:

(1) The carrier has served the complaint, brief, and all supporting testimony and exhibits on the airport owner or operator and all other air carriers and foreign air carriers serving the airport by hand, by electronic transmission, or by overnight express delivery. (Unless an air carrier or foreign air carrier has informed the complaining carrier that a different person should be served, service may be made on the person responsible for communicating with the airport on behalf of the carrier about airport fees.);

(2) The parties served have received the complaint, brief, and all supporting testimony and exhibits or will receive them no later than the date the complaint is filed;

(3) The carrier has previously attempted to resolve the dispute directly with the airport owner or operator;

(4) When there is information on which the carrier intends to rely that is not included with the brief, exhibits, or testimony, the information has been omitted because the airport owner or operator has not made that information available to the carrier. The certification shall specify the date and form of the carrier's request for information from the airport owner or operator; and

(5) Any submission on computer diskette is a true copy of the data file used to prepare the printed versions of the exhibits or briefs.

(d) When an airport owner or operator files a request for determination, it must also submit the following certifications:

(1) The airport owner or operator has served the request, brief, and all supporting testimony and exhibits on all air carriers and foreign air carriers serving the airport by hand, by electronic transmission, or by overnight express delivery. (Unless the air carrier or foreign air carrier has informed the airport owner or operator that a different person should be served, service may be made on the person responsible for communicating with the airport on behalf of the carrier about airport fees.);

(2) The carriers served have received the request, brief, and all supporting testimony and exhibits or will receive them no later than the date the request is filed;

(3) The airport owner or operator has previously attempted to resolve the dispute directly with the carriers; and

(4) Any submission on computer diskette is a true copy of the data file used to prepare the printed versions of the exhibits or briefs.

§ 302.607 Answers to a complaint or request for determination.

(a)(1) When an air carrier or foreign air carrier files a complaint under this subpart, the owner or operator of an airport and any other air carrier or foreign air carrier serving the airport may file an answer to the complaint as provided in paragraphs (b) and (c) of this section.

(2) When the owner or operator of an airport files a request for determination of the reasonableness of a fee it has imposed, any air carrier or foreign air carrier serving the airport may file an answer to the request.

(b) The answer to a complaint or request for determination shall set forth the answering party's entire response. When one or more additional complaints or a request for determination has been filed pursuant to § 302.603(b) with respect to the same airport's fee or fees, the answer shall set forth the answering party's entire response to all complaints and any such request for determination. The answer shall include a statement of position with a brief and any supporting testimony and exhibits on which the answering party intends to rely. In lieu of submitting duplicative exhibits or testimony, the answering party may incorporate by reference testimony and exhibits already filed in the same proceeding.

(c) Answers to a complaint shall be filed no later than fourteen calendar days after the filing date of the first complaint with respect to the fee or fees in dispute at a particular airport. Answers to a request for determination shall be filed no later than fourteen calendar days after the filing date of the request.

(d) All exhibits and briefs prepared on electronic spreadsheet or word processing programs should be accompanied by standard-format computer diskettes containing those submissions. Word processing and spreadsheets files must be readable by current versions of one or more of the following programs, or in such other format as may be specified by notice in the **Federal Register**: Microsoft Word, Word Perfect, Ami Pro, Microsoft Excel, Lotus, Quattro Pro, or ASCII tab-delineated files. Parties should submit one copy of each diskette to the docket section, one copy to the office of the Chief Administrative Law Judge (M–50), and one copy to the Chief, Economic and Financial Analysis Division (X–55), of the Office of Aviation Analysis. Filers should ensure that files on the diskettes are unalterably locked.

(e) The answering party must also submit the following certifications:

(1) The answering party has served the answer, brief, and all supporting testimony and exhibits by hand, by electronic transmission, or by overnight express delivery on the carrier filing the complaint or the airport owner or operator requesting the determination;

(2) The parties served have received the answer and exhibits or will receive them no later than the filing date of the answer; and

(3) Any submission on computer diskette is a true copy of the data file used to prepare the printed versions of the exhibits or briefs.

§ 302.609 Replies.

(a) The carrier submitting a complaint may file a reply to any or all of the answers to the complaint. The airport owner or operator submitting a request for determination may file a reply to any or all of the answers to the request for determination.

(b) The reply shall be limited to new matters raised in the answers. It shall constitute the replying party's entire response to the answers. It shall be in the form of a reply brief and may include supporting testimony and exhibits responsive to new matters raised in the answers. In lieu of submitting duplicative exhibits or testimony, the replying party may incorporate by reference testimony and

exhibits already filed in the same proceeding.

(c) The reply shall be filed no later than two calendar days after answers are filed.

(d) All exhibits and briefs prepared on electronic spreadsheet or word processing programs should be accompanied by standard-format computer diskettes containing those submissions. Word processing and spreadsheets files must be readable by current versions of one or more of the following programs, or in such other format as may be specified by notice in the **Federal Register**: Microsoft Word, Word Perfect, Ami Pro, Microsoft Excel, Lotus, Quattro Pro, or ASCII tab-delineated files. Parties should submit one copy of each diskette to the docket section, one copy to the office of the Chief Administrative Law Judge (M–50), and one copy to the Chief, Economic and Financial Analysis Division, (X–55) of the Office of Aviation Analysis. Filers should ensure that files on the diskettes are unalterably locked.

(e) The carrier or airport owner or operator submitting the reply must certify that it has served the reply and all supporting testimony and exhibits on the party or parties submitting the answer to which the reply is directed and that any submission on computer diskette is a true copy of the data file used to prepare the printed versions of the exhibits or briefs.

§ 302.611 Review of complaints.

(a) Within 30 days after a complaint is filed under this subpart, the Secretary will determine whether the complaint meets the procedural requirements of this subpart and whether a significant dispute exists, and take appropriate action pursuant to paragraph (b), (c), or (d) of this section.

(b) If the Secretary determines that a significant dispute exists, he or she will issue an instituting order assigning the complaint for hearing before an administrative law judge. The instituting order will—

(1) Establish the scope of the issues to be considered and the procedures to be employed;

(2) Indicate the parties to participate in the hearing;

(3) Consolidate into a single proceeding all complaints and any request for determination with respect to the fee or fees in dispute; and

(4) Include any special provisions for exchange or disclosure of information by the parties.

(c) The Secretary will dismiss any complaint if he or she finds that no significant dispute exists. The order dismissing the complaint will contain a concise explanation of the reasons for the determination that the dispute is not significant.

(d) If the Secretary determines that the complaint does not meet the procedural requirements of this subpart, the complaint will be dismissed without prejudice to filing a new complaint. The order of the Secretary will set forth the terms and conditions under which a revised complaint may be filed.

§ 302.613 Review of requests for determination.

(a) Except as provided in paragraph (e) of this section, within 30 days after an airport owner or operator files a request for determination of the reasonableness of a fee under this subpart, the Secretary will determine whether the request meets the procedural requirements of this subpart and whether a significant dispute exists.

(b) If the Secretary determines that a significant dispute exists, he or she will issue an instituting order assigning the request for hearing before an administrative law judge. The instituting order will establish the scope of the issues to be considered and the procedures to be employed and will indicate the parties to participate in the hearing. The instituting order will consolidate into a single proceeding all complaints and any request for determination with respect to the fee or fees in dispute.

(c) If the Secretary finds that the request for determination presents no significant dispute, the Secretary will either issue a final order as provided in § 302.621 or set forth the schedule for any additional procedures required to complete the proceeding.

(d) If the Secretary determines that the request does not meet the procedural requirements of this subpart, the request for determination will be dismissed without prejudice to filing a new request. The order of the Secretary will set forth the terms and conditions under which a revised request may be filed.

(e) When both a complaint and a request for determination have been filed with respect to the same airport fee or fees, the Secretary will issue a determination as to whether the complaint, the request, or both meet the procedural requirements of this subpart and whether a significant dispute exists within 30 days after the complaint is filed.

§ 302.615 Decision by administrative law judge.

The administrative law judge shall issue a decision recommending a disposition of a complaint or request for determination within 60 days after the date of the instituting order, unless a shorter period is specified by the Secretary.

§ 302.617 Petitions for discretionary review.

(a) Within 5 calendar days after service of a decision by an administrative law judge, any party may file with the Secretary a petition for discretionary review of the administrative law judge's decision.

(b) Petitions for discretionary review shall comply with § 302.28(a). The petitioner must also submit the following certifications:

(1) The petitioner has served the petition by hand, by electronic transmission, or by overnight express delivery on all parties to the proceeding; and

(2) The parties served have received the petition or will receive it no later than the date the petition is filed.

(c) Any party may file an answer in support of or in opposition to any petition for discretionary review. The answer shall be filed within 4 calendar days after service of the petition for discretionary review. The answer shall comply with the page limits specified in § 302.28(b).

§ 302.619 Completion of proceedings.

(a) When a complaint with respect to an airport fee or fees has been filed under this subpart and has not been dismissed, the Secretary will issue a determination as to whether the fee is reasonable within 120 days after the complaint is filed.

(b) When a request for determination has been filed under this subpart and has not been dismissed, the Secretary will issue a determination as to whether the fee is reasonable within 120 days after the date the request for determination is filed.

(c) When both a complaint and a request for determination have been filed with respect to the same airport fee or fees and have not been dismissed, the Secretary will issue a determination as to whether the fee is reasonable within 120 days after the complaint is filed.

§ 302.621 Final order.

(a) When a complaint or request for determination stands submitted to the Secretary for final decision on the merits, he or she may dispose of the issues presented by entering an appropriate order, which will include a statement of the reasons for his or her findings and conclusions. Such an order shall be deemed a final order of the Secretary.

(b) The final order of the Secretary shall include, where necessary,

directions regarding an appropriate refund or credit of the fee increase or newly established fee which is the subject of the complaint or request for determination.

(c) If the Secretary has not issued a final order within 120 days after the filing of a complaint by an air carrier or foreign air carrier, the decision of the administrative law judge shall be deemed to be the final order of the Secretary.

Issued in Washington, DC, on January 30, 1995.

Federico Peña,

Secretary.

[FR Doc. 95–2674 Filed 1–31–95; 3:15 pm]

BILLING CODE 4910–62–P

Friday
February 3, 1995

Part V

Federal Emergency Management Agency

Changes to the Hotel and Motel Fire Safety Act National Master List; Notice

FEDERAL EMERGENCY MANAGEMENT AGENCY

Changes to the Hotel and Motel Fire Safety Act National Master List

AGENCY: United States Fire Administration, FEMA.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA or Agency) gives notice of additions and corrections/changes to, and deletions from, the national master list of places of public accommodations which meet the fire prevention and control guidelines under the Hotel and Motel Fire Safety Act.

EFFECTIVE DATE: March 6, 1995.

ADDRESSES: Comments on the master list are invited and may be addressed to the Rules Docket Clerk, Federal Emergency Management Agency, 500 C Street, SW., room 840, Washington, D.C. 20472, (fax) (202) 646–4536. To be added to the National Master List, or to make any other change to the list, please see **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: John Ottoson, Fire Management Programs Branch, United States Fire Administration, Federal Emergency Management Agency, National Emergency Training Center, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447–1272.

SUPPLEMENTARY INFORMATION: Acting under the Hotel and Motel Fire Safety Act of 1990, 15 U.S.C. 2201 note, the United States Fire Administration has worked with each State to compile a national master list of all of the places of public accommodation affecting commerce located in each State that meet the requirements of the guidelines under the Act. FEMA published the national master list in the **Federal Register** on Tuesday, November 29, 1993, 58 FR 62718, and published changes approximately monthly since then.

Parties wishing to be added to the National Master List, or to make any other change, should contact the State office or official responsible for compiling listings of properties which comply with the Hotel and Motel Fire Safety Act. A list of State contacts was published in 58 FR 17020 on March 31, 1993. If the published list is unavailable to you, the State Fire Marshal's office can direct you to the appropriate office. Periodically FEMA will update and redistribute the national master list to incorporate additions and corrections/changes to the list, and deletions from the list, that are received from the State offices.

Each update contains or may contain three categories: ''Additions;'' ''Corrections/changes;'' and ''Deletions.'' For the purposes of the updates, the three categories mean and include the following:

''Additions'' are either names of properties submitted by a State but inadvertently omitted from the initial master list or names of properties submitted by a State after publication of the initial master list;

''Corrections/changes'' are corrections to property names, addresses or telephone numbers previously published or changes to previously published information directed by the State, such as changes of address or telephone numbers, or spelling corrections; and

''Deletions'' are entries previously submitted by a State and published in the national master list or an update to the national master list, but subsequently removed from the list at the direction of the State. Copies of the national master list and its updates may be obtained by writing to the Government Printing Office, Superintendent of Documents, Washington, DC 20402–9325. When requesting copies please refer to stock number 069–001–00049–1.

The update to the national master list follows below.

Dated: January 30, 1995.

John P. Carey,

General Counsel.

HOTEL AND MOTEL FIRE SAFETY ACT NATIONAL MASTER LIST JANUARY 20, 1995 UPDATE

Index and Property name	PO Box/Rt No.	Street address	City, State/ZIP	Telephone
ADDITIONS				
Alaska				
AK0042 Alaska Ocean View Bed and Breakfast		1101 Edgecumbe Dr .	Sitka, AK 99835	(907) 747–8310
California				
CA1441 Mandarin Oriental, San Francisco		222 Sansome St	San Francisco, CA 94109.	(415) 885–0999
Kansas				
KS0153 Hampton Inn, Topeka		1401 Ashworth Place	Topeka, KS 66604	(913) 273–0003
Maine				
ME0056 Holiday Inn		404 Odlin Rd	Bangor, ME 04401	(207) 947–0101
Minnesota				
MN0288 Park Inn International		250 Canal Park Drive	Duluth, MN 55802	(218) 727–8821
MN0292 Hanpton Inn, Eagan		3000 Eagandale Place.	Eagan, MN 55121	(612) 688–3343
MN0290 The Old Railroad Inn		219 Moore Street	Jackson, MN 56143	(507) 847–5348
MN0291 Motel 6		11274 210th Street	Lakeville, MN 55044	(612) 469–1900
MN0289 Motel 6		2107 West Frontage Road.	Rochester, MN 55901	(507) 282–6625
New York				
NY0606 Howard Johnson Lodge		551 Rt. 211 East	Middletown, NY 10954.	(914) 342–5822
NY0605 Ramada Inn, Airport		1273 Chili Ave	Rochester, NY 14624	(716) 464–8800
Oklahoma				
OK0098 Century Center Hotel		1 North Broadway	Oklahoma City, OK 73102.	(405) 235–2780

HOTEL AND MOTEL FIRE SAFETY ACT NATIONAL MASTER LIST JANUARY 20, 1995 UPDATE—Continued

Index and Property name	PO Box/Rt No.	Street address	City, State/ZIP	Telephone
Oregon				
OR0182 Portland/Beaverton Shilo Inn		9900 SW Canyon Rd	Beaverton, OR 97225	(503) 297–2551
OR0172 Bend Alpine Hotel		19 SW Century Drive	Bend, OR 97702	(503) 389–3813
OR184 Motel 6		997 Oregon Ave	Burns, OR 97720	(503) 573–3013
OR0171 Wilderness Inn Motel		301 W. North St	Enterprise, OR 97828	(503) 426–4535
OR0183 Mt. Hood Inn		87450 E. Government Camp Loop.	Government Camp, OR 97028.	(503) 272–3205
OR0181 Grants Pass Shilo Inn		1880 NW 6th St	Grants Pass, OR 975261038.	(503) 479–8391
OR0186 Motel 6		5136 S. 6th Street	Klamath Falls, OR 97601.	(503) 884–2110
OR0180 Lakeview Lodge Motel		301 North 9 Street	Lakeview, OR 97630	(503) 947–2225
OR0187 Motel 6	US 5 Rt 62	2400 Biddle Road	Medford, OR 97504	(503) 779–0550
OR0173 The Vikings Cottages and Condominiums		729 NW Coast St	Newport, OR 97365	(503) 265–2477
OR0185 Motel 6		275 NE 12 St	Ontario, OR 97914	(503) 889–6617
OR0178 Motel 6		17959 SW McEwan Rd.	Portland, OR 97224	(503) 684–0760
OR0179 Motel 6		3104–06 SE Powelll Blvd.	Portland, OR 97202	(503) 238–0600
OR174 Oxford Suites		12226 N. Jantzen Ave..	Portland, OR 97217	(503) 283–3030
OR0175 Best Western Mill Creek Inn		3125 Ryan Dr. NE	Salem, OR 97301	(503) 585–3332
OR0177 Motel 6		1401 Hawthorne Ave. NE.	Salem, OR 97301	(503) 371–8024
OR0188 Kah Nee Ta Resort	PO Box K	100 Main St	Warm Sprints, OR 97761.	(503) 553–1112
South Carolina				
SC0216 Jameson Inn		128 Interstate Blvd	Anderson, SC 29621	(803) 375–9800
SC0215 Knights Inn, Airport Boulevard		1987 Airport Blvd	Cayce, SC 29033	(803) 794–0222
SC0217 Hawthorne Suites Hotel		181 Church St	Charleston, SC 29401.	(803) 577–2644
Texas				
TX0626 Hawthorn Suites Hotel-Austin South		4020 I–35 South	Austin, TX	(512) 440–7722
TX0625 Hawthorn Suites Hotel		250 Municipal Dr	Richardson, TX	(214) 669–1000
TX0627 Hawthorn Suites Hotel-San Antonio		4041 Bluemel Dr	San Antonio Rd, TX	(210) 561–9660
Utah				
UT0087 Salt Lake City Shilo Inn		206 S. West Temple	Salt Lake City, UT 841011994.	(801) 521–9500
Wyoming				
WY0089 Hitching Post Inn		1700 W. Lincolnway	Cheyenne, WY 82001.	(307) 638–3301
CORRECTIONS/CHANGES				
Arizona				
AZ0128 Mesa Pavilion Hilton		1011 W. Homes Ave	Mesa, AZ 85210	(602) 833–5555
Kansas				
KS0045 Holiday Inn		1118 N. 6th St	Levenworth, KS 66048.	(913) 651–5800
KS0053 Holiday Inn		530 Richards Dr	Manhattan, KS 66502	(913) 539–5311
Minnesota				
MN0112 Econo Lodge Airport		4197 Haines Rd	Duluth, MN 55811	(218) 722–5522
MN0216 Holiday Inn, Minneapolis Airport		2700 Pilot Knob Rd	Eagan, MN 55121	(612) 454–3434
MN0254 Econolodge of Mille Lacs		40993 U.S. Hwy. 169	Onamia, MN 56359	(612) 532–3838
Oregon				
OR0119 Peppertree Motel		10720 SW Allen	Beverton, OR 97005	(503) 641–7477
OR0158 Motel 6 #1244		1445 Bayshore Dr	Coos Bay, OR 97420	(503) 267–7171
OR0159 Motel 6 #418		3752 International Ct	Eugene, OR 97477	(503) 741–1105
OR0128 Mt Hood Inn	PO Box 400	87450 E. Govt Camp Loop.	Government Camp, OR 97028.	(503) 272–3307
OR0154 Holiday Inn Express, Grants Pass		105 NE Agness Ave	Grants Pass, OR 97526.	(503) 471–6144
OR0038 Pony Soldier Motor Inn		1060 E Cleveland Ave	Gresham, OR 97030	(503) 665–1591
OR0165 Best Western Klamath Inn		4061 S. 6th St	Klamath Falls, OR 97603.	(503) 882–1200
OR0153 Best Western Rama Inn		4430 SE Hwy. 101	Lincoln City, OR 97367.	(503) 994–6060

HOTEL AND MOTEL FIRE SAFETY ACT NATIONAL MASTER LIST JANUARY 20, 1995 UPDATE—Continued

Index and Property name	PO Box/Rt No.	Street address	City, State/ZIP	Telephone
OR0168 Best Western Vineyard Inn		2035 S. Hwy. 99 W	McMinnville, OR 97128.	(503) 472–4900
OR0162 Motel 6 #89		950 Alba Dr	Medford, OR 97504	(503) 773–4290
OR0160 Motel #349		325 SE Nye Ave	Pendleton, OR 97801	(503) 276–3160
OR0170 Best Western New Kings Inn		3658 Market St. NE	Salem, OR 97301	(503) 582–1559
OR0169 Best Western Pacific Hwy Inn		4646 Portland Rd. NE	Salem, OR 97305	(503) 390–3200
OR0134 Shilo Inn Seaside East		900 S. Holladay	Seaside, OR 97138	(503) 641–6565
OR0133 Shilo Inn Seaside Oceanfront		30 N. Prom	Seaside, OR 97138	(503) 641–6565
OR0149 Rodeway Inn		3480 Hutton St	Springfield, OR 97477.	(503) 746–8471
OR0099 Springfield Shilo Inn		3350 Gateway	Springfield, OR 974771094.	(503) 641–6565
OR0131 Shilo Inn Tillamook		2525 N. Main	Tillamook, OR 97141	(503) 641–6565
OR0129 Shilo Inn		1609 East Harbor Dr	Warrenton, OR 97146.	(503) 641–6565
OR0163 B/W Willamette Inn		30800 SW Pkwy	Wilsonville, OR 97070.	(503) 682–2288
Washington				
WA0187 Hawthorn Suites		6329 S. 212th St	Seattle/Kent, WA 98032.	(206) 395–3800
DELETIONS				
Oregon				
OR0127 Val-U Inn (Newport)		531 SW Fall Street	Newport, OR 97365	(503) 265–6623
OR0138 Silo Inn Eugene		3350 Gateway	Springfield, OR 97477.	(503) 641–6565
Virginia				
VA0209 Holiday Inn, Hampton Coliseum		1815 West Mercury Blvd..	Hampton, VA 236660000.	(804) 838–0200

[FR Doc. 95–2709 Filed 2–2–95; 8:45 am]

BILLING CODE 6718–26–U

Friday
February 3, 1995

Part VI

Federal Emergency Management Agency

Changes to the Hotel and Motel Fire Safety Act National Master List; Notice

FEDERAL EMERGENCY MANAGEMENT AGENCY

Changes to the Hotel and Motel Fire Safety Act National Master List

AGENCY: United States Fire Administration, FEMA.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA or Agency) gives notice of additions and corrections/changes to, and deletions from, the national master list of places of public accommodations which meet the fire prevention and control guidelines under the Hotel and Motel Fire Safety Act.

EFFECTIVE DATE: March 6, 1995.

ADDRESSES: Comments on the master list are invited and may be addressed to the Rules Docket Clerk, Federal Emergency Management Agency, 500 C Street, SW., room 840, Washington, D.C. 20472, (fax) (202) 646–4536. To be added to the National Master List, or to make any other change to the list, please see Supplementary Information below.

FOR FURTHER INFORMATION CONTACT: John Ottoson, Fire Management Programs Branch, United States Fire Administration, Federal Emergency Management Agency, National Emergency Training Center, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447–1272.

SUPPLEMENTARY INFORMATION: Acting under the Hotel and Motel Fire Safety Act of 1990, 15 U.S.C. 2201 note, the United States Fire Administration has worked with each State to compile a national master list of all of the places of public accommodation affecting commerce located in each State that meet the requirements of the guidelines under the Act. FEMA published the national master list in the **Federal Register** on Tuesday, November 29, 1993, 58 FR 62718, and published changes approximately monthly since then.

Parties wishing to be added to the National Master List, or to make any other change, should contact the State office or official responsible for compiling listings of properties which comply with the Hotel and Motel Fire Safety Act. A list of State contacts was published in 58 FR 17020 on March 31, 1993. If the published list is unavailable to you, the State Fire Marshal's office can direct you to the appropriate office. Periodically FEMA will update and redistribute the national master list to incorporate additions and corrections/changes to the list, and deletions from the list, that are received from the State offices.

Each update contains or may contain three categories: ''Additions;'' ''Corrections/changes;'' and ''Deletions.'' For the purposes of the updates, the three categories mean and include the following:

''Additions'' are either names of properties submitted by a State but inadvertently omitted from the initial master list or names of properties submitted by a State after publication of the initial master list;

''Corrections/changes'' are corrections to property names, addresses or telephone numbers previously published or changes to previously published information directed by the State, such as changes of address or telephone numbers, or spelling corrections; and

''Deletions'' are entries previously submitted by a State and published in the national master list or an update to the national master list, but subsequently removed from the list at the direction of the State.

Copies of the national master list and its updates may be obtained by writing to the Government Printing Office, Superintendent of Documents, Washington, DC 20402–9325. When requesting copies please refer to stock number 069–001–00049–1.

The update to the national master list follows below.

Dated: January 30, 1995.

John P. Carey,

General Counsel.

HOTEL AND MOTEL FIRE SAFETY ACT NATIONAL MASTER LIST 12/16/94 UPDATE

INDEX/PROPERTY NAME		PO BOX/RT NO AND STREET ADDRESS	CITY	STATE/ZIP	TELEPHONE
ADDITIONS					
AR:					
AR0074	BUDGETEL INN	1300 SOUTH 48TH STREET	SPRINGDALE	AR 72764	(501) 751–2626
AR0075	SHONEY'S INN	5210 NORTH STATE LINE	TEXARKANA	AR 75502	(501) 772–0070
CA:					
CA1438	BEST WESTERN VINEYARD INN	877 E. D ST	LEMOORE	CA 93245	(209) 924–1261
CA1439	LIGHTHOUSE LODGE AND SUITES	1249 LIGHTHOUSE AVE	PACIFIC GROVE	CA 93950	(408) 655–2111
CA1440	YORK HOTEL	940 SUTTER ST	SAN FRANCISCO	CA 94109	(415) 885–6800
GA:					
GA0340	MOTEL 6 ALBANY	201 S. THORNTON DR	ALBANY	GA 31705	(912) 439–0078
GA0337	MOTEL 6 ATLANTA	3585 CHAMBLEE-TUCKER RD	ATLANTA	GA 30341	(404) 455–8000
GA0344	MOTEL 6 AUGUSTA	2650 CENTER WEST PKWY	AUGUSTA	GA 30909	(706) 736–1934
GA0332	BEST WESTERN BURNSWICK	I–95 & U.S. 341	BRUNSWICK	GA 31520	(912) 264–0144
GA0331	DAYS INN BRUNSWICK	2307 GLOUCESTER ST	BRUNSWICK	GA 31520	(912) 265–8830
GA0334	HOLIDAY INN JESUP	5252 NEW JESUP HWY	BRUNSWICK	GA 31525	(912) 264–4033
GA0339	MOTEL 6 COLUMBUS	3050 VICTORY DR	COLUMBUS	GA 31903	(706) 687–7214
GA0335	MOTEL 6 DALTON	2200 CHATTANOOGA RD	DALTON	GA 30720	(706) 278–5522
GA0336	MOTEL 6 DECATUR	2565 WESLEY CHAPEL RD	DECATUR	GA 30035	(404) 288–6911
GA0341	MOTEL 6 MACON	4991 HARRISON RD	MACON	GA 31206	(912) 474–2870
GA0333	CLUBHOUSE INN NORCROSS	5945 OAKBROOK PKWY	NORCROSS	GA 30093	(404) 368–9400
GA0338	MOTEL 6 NORCROSS	6015 OAKBROOK PKWY	NORCROSS	GA 30093	(404) 446–2311
GA0343	MOTEL 6 RICHMOND HILL	I–95 & U.S. HWY. 17	RICHMOND HILL	GA 31324	(912) 756–3543
GA0342	MOTEL 6 VALDOSTA	2003 WEST HILL AVE	VALDOSTA	GA 31601	(912) 333–0047
IA:					
IA0141	MOTEL 6	810 1ST AVENUE	CORALVILLE	IA 52241	(319) 354–0030
IA0147	MOTEL 6	3032 S. EXPRESSWAY	COUNCIL BLUFFS	IA 51501	(712) 366–2405
IA0144	MOTEL 6	6111 N BRADY	DAVENPORT	IA 52806	(319) 391–8997
IA0142	MOTEL 6	PO BOX 3002, 4940 NE 14TH STREET.	DES MOINES	IA 50316	(515) 266–5456
IA0145	MOTEL 6	4817 FLEUR DR	DES MOINES	IA 50321	(515) 287–6364
IA0146	MOTEL 6	2670 DODGE ST	DUBUQUE	IA 52003	(319) 556–0880
IA0143	MOTEL 6	GEN. DEL., 6166 HARBOR DR	SERGEANT BLUFF	IA 51054	(712) 277–3131
IL:					
IL0540	HAWTHORN SUITES	10 WESTMINSTER WAY	LINCOLNSHIRE	IL 60069	(708) 945–9300

HOTEL AND MOTEL FIRE SAFETY ACT NATIONAL MASTER LIST 12/16/94 UPDATE—Continued

INDEX/PROPERTY NAME	PO BOX/RT NO AND STREET ADDRESS	CITY	STATE/ZIP	TELEPHONE
IN:				
IN0413 MOTEL 6	5810 SCATTERFIELD RD	ANDERSON	IN 46013	(317) 642–9023
IN0415 MOTEL 6	4201 WHY 41 N & YOKEL RD	EVANSVILLE	IN 47711	(812) 424–6431
IN0414 MOTEL 6	3003 COLISEUM BLVD WEST	FORT WAYNE	IN 46808	(219) 482–3972
IN0416 MOTEL 6	3840 179TH ST	HAMMOND	IN 46324	(219) 845–8330
IN0417 MOTEL 6	2016 OLD HIGHWAY 31 EAST	JEFFERSONVILLE	IN 47129	(812) 283–7703
KY:				
KY0413 COMFORT INN	3749 NASHVILLE RD	FRANKLIN	KY 42134	(502) 586–6100
KY0411 FRIENDSHIP INN	2923 FT. CAMPBELL BLVD	HOPKINSVILLE	KY 42240	(502) 885–1126
KY0412 COMFORT SUITES	3820 SCOTSVILLE ROAD	LONDON	KY 40741	(606) 877–7848
LA:				
LA0122 HOLIDAY INN MACARTHUR DRIVE	2716 N. MACARTHUR DR	ALEXANDRIA	LA 71303	(318) 487–4261
NY:				
NY0603 MOTEL 6	155 BUELL ROAD	GATES	NY 14624	(716) 436–2170
NY0634 TRAVELODGE INTERNATIONAL HOTEL	BLDG. #144, VAN WYCK EXPWAY	JAMAICA	NY 11430	(718) 995–9000
TX:				
TX0624 RAMADA EMILY MORGAN HOTEL	705 E. HOUSTON ST	SAN ANTONIO	TX 78205	(210) 225–8486
VA:				
VA0599 BEST WESTERN HANOVER HOUSE	I–95 EXIT 86, ATLEE-ELMONT	ASHLAND	VA 23005	(804) 550–2805
WV:				
WV0202 BRIAR MOTEL	3206 CUMBERLAND RD	BLUEFIELD	WV 24701	(304) 325–9111
CORRECTIONS/CHANGES				
GA:				
GA0324 COMFORT INN ASHBURN	820 SHOENYS DR	ASHBURN	GA 31214	(912) 567–0080
GA0250 BUDGETEL INN LENOX	2535 CHANTILLY DR	ATLANTA	GA 30324	(404) 321–0999
GA0270 DAYS INN ATLANTA	300 SPRING ST	ATLANTA	GA 30308	(404) 523–1144
GA0327 ECONO LODGE AUGUSTA	2852 WASHINGTON RD	AUGUSTA	GA 30909	(706) 736–0707
GA0266 WELCOME INN MACON	4709 CHAMBERS RD	MACON	GA 31206	(912) 781–6680
GA0277 DAVIS INN	STATE PARK RD	PINE MOUNTAIN	GA 31822	(706) 663–2522
GA0316 ISLAND INN	301 MAIN ST	SAINT SIMON'S ISLA	GA 31522	(912) 638–7805
GA0313 CLOISTER HOTEL	100 FIRST ST	SEA ISLAND	GA 31561	(912) 638–3611
GA0309 MOTEL 6 STOCKBRIDGE	7233 DAVIDSON PKWY	STOCKBRIDGE	GA 30281	(404) 389–1142
GA0169 CLUBHOUSE INN VALDOSTA	1800 CLUBHOUSE DR	VALDOSTA	GA 31601	(912) 247–7755
HI:				
HI0168 ASTON AT THE WAIKIKI BANYAN	201 OHUA ST	HONOLULU, OAHU	HI 96815	(808) 922–0555
HI0159 HILTON WAIKOLOA VILLAGE	69–425 WAIKOLOA DR	KAMUELA	HI 967439791	(808) 885–1234
HI0030 SHERATON LUXURY PRINCEVILLE HOTEL.	PO BOX 3069, 5520 KA HAKU RD	PRINCEVILLE, KAUAI	HI 967223069	(808) 826–9644
IL:				
IL0516 FAIRFIELD INN CHAMPAIGN	187 MORELAND BLVD	CHAMPAIGN	IL 61820	(217) 355–0604
KY:				
KY1062 COMFORT INN	2381 BUENA VISTA DR	LEXINGTON	KY 40505	(606) 299–0302
DELETIONS				
HI:				
HI0127 BREAKERS HOTEL	250 BEACHWALK	HONOLULU, OAHU	HI 96815	(808) 923–3181
HI0050 HAWAIIAN REGENT HOTEL KUHIO	2552 KALAKAUA AVE	HONOLULU, OAHU	HI 96815	(808) 922–6611
HI0131 HAWAIIANA HOTEL	260 BEACH WALK	HONOLULU, OAHU	HI 96815	(808) 923–3811
HI0073 MOANA HOTEL DIAMOND	2365 KALAKAUA AVE	HONOLULU, OAHU	HI 96815	(808) 923–3111
HI0113 WAIKIKI BEACHSIDE HOTEL	2452 KALAKAUA AVE	HONOLULU, OAHU	HI 96815	(808) 931–2180
HI0144 PLANTATION HALE	484 KUHIO HWY	KAPAA, KAUAI	HI 96746	(808) 822–4941
HI0151 SHERATON MAUI HOTEL	2605 KAANAPALI PKWY	LAHAINA, MAUI	HI 967611991	(808) 661–0031
HI0013 MANELE BAY HOTEL	MANELE HWY	LANAI CITY, LANAI	HI 96763	(808) 565–7700
HI0155 ASTON KAUAI BEACH VILLAS	4330 KAUAI BEACH DR	LIHUE, KAUAI	HI 96766	(808) 245–7711
HI0026 THE WESTIN KAUAI	3610 RICE ST	LIHUE, KAUAI	HI 96766	(808) 245–5050

[FR Doc. 95–2710 Filed 2–2–95; 8:45 am]

BILLING CODE 6718–26–M

Friday
February 3, 1995

Part VII

Department of Education

34 CFR Part 668

Student Assistance General Provisions; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Part 668

RIN 1840–AC14

Student Assistance General Provisions

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the Student Assistance General Provisions regulations. These amendments are necessary to implement a new requirement in the Higher Education Act of 1965, as amended (HEA), recently added by the Improving America's Schools Act of 1994 (IASA). The IASA provision, titled the ''Equity in Athletics Disclosure Act (EADA),'' requires certain coeducational institutions of higher education to prepare—and make available to students, potential students, and the public—a report on participation rates, financial support, and other information on men's and women's intercollegiate athletic programs. These proposed regulations would implement this new statutory requirement. The statute requires that the Secretary issue final regulations implementing the EADA not later than 180 days following enactment. Thus, the statute requires that final regulations be issued by April 18, 1995.

DATES: Comments must be received on or before April 4, 1995.

ADDRESSES: All comments concerning these proposed regulations should be addressed to: Ms. Paula M. Husselmann, U.S. Department of Education, 600 Independence Avenue, S.W., ROB3, Room 4318, Washington, D.C. 20202–5346, or to the following internet address: Athletic—Data@ed.gov.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Ms. Paula Husselmann, U.S. Department of Education, 600 Independence Avenue, S.W., ROB3, Room 4318, Washington, D.C. 20202–5346. Telephone: (202) 708–7888. Individuals who use a telecommunications device 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 time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Student Assistance General Provisions regulations (34 CFR part 668) apply to all institutions that participate in the Title IV, HEA programs. The proposed changes in these regulations are necessary to implement changes to the HEA made by the Equity in Athletics Disclosure Act (EADA), which was included in the Improving America's Schools Act of 1994 (IASA), Pub. L. 103–382, enacted on October 20, 1994. The EADA requires that certain institutions of higher education disclose—to students, potential students, and the public—financial, participation, and other information concerning the institutions' women's and men's intercollegiate athletic programs. The EADA is a ''sunshine'' law designed to make ''prospective students and prospective student athletes . . . aware of the commitments of an institution to providing equitable athletic opportunities for its men and women students.'' (IASA, section 360B(b)(7)) In enacting the EADA, Congress expected that ''knowledge of an institution's expenditures for women's and men's athletic programs would help prospective students and prospective student athletes make informed judgments about the commitments of a given institution of higher education to providing equitable athletic benefits to its men and women students.'' (IASA, section 360B(b)(8))

The EADA does not require that this information be submitted to the Federal Government. Institutions of higher education that are subject to the EADA must make the information available to students, potential students, and the public.

Summary of the Proposed Regulations

The following is a summary of the regulations that the Secretary proposes to implement the EADA. The Secretary is interested both in ensuring that students and the public receive consistent, useful information from institutions of higher education about their intercollegiate athletic programs, and in keeping regulatory burden on those institutions to the minimum necessary to carry out congressional intent. The Secretary is also committed to working with organizations that are interested in women's and men's sports in implementing the EADA, including development of proposed and final regulations and any optional reporting formats. The Secretary began consulting with a number of these organizations soon after the law was enacted, and will continue to do so in the future.

The proposed regulations include only the statutory requirements contained in the EADA, as described below. The proposed regulations do not include any requirements except those imposed by the statute. In this summary, the Secretary describes a number of issues that could be addressed in regulations or in non-binding guidance and requests comments on the following questions:

- Which, if any, of these issues should be addressed in the final regulations and how should they be addressed?
- Which issues instead should be addressed in non-binding guidance provided by the Department and how should they be addressed?
- Which issues should not be addressed by the Department because the statutory language is clear or for other reasons?
- Which other issues should be addressed in the final regulations or in non-binding guidance from the Department and how should they be addressed?

1. *Institutions of higher education that are subject to the EADA.*

The EADA applies to any coeducational institution of higher education (IHE) that participates in a Title IV, HEA program and has an intercollegiate athletic program. This statutory provision is set forth in proposed § 668.48(a).

The Secretary interprets ''intercollegiate athletic program'' to refer to varsity teams. The term ''varsity'' is also used in the EADA. These are the teams that compete at a certain level of play (against other IHEs' varsity-level teams). The EADA does not apply to intramural teams or to club teams even if such a team plays a limited number of intercollegiate games against varsity teams. The Secretary requests comments on whether the type or level of financial support by the IHE should also be a determinant of whether a team should be considered a varsity team under the EADA.

The Secretary interprets the term ''coeducational'' to refer to the composition of an IHE's undergraduate student body. Thus, if an IHE has undergraduate students of only one gender, the EADA would not apply to the IHE's intercollegiate athletic program.

2. *Annual report.*

The EADA requires that an institution subject to this law shall annually, for the immediately preceding academic year, prepare a report that contains certain information regarding intercollegiate athletics. The EADA specifies the information that must be included in the report. The statutory reporting requirement is in proposed § 668.48(b).

3. *Full-time male and female undergraduates.*

The report must include the number of male and female full-time

undergraduates that attended the institution for the immediately preceding academic year. (Proposed § 668.48(b)(1))

The terms ''academic year'' and ''full-time student'' are defined in the Student Assistance General Provisions (34 CFR 668.2(b)). For the definition of ''full-time student,'' see 59 FR 22419, published on April 29, 1994. For the definition of ''academic year,'' see 59 FR 61178, published on November 29, 1994. The Secretary could apply these definitions to the EADA regulations and requests comments on whether to use (1) these definitions, (2) other definitions, or (3) no definitions. In particular, should the definition of ''academic year,'' which does not refer to a 12-month period, apply? The Secretary believes that the categories of information required to be reported by the EADA should be with respect to a 12-month period, but requests comments on this issue.

The Secretary also requests comments on whether the term ''undergraduate'' should be defined, and, if so, how.

4. *Participants on varsity teams.*

The report must include—for the immediately preceding academic year—a listing of the varsity teams that competed in intercollegiate athletic competition and—for each team—the total number of participants, by team, as of the day of the first scheduled contest for the team. (Proposed § 668.48(b)(2)(i))

The Secretary requests comments on who should be included and who should be excluded as team ''participants'' under the EADA. For example, since ''red-shirted'' players typically practice with a team and receive athletically-related financial aid, should they be included as ''participants?''

5. *Operating expenses.*

The report must include—for the immediately preceding academic year—the total operating expenses attributable to each varsity team. The EADA defines ''operating expenses'' to mean expenditures on lodging and meals, transportation, officials, uniforms, and equipment. In addition to reporting total operating expenses for each team, an institution may also report those expenses on a per capita basis for each team. An institution may report combined expenditures attributable to closely related teams—such as track and field or swimming and diving. Any such combinations must be reported separately for men's and women's teams. (Proposed § 668.48(b)(2)(ii))

The Secretary interprets the EADA to include expenses for both home and away games and training sessions, including lodging and meals. The Secretary also believes that ''total operating expenses'' should include the expenses incurred by a team during an entire year, not just those incurred during the sports season of a team. The Secretary interprets the statute to exclude any categories of expenses that are not specifically listed in the law. The Secretary is interested in comments on which expenses should or should not be included under each of the statutory categories (lodging and meals, transportation, officials, uniforms, and equipment).

6. *Head coaches and assistant coaches.*

The institution must indicate in its report—for the immediately preceding academic year—whether the head coach for each varsity team was male or female and whether the head coach was assigned to that team on a full-time or part-time basis. The EADA requires that the institution consider graduate assistants and volunteers who served as head coaches to be head coaches for the purposes of this requirement. The institution must also indicate, for each team, the number of assistant coaches who were male and the number of assistant coaches who were female and whether a particular coach was assigned to that team on a full-time or part-time basis. As with head coaches, the EADA requires the institution to consider graduate assistants and volunteers who served as assistant coaches to be assistant coaches for the purposes of this requirement. (Proposed § 668.48(b)(2)(iii) and (iv))

7. *Total amount of athletically related student aid.*

The report must include—for the immediately preceding academic year—the total amount of money spent on athletically related student aid, including the value of waivers of educational expenses, separately for men's and women's teams overall. (Proposed § 668.48(b)(3))

The Secretary interprets this provision of the statute to require that the IHE report two totals—one total for men's teams and one total for women's teams.

The term ''athletically related student aid'' is defined in section 485(e)(8) of the HEA to mean any scholarship, grant, or other form of financial assistance, the terms of which require the recipient to participate in a program of intercollegiate athletics at an IHE in order to receive that assistance. This definition does not apply automatically to the EADA, which is in subsection (g) of section 485. However, the Secretary believes that the definition in subsection (e)(8) would provide useful guidance for the purposes of the EADA and that having a single definition would promote clarity and consistency in the administration of these statutes. Thus, the Secretary proposes that the definition in subsection (e)(8) be made applicable to the EADA. The Secretary requests comments on whether ''athletically related student aid'' should also include scholarships to students who are on medical waivers (who therefore are not currently participating on the team) or who continue to receive athletically related aid after they cease to participate on a team for which they had been awarded that aid.

8. *Ratio of aid to male and female athletes.*

The report must give—for the immediately preceding academic year—the ratio of athletically related student aid awarded male athletes to athletically related student aid awarded female athletes. (Proposed § 668.48(b)(4))

The Secretary interprets this provision to require an IHE to calculate a ratio of the total of athletically related student aid awarded male athletes to the total of athletically related student aid awarded female athletes.

9. *Expenditures on recruiting.*

The report must include—for the immediately preceding academic year—the total amount of expenditures on recruiting, separately for men's and women's teams overall. (Proposed § 668.48(b)(5))

The Secretary interprets this provision of the statute to require that the IHE report two totals—one total for men's teams and one total for women's teams.

The Secretary requests comments on whether a definition of ''expenditures on recruiting'' is necessary, and, if so, which expenditures should or should not be included in the report as ''expenditures on recruiting.''

10. *Total annual revenues.*

The report must include—for the immediately preceding academic year—the total annual revenues generated across all men's teams and across all women's teams. In addition, an institution may report those revenues by individual team. (Proposed § 668.48(b)(6))

The Secretary interprets this provision of the statute to require that the IHE report two totals—one total for men's teams and one total for women's teams. The Secretary interprets the term ''total annual revenues'' to mean gross income, since there is no indication in the EADA that Congress intended anything less than that amount.

Under section 487(a)(18) of the HEA, IHEs are currently required to make an annual compilation of revenues and expenses attributable to ''football, men's

basketball, women's basketball, all other men's sports combined, and all other women's sports combined [with respect to the institution's] intercollegiate athletics activities.'' The revenues and expenses to be calculated for this purpose are set forth in section 487(a)(18)(B) (i) and (ii) (20 U.S.C. 1094(a)(18)(B) (i) and (ii)). The Department's regulations implementing these statutory requirements are in 34 CFR 668.14 (d) and (e) (59 FR 22427–22428, published April 29, 1994). The specific definition of ''operating expenses'' in the EADA precludes using the definition of ''expenses'' in section 487 and the Department's regulations. However, the Secretary will consider the extent to which the definition of ''revenue'' in these provisions should be used in deciding what should be included in ''total annual revenues'' under the EADA.

The Secretary requests comments on whether the EADA regulations should adopt a definition of ''total annual revenues'' that is different from the definition of ''revenue'' in § 668.14, and, if so, what specific sources of income should or should not be included in ''total annual revenues.''

11. *Coaches' and assistant coaches' salaries.*

The report must include—for the immediately preceding academic year—the average annual institutional salary of the head coaches of men's teams, across all offered sports, and the average annual institutional salary of the head coaches of women's teams, across all offered sports. If a head coach had responsibilities for more than one team and the institution does not allocate that coach's salary by team, the EADA states that the institution should divide the salary by the number of teams for which the coach had responsibility and allocate the salary among the teams on a basis consistent with the coach's responsibilities for the different teams. The report must also include the average annual institutional salary of the assistant coaches of men's teams, across all offered sports, and the average annual institutional salary of the assistant coaches of women's teams, across all offered sports. (Proposed § 668.48(b) (7) and (8))

The Secretary interprets ''across all offered sports'' to mean a single average for all men's sports in the aggregate and a single average for all women's sports in the aggregate.

The Secretary requests comments on what types of compensation should be included in a coach's or assistant coach's ''salary'' to provide an accurate picture of relative compensation. For example, should ''salary'' include bonuses or other monetary benefits?

The Secretary also requests comments on the determination of an average annual institutional salary if unpaid volunteers serve as head coaches or assistant coaches. Consistent with the provisions in the EADA that volunteers serving as part-time or full-time coaches or assistant coaches should be counted as such, the Secretary believes that their salaries (or lack thereof) should be reflected in the average annual institutional salaries calculated by the IHE. The Secretary believes that unpaid volunteer coaches and assistant coaches could be included in these computations with a designated salary of zero dollars. However, the Secretary requests comments as to whether the report should instead simply include the number of unpaid volunteers who served as coaches and assistant coaches without including them in the computation of average annual institutional salaries.

Because the EADA states that an IHE ''should'' allocate a coach's salary if he or she coaches more than one team, the Secretary believes that the statute requires that an IHE shall do the allocation, and the proposed regulations so provide.

12. *General issues.*

The Secretary believes that coeducational teams should be reflected in the IHE's report, and requests comments on how this could be done most accurately and with minimal burden, particularly under the EADA provisions that ask for information separately for ''men's and women's teams.'' For example, the salary for a head coach of a coeducational team could be prorated according to how many members of the team are male and how many are female.

Some expenses, revenues, and salaries may be attributable to more than one activity. In general, the Secretary believes that an IHE should prorate these figures in a reasonable manner and to indicate in the report how the figures were calculated, so that students, potential students, and the public will understand the basis for the calculations. If a faculty or staff member also coaches, the IHE should make a reasonable determination of how much of the professor's salary is attributable to his or her coaching duties. If a women's team and a men's team share transportation to competitions held at the same site, the transportation expense should be prorated according to the relative number of female and male athletes who share the transportation. Are there other situations where proration would be necessary to develop the information required by the EADA? What guidance should the Secretary offer to assist schools in making the prorations in a consistent manner that allows for comparisons among schools? What burdens would be imposed on IHEs in prorating expenses, revenues, or salaries?

In calculating and reporting expenses, revenues, and salaries, the Secretary interprets the EADA to require IHEs to use actual amounts expended or earned during the immediately preceding academic year, not budgeted or estimated amounts. The Secretary requests comments on any burdens that would be imposed on schools in meeting an October 1 deadline and in using actual data.

The EADA requires that the information in the annual report be for the immediately preceding academic year. How can this requirement be made to work for an IHE whose fiscal year is not the same as its academic year?

As noted above, certain definitions in 34 CFR Part 668, the Student Assistance General Provisions (SAGP), could apply to these regulations. The SAGP also contains other regulations that are pertinent to the EADA, including recordkeeping requirements in § 668.23 and the enforcement and appeal provisions in Subparts G and H of Part 668. Under section 443 of the General Education Provisions Act (20 U.S.C. 1232f), as amended by the IASA, records under the EADA generally will have to be maintained by an IHE for three years.

Under the Student Right-to-Know Act (20 U.S.C. 1092(a)(5)), the Secretary is required to permit an IHE that is a member of an athletic association or athletic conference that has voluntarily published data, or has agreed to publish data, that the Secretary considers substantially comparable to the information required under the Act, to use that data to satisfy the requirements of the Act. The Secretary requests comment on whether a similar provision should be included in the EADA regulations.

13. *Format for the report.*

The Secretary believes that the information in IHEs' reports under the EADA should be as consistent as possible to assist students, potential students, and the public understand and use that information. The Secretary is also aware that differences exist among intercollegiate athletic programs. Given these factors, the Department is considering development of an optional model format that IHEs could use for the annual report required by the EADA. Such a format would be based on and developed in consultation with athletic

conferences, schools, and groups interested in women's and men's sports. Should such a form be developed and made available? Can one format be used by all of the types of IHEs that will be subject to the law, or will a small number of different formats be necessary? If the latter, on what basis should institutions be differentiated?

Do any of the categories of information required by the EADA simply not apply to some IHEs? If so, how should regulations, non-regulatory guidance, or a model format address this situation?

14. *Disclosure to students and the public.*

The EADA requires that an institution of higher education subject to the Act shall make available to students and potential students, upon request, and to the public, the information contained in the report. The institution shall inform all students of their right to request that information. The Act requires that each institution make available its first report not later than October 1, 1996. These statutory provisions are set forth in proposed § 668.41(e).

Each IHE must make its first report available by October 1, 1996. The Secretary believes that October 1 also should be the deadline for subsequent annual reports, and would best meet the needs of IHEs, students, and potential students.

The Secretary believes it is particularly important that students, potential students, and parents have easy and timely access to the information in this report. How should an IHE give notice to each of these groups that the report is available? How should the IHE make the information accessible to students, potential students, and the public? The Secretary does not believe that students or potential students should be charged for copies of the report but is sensitive to the possible financial burden on IHEs and requests comments on this matter. Also, should an IHE be allowed to charge the public for copies of the report?

Executive Order 12866

1. Assessment of Costs and Benefits

These proposed regulations have been reviewed in accordance with Executive Order 12866. Under the terms of the order the Secretary has assessed the potential costs and benefits of the regulatory action. The potential costs associated with the proposed regulations are those resulting from statutory requirements. Burdens specifically associated with information collection requirements are identified and explained elsewhere in this preamble under the heading *Paperwork Reduction Act of 1980.*

To assist the Department in complying with the specific requirements of Executive Order 12866, the Secretary invites comment on how the final regulations should be written to minimize potential costs or to increase potential benefits resulting from these proposed regulations consistent with the purposes of the EADA.

2. Clarity of the Regulations

Executive Order 12866 requires each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make these regulations easier to understand, including answers to questions such as the following: (1) Are the requirements in the regulations clearly stated? (2) Do the regulations contain technical terms or other wording that interferes with their clarity? (3) Does the format of the regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity? Would the regulations be easier to understand if they were divided into more (but shorter) sections? (A ''section'' is preceded by the symbol ''§ '' and a numbered heading; for example, § 668.48 *Report on athletic program participation rates and financial support data.*) (4) Is the description of the proposed regulations in the ''Supplementary Information'' section of this preamble helpful in understanding the proposed regulations? How could this description be more helpful in making the proposed regulations easier to understand? (5) What else could the Department do to make the regulations easier to understand?

A copy of any comments that concern how the Department could make these proposed regulations easier to understand should be sent to Stanley M. Cohen, Regulations Quality Officer, U.S. Department of Education, 600 Independence Avenue, S.W. (Room 5121, FB–10), Washington, D.C. 20202–2241.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. The small entities that would be affected by these regulations are small coeducational institutions of higher education that participate in Title IV, HEA programs and that have intercollegiate athletic programs. However, the regulations would not have a significant economic impact on these small entities because the regulations would not impose excessive regulatory burdens or require unnecessary Federal supervision. The proposed regulations would not impose any requirements except the statutory requirements in the EADA.

Paperwork Reduction Act of 1980

Section 668.48 contains information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these sections to the Office of Management and Budget (OMB) for its review. (44 U.S.C. 3504(h))

Educational institutions that are public or nonprofit institutions or businesses or other for-profit institutions may participate in the Title IV, HEA programs. IHEs will need and use the information required by these regulations to meet the disclosure requirements of the EADA.

Annual public reporting and recordkeeping burden contained in the collection of information proposed in these regulations is estimated to be 18,000 hours, including the time for searching existing data sources and gathering and maintaining the data needed.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 3002, New Executive Office Building, Washington, D.C. 20503; Attention: Daniel J. Chenok.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 4318, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 668

Administrative practice and procedure, Colleges and universities, Consumer protection, Education, Grant

programs—education, Loan programs—education, Reporting and recordkeeping requirements, Student aid.

Dated: January 26, 1995.

Richard W. Riley,

Secretary of Education.

(Catalog of Federal Domestic Assistance Numbers: 84.007 Federal Supplemental Educational Opportunity Grant Program; 84.032 Federal Stafford Loan Program; 84.032 Federal PLUS Program; 84.032 Federal Supplemental Loans for Students Program; 84.033 Federal Work-Study Program; 84.038 Federal Perkins Loan Program; 84.063 Federal Pell Grant Program; 84.069 State Student Incentive Grant Program; 84.268 Federal Direct Student Loan Program; and 84.272 National Early Intervention Scholarship and Partnership Program. Catalog of Federal Domestic Assistance Number for the Presidential Access Scholarship Program has not been assigned.)

The Secretary proposes to amend Part 668 of Title 34 of the Code of Federal Regulations as follows:

PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

1. The authority citation for Part 668 is revised to read as follows:

Authority: 20 U.S.C. 1085, 1088, 1091, 1092, 1094, 1099c, and 1141, unless otherwise noted.

2. Section 668.41 is amended by revising the heading, removing and reserving paragraphs (a) and (b), reserving paragraphs (c) and (d), and adding a new paragraph (e), to read as follows:

§ 668.41 Reporting and disclosure of information.

(a)–(d) [Reserved]

(e)(1)(i) An institution of higher education subject to § 668.48 shall make available to students and potential students, upon request, and to the public, the information contained in the report described in § 668.48(b).

(ii) The institution shall inform all students of their right to request that information.

(2) Each institution shall make available its first report under § 668.48 not later than October 1, 1996.

(Authority: 20 U.S.C. 1092(g)(3), (5))

3. Section 668.48 is added to subpart D to read as follows:

§ 668.48 Report on athletic program participation rates and financial support data.

(a) *Applicability.* This section applies to each coeducational institution of higher education that—

(1) Participates in any Title IV, HEA program; and

(2) Has an intercollegiate athletic program.

(b) *Report.* An institution subject to this section shall annually, for the immediately preceding academic year, prepare a report that contains the following information regarding intercollegiate athletics:

(1) The number of male and female full-time undergraduates that attended the institution.

(2) A listing of the varsity teams that competed in intercollegiate athletic competition and for each team the following data:

(i) The total number of participants, by team, as of the day of the first scheduled contest for the team.

(ii) Total operating expenses attributable to those teams. For the purposes of this section, the term ''operating expenses'' means expenditures on lodging and meals, transportation, officials, uniforms and equipment. An institution—

(A) Also may report those expenses on a per capita basis for each team; and

(B) May report combined expenditures attributable to closely related teams—such as track and field or swimming and diving. Those combinations must be reported separately for men's and women's teams.

(iii) (A) Whether the head coach was male or female and whether the head coach was assigned to that team on a full-time or part-time basis.

(B) The institution shall consider graduate assistants and volunteers who served as head coaches to be head coaches for the purposes of this report.

(iv)(A) The number of assistant coaches who were male and the number of assistant coaches who were female for each team and whether a particular coach was assigned to that team on a full-time or part-time basis.

(B) The institution shall consider graduate assistants and volunteers who served as assistant coaches to be assistant coaches for the purposes of this report.

(3) The total amount of money spent on athletically related student aid, including the value of waivers of educational expenses, separately for men's and women's teams overall.

(4) The ratio of—

(i) Athletically related student aid awarded male athletes; to

(ii) Athletically related student aid awarded female athletes.

(5) The total amount of expenditures on recruiting, separately for men's and women's teams overall.

(6) The total annual revenues generated across all men's teams and across all women's teams. An institution may also report those revenues by individual team.

(7)(i) The average annual institutional salary of the head coaches of men's teams, across all offered sports, and the average annual institutional salary of the head coaches of women's teams, across all offered sports.

(ii) If a head coach had responsibilities for more than one team and the institution does not allocate that coach's salary by team, the institution shall divide the salary by the number of teams for which the coach had responsibility and allocate the salary among the teams on a basis consistent with the coach's responsibilities for the different teams.

(8) The average annual institutional salary of the assistant coaches of men's teams, across all offered sports, and the average annual institutional salary of the assistant coaches of women's teams, across all offered sports.

(Authority: 20 U.S.C. 1092(g)(1), (2), (4))

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